CHILD SAFETY ACT AND PERSONNEL TRAINING

HEARINGS

BEFORE THE

SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

EIGHTY-NINTH CONGRESS

SECOND SESSION

ON

H.R. 13884, H.R. 14634

BILLS TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT FOR THE PURPOSE OF STRENGTHENING AND FACILITATING MUTUAL COOPERATION AND ASSISTANCE, INCLUDING TRAINING OF PERSONNEL, IN THE ADMINISTRATION AND ENFORCEMENT OF THAT ACT AND OF STATE AND LOCAL LAWS RELATING TO FOOD, DRUGS, DEVICES, OR COSMETICS, AND FOR OTHER PURPOSES

H.R. 13886, H.R. 14557, H.R. 14632

BILLS TO PROTECT CHILDREN AND OTHERS FROM ACCIDENTAL DEATH OR INJURY BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO ASPIRIN INTENDED FOR CHILDREN, SAFETY CLOSURES ON DRUG CONTAINERS, AND CAUTIONARY LABELING OF CONTAINERS OF ARTICLES SUBJECT TO THE ACT WHERE NECESSARY TO THAT END, AND BY AMENDING THE FEDERAL HAZARDOUS SUBSTANCES LABELING ACT TO BAN HAZARDOUS TOYS AND ARTICLES INTENDED FOR CHILDREN, AND OTHER ARTICLES SO HAZARDOUS AS TO BE DANGEROUS IN THE HOUSEHOLD REGARDLESS OF LABELING, AND TO APPLY TO UNPACKAGED ARTICLES INTENDED FOR HOUSEHOLD USE, AND FOR OTHER PURPOSES

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CHILD SAFETY ACT AND PERSONNEL TRAINING

FRIDAY, JUNE 24, 1966

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met at 10 a.m., pursuant to call, in room 2218, Rayburn House Office Building, Hon. Paul G. Rogers presiding.

Mr. ROGERS of Florida. The subcommittee will please be in order.

The hearings today are on H.R. 13886, the proposed Child Safety Act of 1966, and H.R. 13884 the proposed Professional Training and Cooperation Amendments of 1966, introduced by our chairman, Mr. Staggers, and three other bills—H.R. 14634, which is identical to the professional training and cooperation amendments, introduced by our colleague, Mr. Donohue, and H.R. 14557, introduced by our colleague Mr. McCarthy, and H.R. 14632 by Mr. Donohue, which are identical to the proposed Child Safety Act.

The Child Safety Act would make several amendments to the Federal Food, Drug and Cosmetic Act. One amendment would limit the quantity of children's aspirin that may be included in one single retail package; another amendment would authorize the Secretary of Health, Education, and Welfare to require retail containers of drugs to be secured by a safety closure; and a third amendment would require cautionary labeling to protect against accidental injuries.

The bill would also amend the Hazardous Substances Labeling Act to extend the coverage of the act to hazardous substances intended for household use or by children; and would ban from commerce certain hazardous toys or other children's articles, or dangerous household articles.

The proposed professional training and cooperation amendments would clarify the Department's authority for training personnel of State and local authorities in matters relating to the Federal Food, Drug and Cosmetic Act, and would provide explicit authority for the Department to cooperate with and give technical assistance to State and local authorities.

At this point in the record there will be inserted the text of H.R. 13884 and H.R. 13886 and the departmental reports thereon.

(The bills and reports referred to follow:)

[H.R. 13884, 89th Cong., 2d sess.]

A BILL To protect the public health by amending the Federal Food, Drug, and Cosmetic Act for the purpose of strengthening and facilitating mutal cooperation and assistance, including training of personnel, in the administration and enforcement of that Act and of State and local laws relating to food, drugs, devices, or cosmetics, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Professional Training and Cooperation Amendments of 1966".

SEC. 2. Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by adding at the end thereof the following new subsection:

"(f)(1) The Secretary is authorized to accept from State and local authorities, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of this Act which he may request and which they may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance.

"(2) The Secretary may cooperate with and give technical and other assistance to State and local authorities in the administration and enforcement of their laws and regulations relating to food, drugs, devices, or cosmetics.

"(3) In order to assist in carrying out the purposes of this subsection, the Secretary may provide training (including necessary curricular and instructional materials and equipment) to personnel of State or local authorities (in matters relating to the administration or enforcement of this Act or of the laws administered by such authorities) as an integral part of any training program for personnel of the Department, or may (pursuant to arrangement with such authorities) establish and carry out a special training program or programs in such matters for personnel of such authorities either directly or through contracts or arrangements with appropriate institutions or agencies, including Federal agencies, and may in either case pay to such State or local personnel, while attending such training programs away from their homes or regular places of employment and while traveling in connection therewith, their travel expenses, including per diem in lieu of subsistence, as authorized by section 5 of the Administrative Expenses Act of 1946 (5 U.S.C. 73b–2) for persons in the Government service employed intermittently."

SEC. 3. Section 702 of such Act is further amended by adding at the end of subsection (a) of such section the following new sentences: "In carrying out this subsection, the Secretary may make contracts for the conduct of special tests and analyses and may pay therefor in advance or otherwise, as he may determine. The Secretary may likewise contract, and pay in advance or otherwise, for information (1) furnished to him by hospitals or other institutions or organizations or informants (except information furnished to him by manufacturers and others required by or pursuant to this Act to furnish such information) and (2) bearing on the safety or effectiveness of drugs or other articles within the scope of this Act."

[H.R. 13886, 89th Cong., 2d sess.]

A BILL To protect children and others from accidental death or injury by amending the Federal Food, Drug, and Cosmetic Act with respect to aspirin intended for children, safety closures on drug containers, and cautionary labeling of containers of articles subject to the Act where necessary to that end, and by amending the Federal Hazardous Substances Labeling Act to ban hazardous toys and articles intended for children, and other articles so hazardous as to be dangerous in the household regardless of labeling, and to apply to unpackaged articles intended for household use, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Child Safety Act of 1966".

TITLE I—AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

LIMITATION OF QUANTITY OF CHILDREN'S ASPIRIN IN RETAIL PACKAGE

SEC. 2. Paragraph (a) of section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351), relating to drugs or devices deemed to be adulterated, is amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: "or (5) if it is an aspirin (acetylsalicylic acid), or other form of salicylic acid, preparation in a dosage form intended for use by children and is packaged in a retail container, unless the aggregate quantity of such drug in such container does not exceed a limit which has been established by the

Secretary by regulation after consideration of the total quantity of such drug that, if ingested by a child of tender age at one time, is likely to cause death or serious injury."

SAFETY CLOSURES ON RETAIL DRUG CONTAINER

SEC. 3. Paragraph (a) of such section 501, as amended by section 2 of this Act, is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: "or (6) if it is a drug packaged in a retail container (including a container in which such drug is dispensed on prescription) and the Secretary has, in the interest of protecting the health and safety of children, by regulation applicable to such drug (whether or not such drug is intended for children) required the retail container to be secured by a safety closure, unless such container is so secured in conformity with such regulation."

CAUTIONARY LABELING REQUIREMENTS

SEC. 4. (a) Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end thereof a new paragraph as follows:

"(n) If it is contained in a dispenser pressurized by a gaseous propellant unless it bears such cautionary labeling with respect to handling, storage, and use of such container as is necessary to prevent the causing of injury to the health of any user or other individual during, or as the result of, reasonably foreseeable handling, storage, or use thereof, intentional or otherwise."

(b) Section 502(f) of such Act (21 U.S.C. 352(f)) is amended to read as follows:

"(f) Unless its labeling bears (1) adequate directions for use; (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, or against a substantial and reasonably foreseeable risk of causing accidental injury, in such manner and form, as are necessary for the protection of users, including instructions for first-aid treatment when necessary or appropriate; and (3) such other information relating to the foregoing matters and to side effects, contraindications, effectiveness, and other matters as may be required by or pursuant to regulations (applicable to the labeling of such drug) prescribed by the Secretary in order to carry out the purposes of this paragraph; and unless such labeling is in all respects in conformity (with respect to matters to be included in or omitted from such labeling, and with respect to manner and form of statement of matters included) with the requirements (applicable to the labeling of such drug) prescribed by the Secretary by or pursuant to regulation on the basis of a finding that such requirements are necessary for the safe and effective use of drugs or of the specific drug or class of drugs involved: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

(c)(1) Section 602 of such Act (21 U.S.C. 362) is amended by adding at the end thereof the following new paragraph:

"(f) If because of its nature, composition, or packaging it involves a substantial risk of causing injury to health during or as the result of any reasonably foreseeable handling, storage, or use by any individuals, whether intentional or otherwise, unless in either case it bears (in addition to any other prescribed labeling) (1) such cautionary labeling as is necessary for the protection of such individuals and (2), where necessary or appropriate, instructions for first-aid treatment. Whenever the Secretary finds that any cosmetic or class of cosmetics is subject to the provisions of this paragraph and in his judgment a declaration to that effect will promote the objectives of this paragraph by avoiding or resolving uncertainty as to its application, he may by regulation declare any such cosmetic or class of cosmetics to be, and it shall during the effectiveness of such regulation be deemed to be, subject to such provisions. Nothing in this paragraph shall be construed to exempt any article otherwise subject to the requirements of this paragraph from such requirements by reason of the absence of such a regulation."

(2) The first sentence of section 701(e) of such Act (21 U.S.C. 371(e)) is amended by striking out "or 502 (d) or (h)" and inserting in lieu thereof the following: "502 (d) or (h), or the second sentence of section 602(f)".

(d) Section 18 of the Federal Hazardous Substances Labeling Act (74 Stat. 372) is amended by striking out the following: ", except that the Federal Caustic Poison Act shall remain in full force and effect with respect to any 'dangerous caustic or corrosive substance' (as defined by that Act) which is an article subject to the Federal Food, Drug, and Cosmetic Act and which is, by virtue of paragraph 2 of

section 2(f) of this Act, excluded from the term 'hazardous substance' as defined in this Act".

(e) The amendments made by this section shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted, except that (1) so much of the new matter inserted in section 502(f) of the Federal Food, Drug, and Cosmetic Act as follows clause (2) thereof shall take effect upon such enactment, and (2) proceedings to issue regulations authorized by such amendments may be commenced at any time after such enactment.

TITLE II—AMENDMENTS TO FEDERAL HAZARDOUS SUBSTANCES LABELING ACT

APPLICATION OF ACT TO ARTICLES BEARING OR CONTAINING PESTICIDES, AND TO UNPACKAGED HAZARDOUS SUBSTANCES

SEC. 201. (a) Section 2(f)2. of such Act (15 U.S.C. 1261(f)(2)), which excludes "economic poisons" subject to the Federal Insecticide, Fungicide, and Rodenticide Act and certain other articles from the term "hazardous substance", is amended by inserting before the period at the end thereof the following: ", but such term shall apply to any article which is not itself an economic poison within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazardous substance within the meaning of subparagraph 1 of this paragraph by reason of bearing or containing such an economic poison".

(b) So much of section 2(n) of such Act (15 U.S.C. 1261(n)), defining the term "label", as precedes the semicolon is amended to read as follows:

"(n) the term 'label' means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto".

(c)(1) Paragraph (p) of section 2 of such Act (15 U.S.C. 1261(p)), defining the terms "misbranded package" and "misbranded package of a hazardous substance", is amended by changing so much of such paragraph as precedes subparagraph (1) thereof to read as follows:

"(p) The term 'misbranded hazardous substance' means a hazardous substance (including a toy, or another article intended for use by children, which is, bears, or contains a hazardous substance) intended, or packaged in a form suitable for use in the household or by children, which substance, except as otherwise provided by or pursuant to section 3, fails to bear a label—".

(2) Such paragraph (p) is further amended by striking out, in subparagraph (1), all of clause (J) through the word "and", and inserting in lieu thereof the following: "(J) the statement (i) 'Keep out of the reach of children' or its practical equivalent, or (ii), if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard, and".

(d) Section 3(b) of such Act (15 U.S.C. 1262(b)), authorizing the Secretary to establish reasonable variations or additional label requirements necessary for the protection of the public health and safety, is amended by changing so much of such subsection as follows the semicolon to read as follows: "and any such hazardous substance intended, or packaged in a form suitable, for use in the household or by children, which fails to bear a label in accordance with such regulations shall be deemed to be a misbranded hazardous substance."

(e) Subsection (d) of section 3 of such Act (15 U.S.C. 1262(d)), authorizing the Secretary to exempt containers of hazardous substances with respect to which adequate requirements satisfying the purposes of such Act have been established by or pursuant to another Act, is amended by inserting "hazardous substance or" before "container of a hazardous substance".

(f) Section 4 of such Act (15 U.S.C. 1263), setting forth prohibited acts, is amended as follows:

(1) Paragraphs (a), (c), and (g) of such section are each amended by striking out "misbranded package of a hazardous substance" and inserting in lieu thereof "misbranded hazardous substance";

(2) Paragraphs (b) and (f) of such section are each amended by striking out "being in a misbranded package" and inserting in lieu thereof "being a misbranded hazardous substance".

(g) Subsection (b) of section 5 of such Act (15 U.S.C. 1264) is amended by striking out "in misbranded packages" in clause (2) thereof and inserting in lieu thereof "a misbranded hazardous substance".

(h) Section 6(a) of such Act (15 U.S.C. 1265(a)) is amended by striking out "Any hazardous substance that is in a misbranded package" and inserting in lieu thereof "Any misbranded hazardous substance".

(i) Section 14(a) of such Act (15 U.S.C. 1273(a)) is amended by striking out "in misbranded packages" in the second sentence thereof and inserting in lieu thereof "a misbranded hazardous substance".

EXCLUSION, FROM INTERSTATE COMMERCE, OF TOYS AND OTHER CHILDREN'S ARTICLES CONTAINING HAZARDOUS SUBSTANCES, AND OF OTHER SUBSTANCES SO DANGEROUS THAT CAUTIONARY LABELING IS NOT ADEQUATE

SEC. 202. (a) Section 2 of such Act (15 U.S.C. 1261) is further amended by adding at the end thereof the following new paragraph:

"(q)(1) The term 'banned hazardous substance' means (A) any toy, or other article intended for use by children, which is or bears a hazardous substance, or which contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or (B) any hazardous substance intended or offered for household use, or so packaged as to be suitable for such use, which the Secretary by regulation classifies as a 'banned hazardous substance' on the basis of a finding that the hazard involved in the use of such substance in households is such that cautionary labeling would not be an adequate safeguard against substantial personal injury or substantial illness occurring during or as a proximate result of any customary or reasonably foreseeable handling or use of such substance: *Provided*, That the Secretary shall by regulation exempt from clause (A) of this paragraph articles, such as chemical sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved and which are intended for use by children who have attained sufficient maturity to read and heed the directions and warnings in the labeling of such article.

"(2) Proceedings for the issuance, amendment, or repeal of regulations pursuant to clause (B) of subparagraph (1) of this paragraph shall be governed by the provisions of section 701 (e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act: *Provided*, That if the Secretary finds that the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health, he may by order published in the Federal Register give notice of such finding, and thereupon such substance when intended or offered for household use, or when so packaged as to be suitable for such use, shall be deemed to be a 'banned hazardous substance' pending the completion of proceedings relating to the issuance of such regulation."

(b) Subsections (a), (b), (c), and (g) of section 4 of such Act, as amended by section 201 of this Act, are each further amended by inserting "or banned hazardous substance" after "misbranded hazardous substance."

(c) Clause (2) of section 5(b) of such Act, as amended by section 201 of this Act, is further amended by striking out "within the meaning of that term" in such clause and inserting in lieu thereof "or a banned hazardous substance within the meaning of those terms".

(d) Section 6(a) of such Act, as amended by section 201 of this Act, is further amended by inserting "or banned hazardous substance" after "Any misbranded hazardous substance".

(e) Section 14(a) of such Act, as amended by section 201 of this Act, is further amended by inserting "or banned hazardous substance" after "misbranded hazardous substance" in the second sentence thereof.

CHANGE IN SHORT TITLE OF ACT

SEC. 203. Section 1 of the Federal Hazardous Substances Labeling Act is amended by striking out "Labeling".

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., September 14, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of March 25, 1966, for a report on H.R. 13884, the "Professional Training and Cooperation Amendments of 1966."

This Administration bill would carry out the recommendation, contained in the President's message on Consumer Interests of March 21, 1966, for the enactment of "legislation authorizing expansion of the Food and Drug Administration's training programs for non-Federal officials."

Our testimony before the Subcommittee on Public Health and Welfare on behalf of the Department, presented by the Commissioner of Food and Drugs, set forth a detailed explanation and justification of the proposed measure. We therefore strongly urge the enactment of H.R. 13884.

Sincerely,

WILBUR J. COHEN, *Under Secretary.*

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., June 27, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Bureau of the Budget on H.R. 13884, a bill "To protect the public health by amending the Federal Food, Drug, and Cosmetic Act for the purpose of strengthening and facilitating mutual cooperation and assistance, including training of personnel, in the administration and enforcement of that Act and of State and local laws relating to food, drugs, devices, or cosmetics, and for other purposes."

H.R. 13884 would authorize the Secretary to contract with State and local agencies for the enforcement of the Federal Food, Drug, and Cosmetic Act; to give assistance to State and local authorities in the enforcement of their own laws regarding food, drugs, devices, and cosmetics; and to pay the costs of training and travel for State personnel. The amendment also would authorize the Secretary to contract, and pay in advance, for certain information necessary to the effective enforcement of the Federal Food, Drug, and Cosmetic Act.

This year, in his message to the Congress on consumer interests, the President said:

"The task of protecting the consumer cannot and should not be left solely to the Federal Government. The Government can and should provide creative Federal leadership to help States and local communities in their own constructive and determined efforts.

"As a step forward, Federal assistance is needed to strengthen and enlarge State and local professional staffs in the food and drug areas."

Accordingly, the Bureau of the Budget recommends the enactment of the Professional Training and Cooperation Amendments of 1966.

Sincerely yours,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

GENERAL COUNSEL OF THE DEPARTMENT OF COMMERCE,
Washington, D.C., June 23, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in further reply to your request for the views of this Department with respect to H.R. 13886, a bill to protect children and others from accidental death or injury by amending the Federal Food, Drug, and Cosmetic Act with respect to aspirin intended for children, safety closures on drug containers, and cautionary labeling of containers of articles subject to the Act where necessary to that end, and by amending the Federal Hazardous Substances Labeling Act to ban hazardous toys and articles intended for children, and other articles so hazardous as to be dangerous in the household regardless of labeling, and to apply to unpackaged articles intended for household use, and for other purposes.

H.R. 13886 would amend the Federal Food, Drug, and Cosmetic Act to provide that no aspirin preparation in a dosage form intended for use by children, and packaged in a retail container, may contain an aggregate quantity of aspirin that,

if ingested by a child of tender age at one time, is likely to cause death or serious injury. The Secretary of Health, Education, and Welfare may also require the retail container of a drug to be secured by a safety closure, to protect the health and safety of children. Dispensers pressurized by a gaseous propellant must bear cautionary labeling with respect to handling, storage and use of the container to prevent injury to health. Provisions are also included in the bill to require appropriate labeling of drugs and cosmetics, including instructions for first-aid treatment, where appropriate.

In addition, the bill would amend the Federal Hazardous Substances Labeling Act by bringing within its purview any toys or articles intended for children which bear or contain poisonous or hazardous substances, to provide for appropriate labeling. The bill would ban from interstate commerce any toy or other article intended for use by children which contains a hazardous substance and any hazardous substance intended for household use, if the Secretary determines that cautionary labeling would not provide adequate safeguard against substantial personal injury or illness. An exception is provided for articles, such as chemical sets, which necessarily contain hazardous substances intended for use by children mature enough to read and heed warning labeling.

This Department has no objection to the enactment of H.R. 13886.

It is a constructive measure and represents a forward step in correcting existing deficiencies in the Federal laws for the protection of public health. Its enactment should have the effect of increasing consumer confidence in the products of the industry, and of stimulating research (particularly in the cosmetic field) for the development of products that would meet the requirements of the Act as it would be amended.

We have been advised by the Bureau of the Budget that there would be no objection to the submission of this report from the standpoint of the Administrations' program.

Sincerely,

ROBERT E. GILES,
General Counsel.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., August 18, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your hearing notice of August 4 requesting that we expedite our reports on the following bills: H.R. 13886, H.R. 14557, H.R. 14632, H.R. 15269, and H.R. 15301.

H.R. 13886 is the Administration's proposed "Child Safety Act of 1966" which would carry out the recommendation, contained in the President's message on Consumer Interests of March 21, 1966, to:

"Bring all hazardous substances, regardless of their wrapping, under the safeguards of the Federal Hazardous Substances Labeling Act.

"Ban from commerce those household substances that are so hazardous that warning labels are not adequate safeguards.

"Ban the sale of toys and other children's articles containing hazardous substances, regardless of their packaging.

"Require labels to warn consumers against possible injury from drugs and cosmetics, and from food in pressurized containers.

"Limit the amount of children's aspirin available in retail packages.

"Require certain potent drugs attractive to children to have safety closure caps."

While we have received no request for a report on the other bills referred to in the hearing notice except H.R. 15269, we note that H.R. 14557, H.R. 14632, title IV of H.R. 15269, and H.R. 15301 contain the same legislative proposal as the Administration bill.

Our testimony before the Subcommittee on Public Health and Welfare on behalf of the Department, presented by the Commissioner of Food and Drugs, set forth a detailed explanation and justification of the proposed measure. We therefore strongly urge the enactment of H.R. 13886.

Sincerely,

WILBUR J. COHEN, *Under Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., June 14, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in reply to your letter of May 23.

Products covered by the Federal Hazardous Substances Labeling Act are required to have antidote information printed on their labels. However, many products, including drugs and cosmetics do not fall within the purview of the Federal Hazardous Substances Labeling Act. The "Child Safety Act of 1966," H.R. 13886, which you introduced on March 22 of this year will amend the Federal Food, Drug, and Cosmetic Act to require cautionary labeling of drugs and cosmetics to warn against accidental hazards and to provide information on antidotes where appropriate. We believe that this legislation will, if enacted, close the loopholes in the present law.

If we may be of further assistance, please let us know.

Sincerely yours,

JAMES L. GODDARD, M.D.,
Commissioner of Food and Drugs.

DEPARTMENT OF AGRICULTURE,
Washington, D.C., June 27, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.

DEAR MR. CHAIRMAN: This is in reply to your letter of March 25, 1966, requesting our views on H.R. 13886. The bill is entitled "To protect children and others from accidental death or injury by amending the Federal Food, Drug, and Cosmetic Act with respect to aspirin intended for children, safety closures on drug containers, and cautionary labeling of containers of articles subject to the Act where necessary to that end, and by amending the Federal Hazardous Substances Labeling Act to ban hazardous toys and articles intended for children, and other articles so hazardous as to be dangerous in the household regardless of labeling, and to apply to unpackaged articles intended for household use, and for other purposes."

This Department supports the objectives of H.R. 13886 which are in accord with the President's Message (H. Doc. 413, 89th Congress, 2nd Session) relative to a program recommending legislation to further protect the consumer's interest.

This Department has no objection to H.R. 13886 since its enactment would not affect our jurisdiction over products coming within the purview of the Virus-Serum-Toxin Act (21 U.S.C. 151–158) or the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135–135k) administered by this Department.

The Bureau of the Budget advises that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely yours,

ORVILLE L. FREEMAN, *Secretary.*

DEPARTMENT OF LABOR,
OFFICE OF THE SECRETARY,
Washington, D.C., May 4, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR MR. CHAIRMAN: This is in further response to your request for our views on H.R. 13886, the "Child Safety Act of 1966."

We strongly endorse the purpose of this measure which is designed to carry our President Johnson's recommendations for legislation to provide adequate labeling and packaging of dangerous substances in order to insure the safety of our citizens, and particularly our children's safety. In his Message on Consumer Interests of March 21, 1966, President Johnson stated that "Children must be our first concern * * * Too many children now become seriously ill—too many die—because of accidents that could be avoided by adequate labeling and packaging of dangerous substances."

We defer to the Department of Health, Education, and Welfare for definitive comments on this measure, since that is the agency primarily affected by the provisions of the bill.

The Bureau of the Budget advises that from the standpoint of the Administration's program there is no objection to the submission of this report.

Sincerely,

W. WILLARD WIRTZ,
Secretary of Labor.

DEPARTMENT OF JUSTICE,
OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D.C., June 27, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice on H.R. 13886, a bill "To protect children and others from accidental death or injury, by amending the Federal Food, Drug, and Cosmetic Act with respect to aspirin intended for children, safety closures on drug containers and cautionary labeling of containers of articles subject to the Act where necessary to that end, and by amending the Federal Hazardous Substances Labeling Act to ban hazardous toys and articles intended for children, and other articles so hazardous as to be dangerous in the household regardless of labeling, and to apply to unpackaged articles intended for household use, and for other purposes".

The proposed Act would amend the Federal Food, Drug, and Cosemtic Act by requiring that children's aspirin be packaged in small quantities, by authorizing a requirement of safety closures on drug containers, and by requiring additional information on drug and cosmetic labels. It would amend the Hazardous Substances Labeling Act by making the provisions of that Act applicable to unpackaged hazardous substances as well as to those contained in packages, and by authorizing the exclusion from interstate commerce of toys and other articles intended for use by children that are so hazardous that cautionary labeling does not afford adequate protection.

Whether this legislation should be enacted involves questions as to which the Department of Justice defers to the Department of Health, Education, and Welfare.

The Bureau of the Budget has advised us that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

RAMSEY CLARK,
Deputy Attorney General.

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., June 27, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Bureau of the Budget on H.R. 13886, a bill "To protect children and others from accidental death or injury by amending the Federal Food, Drug, and Cosmetic Act with respect to aspirin intended for children, safety closures on drug containers, and cautionary labeling of containers of articles subject to the Act where necessary to that end, and by amending the Federal Hazardous Substances Labeling Act to ban hazardous toys and articles intended for children, and other articles so hazardous as to be dangerous in the household regardless of labeling, and to apply to unpackaged articles intended for household use, and for other purposes."

This bill would amend the Federal Food, Drug and Cosmetic Act to provide additional protection in a number of areas where serious dangers exist to the health of children and others. In his message to the Congress this year on consumer interests, the President said: "Too many children now become seriously ill—too many die—because of accidents that could be avoided by adequate labeling and packaging of dangerous substances. This is a senseless and needless tragedy."

Accordingly, the Bureau of the Budget supports the objectives of H.R. 13886 and recommends its enactment.

Sincerely yours,

WILFRED H. ROMMEL,
Assistant Director for
Legislative Reference.

FEDERAL TRADE COMMISSION,
Washington, D.C., June 23, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your letter of March 25, 1966, requesting the views of the Commission on H.R. 13886, 89th Congress, 2d Session, a bill "To protect children and others from accidental death or injury by amending the Federal Food, Drug, and Cosmetic Act with respect to aspirin intended for children, safety closures on drug containers, and cautionary labeling of containers of articles subject to the Act where necessary to that end, and by amending the Federal Hazardous Substances Labeling Act to ban hazardous toys and articles intended for children, and other articles so hazardous as to be dangerous in the household regardless of labeling, and to apply to unpackaged articles intended for household use, and for other purposes."

The bill, which provides that it is to be cited as the "Child Safety Act of 1966", has two principal titles: "Title I—Amendments to Federal Food, Drug, and Cosmetic Act" and "Title II—Amendments to Federal Hazardous Substances Labeling Act."

Under the first title, it would amend the Federal Food, Drug, and Cosmetic Act by prohibiting the introduction into interstate commerce of aspirin or other form of salicylic acid in quantities exceeding limits established by the Secretary of Health, Education and Welfare and of drugs packaged in containers not secured by safety closures in conformity with regulations promulgated by the Secretary.

It also would amend sections of the act by providing for additional cautionary labeling of food, drugs, devices and cosmetics introduced into interstate commerce.

Under Title II the bill would amend the sections of the Federal Hazardous Substances Labeling Act by providing for cautionary labeling of articles containing economic poinsons and toys or other articles containing hazardous substances introduced into interstate commerce and suitable for use in the household or by children.

It would also amend that act by banning from interstate commerce toys and other articles intended for use by children and substances fror household use when cautionary labeling would not adequately safeguard the user.

With reference to the cautionary labeling requirements under both Titles I and II of the subject bill, the failure to label consumer products so as to adequately warn users thereof of potential dangers involved in their use may, in a proper case, be a deceptive act or practice in violation of section 5 of the Federal Trade Commission Act. The Commission has exercised jursidiction under this section with respect to cigarettes (*Trade Regulation Rule for the Prevention of Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking* (issued June 22, 1965)); swimming aids *Kirchner* v. *Federal Trade Commission*, 337 F. 2d 751 (9th Cir. 1964)); toys *James B. Tompkins*, Docket 8567 (Dec. 6, 1963)); electrical appliances (*Master Mechanics Mfg. Co.*, 59 FTC 792 (Oct. 16, 1961)); products poisonous if ingested or if fumes inhaled (*The Martin-Senour Co.*, 61 FTC 425 (1962); products injurious in contact with skin (*The L. R. Oatey Co.*, 60 FTC 1642 (1962), *The Martin-Senour Co., supra*).

The Commission has had considerable experience in banning articles from commerce that are so hazardous that labeling would not adequately protect the user of the product. This is the essence of the Flammable Fabrics Act, which is administered by the Commission (15 U.S.C. 1191). Section 3 of that act provides that the introduction into commerce of fabrics so highly flammable as to be dangerous when worn by individuals shall be unlawful and an unfair method of competition and an unfair and deceptive act or practice in commerce under the Federal Trade Commission Act. (See *A. Robbin & Co.* v. *Federal Trade Commission*, 337 F. 2d 441 (7th Cir. 1964)).

The wording of the bill is such that it would not cover such toys as the *Sonic Blaster*, which are dangerous in what they do rather than in what they are made of. The oversight could be easily corrected as the Bill goes through the legislative process, however, and we urge that it be. Both kinds of toys should be outlawed.

Mr. ROGERS of Florida. As our first witness this morning we are pleased to have the Commissioner of the Food and Drug Administration, Dr. James L. Goddard, and his associates.

Dr. Goddard, we are pleased to have you this morning. The committee has been following your work as you have taken over the administration of the Food and and Drug Administration with a great deal of interest and I might say with a great deal of admiration for the way you have been administering your position as Commissioner of Food and Drugs.

Mr. MACKAY. Mr. Chairman.

Mr. ROGERS of Florida. Yes.

Mr. MACKAY. I would like to bask in some reflected glory at this point because the Commissioner not only is such a distinguished and able Commissioner of Food and Drugs, but he has even had the wisdom to adopt the Fourth Congressional District of Georgia as his domicile. This has eliminated any reservation of doubt that I might have had otherwise about his ability.

Mr. ROGERS of Florida. Mr. Gilligan and I had thought he was going along pretty well. We are delighted to see him here and delighted to know this good news and of his good judgment.

We are delighted, too, to see Mr. Goodrich here, who has helped this committee on many occasions, Mr. Kinslow, and other associates.

Dr. Goddard, we would be pleased to have you proceed.

STATEMENT OF HON. JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS; ACCOMPANIED BY W. W. GOODRICH, ASSISTANT GENERAL COUNSEL FOR FOOD AND DRUGS; M. D. KINSLOW, DIRECTOR OF LEGISLATIVE SERVICES; DR. PAUL PALMISANO, ACTING DEPUTY DIRECTOR, BUREAU OF MEDICINE; E. W. LIGON, CHIEF OF HAZARDOUS SUBSTANCES LABELING BRANCH, BUREAU OF SCIENCE, FOOD AND DRUG ADMINISTRATION; AND THEODORE ELLENBOGEN, ASSISTANT GENERAL COUNSEL, LEGISLATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Dr. GODDARD. Mr. Chairman and members of the committee, we are happy to have the opportunity to appear before you today to discuss the Child Safety Act, H.R. 13886, and the professional training and cooperation amendments, H.R. 13884.

We are well aware of your busy hearing schedule and we appreciate the opportunity to discuss this important legislation.

On March 21, in his message on consumer interests, President Johnson stated:

Too many children now become seriously ill—too many die—because of accidents that could be avoided by adequate labeling and packaging of dangerios substances. This is senseless and needless tragedy.

The Child Safety Act is of great importance, because it is lifesaving. It is intended to prevent needless accidental deaths and injuries, especially among young children, which result from poisonings and

other injuries from the ingestion of drugs, cosmetics, and the handling of unlabeled articles intended for use around the house.

It is a labeling law—to the extent that we think warnings on the label can prevent accidents.

And it prohibits the sale of some hazardous substances that are too dangerous for household use.

Children's aspirin: An especially tragic situation exists with respect to children's aspirin. This aspirin is colored and flavored to ease the parent's task in getting the medicine into a feverish and fretful child. Properly used, this is a useful dosage form, as I am sure most parents will readily concede.

But the tragic part of the picture is that in 1965, 16,328 children under 5 were reported poisoned from the accidental ingestion of aspirin and other salicylates. Many of these children died. These, of course, are the reported cases; the actual numbers are unknown but undoubtedly are much higher.

The Public Health Service reports that aspirin and other salicylates are the leading cause of poisoning in children. Children's aspirin (1¼ grain) is involved in poisoning much more frequently than is the regular 5-grain tablet.

In 1965, for example, where the type of aspirin involved in accidental ingestion was reported, 90 percent of the cases involved children's aspirin. In other words, there were 12,102 cases where a differentiation could be made in the dosage form ingested. Of these 12,102 cases where there is knowledge of the dosage form, 10,854 of them involved children's aspirin.

The statistics lead us to one inescapable conclusion—every 3 days a child dies from an overdose of children's aspirin.

Our attention to the grave hazards posed by the salicylates started with cases of poisoning due to oil of wintergreen (methyl salicylate). Not many years ago, oil of wintergreen rubbing compound was a household standby for grandfather's rheumatism pains.

This very pleasant smelling preparation was available over the counter—and without any warning whatever of the grave hazard it posed to any young child that might drink of it.

We had some scattered reports of accidental deaths—and a very distressing one precipitated action to require a label warning. As reported to us by a Member of Congress, who enclosed a letter written by this child's father to the local medical society, a young couple found that their baby had swallowed some oil of wintergreen and rushed him to the hospital.

The urgency of the danger was not recognized—indeed, the physician in attendance said that any baby that could cry as loud as that one was not seriously ill.

However, a few hours later it became apparent that the baby was quite ill and he was returned to the hospital. The child was dead the next morning. The father protested that the bottle of rubbing solution had no warning of this danger. Had he only known of the danger, he said, the life might have been saved.

And we took action. Existing law requires that drugs bear warnings against unsafe dosage and against use by children where the use would be dangerous. But it says nothing about warnings against accidental injury. Nonetheless, in April 1954, we issued a statement of policy which called for a warning that these preparations were dangerous and should be kept out of the reach of children.

This was followed in 1955 by another policy statement on the labeling of drug preparations containing salicylates.

The following labeling was required: "Warning: Keep out of the reach of children" or "Warning: Keep this and all medications out of the reach of children" and safety closures were also recommended.

This policy statement was based on the recommendations of a medical advisory group, which called for public education as to the aspirin hazard, for standardization of dosage strength of children's aspirin, and for recommendations to the manufacturers that they not increase the size of their package units for children's aspirin and that they seek the development of safety closures.

These warnings have little effect on children who cannot read and understand, and some parents did not read or heed the warning.

It is our belief that a limitation on the quantity of children's aspirin in a retail package is needed to do the job. We do not think it is necessary to forbid the sale of flavored children's aspirin. But since there are so many cases where young children have eaten as many as 50 baby aspirin at one time, and since that is a lethal dose for some children, we feel that the hazard can best be controlled by limiting the bottle contents to less than an amount that might kill.

The two leading producers of children's aspirin package 50 tablet bottles. This is well above the toxic dose for a 3-year-old.

I have here, Mr. Chairman, examples of these bottles if you would like to see them.

This bill would authorize the Secretary of Health, Education, and Welfare to limit the quantity of salicylates intended for children that may be sold in any single retail package to an amount which is below the fatal dose for a small child. This amount will be determined on the basis of medical evidence and fixed by regulation.

Safety closures: Children's aspirin and other salicylates are not the only drugs that have been involved in accidental poisonings. In 1965, 18,155 children under 5 years of age were reported poisoned by drugs other than aspirin. While mortality figures for 1965 are not yet available, 7 children died in 1964 from ingesting such drugs.

This is in addition to the 125 that died that year from aspirin and other salicylate poisonings. Mr. Chairman, these figures refer to accidental ingestions and not adverse reactions or side effects.

In 1965 there were 2,248 reported cases involving accidental ingestion of vitamin and iron preparations, 1,311 involving hormones, 1,275 involving tranquilizers, 1,193 involving other analgesics, 975 involving laxatives, 838 involving antihistamines, 837 involving cough medicines, 786 involving amphetamines, 756 involving antiseptics, 703 involving liniments and rubbing alcohol, and 600 involving sedatives and other barbiturates.

All of these figures are for children under 5.

Despite the current warning on methyl salicylate, there were 61 reports of ingestion, 10 hospitalizations, and 2 fatalities in 1964; 57 reported ingestions, 9 hospitalizations, but no reported deaths in 1965.

Iron preparations are second to aspirin in causing serious injury and death. In October 1964, for example, there were reports of two separate cases of poisoning by iron tablets of 2-year-old children.

These iron tablets (ferrous sulphate) are used in the treatment and prevention of anemia, especially in pregnant women. They are often chocolate or sugarcoated and brightly colored and they taste like candy.

One of the children ate 30 to 60 tablets; it is not known how many the second one ate. Although the children became critically ill, fortunately both recovered.

A 15-month-old boy right here in Washington, D.C., was not so fortunate. He died after eating an unknown quantity of iron tablets. We also have a report of a 2-year-old baby girl, who died after drinking teething lotion containing benzocaine.

We do not know how many children could have been saved by safety closures or by labeling which warned against accidental injuries and contained information on antidotes and first aid treatment.

But it is reasonable to assume that a substantial number of the serious injuries and deaths could have been avoided. We believe that if such labeling will save only one life, it will be well worth it.

Two things can be done to reduce this hazard.

Authority should be given to the Secretary to require safety closures for containers of drugs frequently involved in poisonings. This should apply both to over-the-counter drugs and to drugs dispensed on prescription.

We would gather information about poisoning episodes from the poison control centers, through the National Clearinghouse for Poison Control Centers. To the extent that practicable safety closures are available, and could be adopted, we would have the authority to require them.

Regulations adopted to limit the contents of baby aspirin or to require safety closures would be issued in accordance with the Administrative Procedure Act, and would not be subject to formal rulemaking requirements which call for a hearing and decision on the record.

The issues here are strictly scientific ones (such as the maximum amount of aspirin that can be safely allowed in the container) or practical ones (such as whether a practicable safety closure is available for containers of drugs likely to be involved in accidental ingestions).

Cautionary labeling: The bill also would require warnings on the labels against accidental misuse of drugs where appropriate.

When the Federal Hazardous Substances Labeling Act was enacted in 1960, foods, drugs, and cosmetics were exempted. The reasoning was that warnings on the labels of these products would be more properly dealt with under the Federal Food, Drug, and Cosmetic Act.

But this act has not yet been amended—6 years later—to cover this loophole in consumer protection.

What is needed is clear authority to require cautionary warnings on the labels of drugs and cosmetics—and on pressurized food containers as well—to reduce the hazards against accidental injuries.

Drugs and cosmetics pose some of the same hazards that attend the use of articles subject to the Federal Hazardous Substances Labeling Act.

But they do not contain the same kind of warning information.

In 1964, for example, there were 3,058 reported cases of accidental poisonings of children under 5 by cosmetics.

A 2-year-old boy in Wichita, Kans., drank some of his mother's cologne. He later vomited. In doing so he aspirated some of the contents of the cologne into his lungs and contracted chemical pneumonia.

As there was no warning or ingredient statements on the cologne, the child's mother believed he was all right and did not take him to a physician immediately. When she did, the child had to be hospitalized where he received intensive treatment for 3 days. Fortunately, he recovered.

The point here, Mr. Chairman, is that under the Federal Hazardous Substances Labeling Act, household products which pose the danger of aspiration such as articles containing petroleum distillates, which are not cosmetic or drug products, are required to have the following warning:

> Danger, harmful or fatal if swallowed; contains petroleum distillate, if swallowed do not induce vomiting; call physician immediately; keep out of reach of children.

This kind of warning cannot presently be required on cosmetics under the Food, Drug, and Cosmetic Act.

Another example involves nail hardeners, which recently have caused numerous injuries. Some contain as much as 5 percent formaldehyde and are classified as drugs, but they are not required to bear warning labels. Household products containing the same ingredient are required to have the following labeling:

> Warning, harmful if swallowed; irritant, contains formaldehyde; keep away from the eyes, contact with skin may cause allergic irritation. In case of external contact flush thoroughly with water; if swallowed give water or milk, induce vomiting and call physician at once; keep out of reach of children.

The Child Safety Act would require cautionary labeling statements and appropriate antidotes and instruction for first aid treatment on drugs and cosmetics. These are urgently needed, particularly since cosmetics do not now have to carry a statement of even hazardous ingredients.

In the case of drugs, the bill would expand the warning section of existing law to require warnings against any substantial and reasonably foreseeable risk of accidental injury as may be necessary or appropriate, and such information about side effects, contraindications, effectiveness and other matters as the Department may require in the interest of the safe and effective use of drugs.

As to cosmetics which, because of their nature, composition, or packaging, involve a substantial risk of causing injury in the course of reasonably foreseeable handling, storage, or use, cautionary labeling and any needed first-aid instructions would be required.

The Secretary would be authorized, upon a finding that any cosmetic or class of cosmetics is subject to this new requirement, to issue a regulation to that effect when such a declaration will promote the objectives of the act by avoiding or resolving uncertainty as to application of the warning requirement to the cosmetics involved.

This provision for a declaratory regulation and the procedure for it are parallel to a provision now in the Hazardous Substances Labeling Act.

And pressurized food containers as well as such drug and cosmetic containers would have the same warning against puncturing or overheating that now appear on pressurized containers of hazardous household substances, and as a matter of voluntary practice, on many pressurized containers of food, drugs, and cosmetics.

Hazardous household substances: Title II of the Child Safety Act would change the name of the Federal Hazardous Substances Labeling

Act to the Federal Hazardous Substances Act, and would amend it to ban interstate distribution of hazardous toys and other hazardous articles intended for use by children, to ban some other articles that are so hazardous that they are not suitable for use in and around the household, even if they bear cautionary labeling, and to apply the act to unpackaged hazardous articles intended for household use.

The act now applies only to products that are packaged in containers intended or suitable for household use. It does not apply to unpackaged hazardous substances.

And it is a labeling law. It does not ban the sale of some extremely dangerous products so long as they bear cautionary labeling. Articles intended for use by children that would be very likely to cause substantial injury to them in their anticipated uses can be sold, if labeled "Keep out of the reach of children." This warning is, of course, inconsistent with the whole purpose of sale of the article.

We have had several striking examples of hazardous substances that are not packaged, and thus not required by law to be labeled with warnings about their hazards. During recent Easter seasons, several stores throughout the country were selling imported toy ducklings prepared from the skins of slaughtered ducklings. The stuffed material had been treated with an insecticide, primarily benzene hexachloride.

Clearly, they posed a substantial hazard in the course of their handling by young children. But because they were not sold in a package, FDA had no jurisdiction over them. I have here one of these articles for your examination.

We have also encountered imported Jequirity beans. These brightly colored scarlet and black beans are actually the seed of Indian licorice. They are grown in India, Africa, and in the Caribbean countries.

They are extremely poisonous if ingested and can cause death within a matter of hours. They have been offered for introduction into this country as dolls' eyes, docorations on swizzle sticks, and as beads in necklaces.

These dangerous products are sold loose or as unpackaged articles. We are inadequately equipped to prevent them from being brought into the United States, even though we know their extreme danger.

And here is a necklace made of Jequirity beans.

The authority to require label warnings on either packaged or unpackaged materials is not always adequate to provide the necessary protection. Some hazardous substances are simply too dangerous for use in and around the household and their distribution for household use should not be permitted.

A good example of this was a water repellent sold widely under the trade name "X–33." It was intended for use by the layman for painting basement walls to prevent water leaks. It was offered as a remarkable new product by a company which called itself the Wilmington Chemical Co., and its label said that it contained Du Pont Tyzor.

When this product first appeared on the market, it had a flash point of about 40° F. below zero. This meant that it was more explosive than gasoline.

It was not labeled with adequate warnings. We have reports of 3 deaths and over 30 injuries from the use of this product. X–33

was sold on consignment through filling stations, hardware stores, and other outlets all over the United States.

When we first learned of explosions resulting from the use of this product, we called upon the manufacturer to stiffen his warnings. But even that was not sufficient, and we learned that additional injuries were occurring from the use of the article with both the old and the new warning statement.

It seemed clear to us that X–33 had no place for use in the household. Its danger was too great. A woman in Minnesota was killed as a result of using X–33 in painting her basement walls. Although all the windows were open and no pilot light was on, an explosion occurred which was so great that the roof of the garage over the basement was blown off. The victim's husband was upstairs in the garage and was severely burned.

Other people died from X–33 explosions, and we asked the manufacturer to recall X–33 from the dealers. The company sued us for an injunction to prevent us from requiring the stiffened warnings on all of the containers that were then in the channels of sale, and to enjoin us from requiring the removal of the product from the market.

We were successful in moving to dismiss the action. The company was either unable or unwilling to recall the product from the hands of dealers, and it was necessary for us to make about 600 seizures which involves 50,000 gallons valued at invoice value of $350,000.

Most of these seizures were made possible because the manufacturer would not stiffen his label warnings as we asked him to do. We asked him to warn the layman not to use the article without first consulting a professional expert. We asked him to warn against its highly explosive nature.

Had this labeling been adopted, X–33 might perhaps still be sold. It seems clear to us that this is a product that should be banned from household use.

With your permission, Mr. Chairman, we have arranged for a brief demonstration.

Dr. E. W. Ligon, Chief of the Hazardous Substances Labeling Branch, Bureau of Science, Food and Drug Administration, has here a safe, but I think a rather impressive display of X–33 and its properties.

Dr. LIGON. Mr. Chairman and Commissioner Goddard, I think that perhaps we have cut the quantities that we are using down to the point where there will be no actual hazard under the circumstances, although we do have a fire extinguisher here just in case.

I have two small containers. One contains the familiar lighter fluid which you have all used in cigarette lighters; the other contains some of the original X–33 material.

Now, I would like to place a little of this in each of these two watch glasses, on your left the lighter fluid, on your right the X-33. These small quantities will burn in the open air and they are readily lighted by a match in each case, not too readily for the lighter fluid.

It took a little effort to light the lighter fluid, but with the X–33 of course no trouble at all. With the quantities involved here we are really not concerned with the hazard of the amount used. Let me, now demonstrate the difference between the original X–33 and the lighter fluid by taking two watch glasses supported on ice and placing two or three drops on them.

The X–33 is extremely flammable and readily ignites and burns even at the temperature of ice; the lighter fluid does not. You see that the X–33 readily lights even at the temperature of the ice.

Now I have a little demonstration in which I have attempted to set up conditions comparable to what readily happens in a basement.

I will light the pilot light of the gas hot water heater. While we are using a candle, we could do this with an electric spark. This would take quite a bit of gadgetry, so all I am representing here is the pilot light of the heater.

I have here a simple piece of electrical conduit supported at an angle, leading through this open aluminum foil trough to the candle.

I now paint the basement wall with X–33. I place three or four drops of X–33 in the open upper end of the conduit. The X–33 volatilizes and vapors flow down through the conduit and trought to the candle. They ignite and burn along the trough, then flash up through the conduit.

These X–33 vapors collect in low spots and take a while to build up a critical concentration, then they readily ignite from a flame or spark, and as heat and pressure build up we get an explosion.

Of course, as you know, I used only a few drops here, instead of quarts or gallons of X–33 used on basement walls. Even though lighter fluid under certain circumstances might explode, under the conditions that we have here, it doesn't reach an explosive concentration in air. This X–33 is much more explosive than lighter fluid.

Dr. GODDARD. Thank you, Doctor.

Mr. ROGERS of Florida. Thank you. That is very interesting. Any questions?

Dr. GODDARD. More recently, Mr. Chairman, we have had a great many seizures of "cracker balls" which are small torpedolike firecrackers. These "cracker balls" were imported from Formosa and Hong Kong.

They are brightly colored, resembling candy or breakfast cereal. They were plainly intended for use by young children. They contain arsenic and were sold singly and in pliofilm bags. The bags were also impregnated with arsenic.

The small size of the "cracker balls" and the bags made it difficult or impossible to provide a meaningful warning against the hazards of these substances. The "cracker balls" were used singly, and when they were removed from the bags, or when they were sold singly, they were often mistaken for small pieces of candy by young children.

We have reports that at least 24 children were injured when they put these "cracker balls" in their mouths thinking them to be candy. Several of these children had their teeth loosened when the "cracker balls" exploded in their mouths and often they suffered burns and cuts inside their mouths.

We told the claimants in the seizure cases that we know of no way they could legally label the fireworks. We took the view that each individual "cracker ball" was itself a container, the immediate container of the explosive, and that it would have to be labeled.

The district judge in Houston ruled that the individual "cracker balls" were not containers, and that the product might be labeled to bring it into compliance by putting the "cracker balls" into labeled pliofilm bags.

The "cracker balls" are out of the bag when used, of course, and it is at this time that they are most dangerous. So the labeling on the bags will not protect children from "cracker balls." We believe that this sort of a product is too dangerous for use by small children and should be banned.

We have here, Mr. Chairman, a display to show you cracker balls compared with foods. The cracker balls are in several of these compartments. The others contain breakfast cereals and candies.

Mr. ROGERS of Florida. Which are the cracker balls?

Dr. GODDARD. It is interesting that you should have to ask which are the cracker balls because children also could be deceived and not know that this was not candy or cereal. They are identified on the right-hand side of the display, Mr. Chairman.

Mr. O'BRIEN. They look more like candy than some of the others.

Mr. GILLIGAN. More like candy than candy.

Dr. GODDARD. The bill would authorize the Secretary to impose—after full opportunity for hearing and subject to judicial review—a ban on interstate commerce in hazardous substances intended or suitable for household use when he finds that the hazard involved is such that cautionary labeling would not be an adequate safeguard for public protection.

Where the procedural delay involved in plenary hearing would involve an imminent hazard to the public health, the Secretary would be authorized to suspend the article from the market pending completion of hearing and review.

Toys, or other articles for children, that bear or contain a hazardous substance would be banned by the law itself, provided that the Secretary would be required to exempt by regulation articles which contain hazardous substances intended for use by children of ages capable of reading and understanding the label instructions and warnings.

This proviso would apply to allow the sale of such products as children's chemistry sets with adequate labeling warnings attached to minimize the risk of their being used by younger children.

Finally, the bill would make it clear that household articles treated with pesticides for their protection are not exempt from the Federal Hazardous Substances Labeling Act. This act now exempts pesticides and other economic poisons that are subject to the Federal Insecticide, Fungicide, and Rodenticide Act, and doubts have been expressed whether FDA would have jurisdiction over articles such as the toy ducklings which had been treated by regulated pesticides. This bill would erase those doubts and make clear that the treated household substances were subject to the Federal Hazardous Substances Labeling Act.

Mr. Chairman, I urge enactment of this proposed legislation. President Johnson said in his message that "Children are our first concern. They are our hope and our future." We believe that the Child Safety Act will be an important step forward in protecting children from accidental injuries and death.

While my next subject, Mr. Chairman, is not as grim as the previous ones, the needs are just as important for public health protection.

I am speaking of the professional training and cooperation amendments, H.R. 13884.

Just 2 days ago we met with the Association of Food and Drug Officials of the United States at their annual conference at Kansas City.

I told these leaders of State and local food and drug programs that we believe their agencies play as prominent a role in protecting the health of this Nation as any Federal agency does.

I also told them we believe they are indispensable partners in the enforcement of consumer protection laws.

However, the Food and Drug Administration must provide leadership in helping the States and local communities meet consumer protection responsibilities. In the past, FDA has provided formal training opportunities for State and local food regulatory officials through a "Food Inspection Techniques" course and a training course in "Medicated Feed Inspection."

It has provided a wide variety of training materials for State and local representatives who wished to develop their own training programs. But there is much more to be done.

A recent study of State and local food and drug programs conducted by the Public Administration Service of Chicago and completed in 1965, made the following recommendation on personnel:

> Although there is much that State and local agencies and universities can do for themselves and for each other, important advances in the area of training can be better achieved by a coordinated national effort. A concerted effort to overcome training deficiencies is a necessary element of a needed operational coordination that combines Federal, State, and local efforts. Advantages of such coordinated planning for training of food and drug workers across the country are clear.

The Professional Training and Cooperation Amendments of 1966 would clarify and extend the Department's authority to provide both internal and external training for State and local officials in the administration of the food and drug laws administered by the various States and assisting us in administering the Federal law.

These amendments would help us work toward a coordinated national training effort. The Department would be authorized to pay travel and per diem costs for State and local officials while they are attending such training programs. Without this financial assistance, many officials would not be able to attend these advanced training courses because they could not travel outside their own State borders.

The amendments would also clearly delineate the Department's authority to cooperate with and render technical assistance to State and local authorities in the administration of local laws applying to articles of the kinds covered by the Federal Food, Drug, and Cosmetic Act.

Further, the Department's authority to utilize State and local officials will be improved by the amendments. The Department will be specifically authorized to accept assistance in the enforcement and administration of the pertinent Federal laws and to reimburse the State or local agency for such assistance when appropriate.

(Under present authority, the Secretary is authorized to commission State and local officials to conduct investigations, examinations, and inspections for the purpose of the Federal Food, Drug, and Cosmetic Act.)

Mr. Chairman, this concludes my presentation on H.R. 13886 and H.R. 13884. I want to thank you again for this opportunity to present our views on this important legislation. My colleagues and I will be happy to attempt to answer any questions you might have.

Mr. ROGERS of Florida. Thank you very much, Dr. Goddard, for a very excellent statement and also for the demonstrations that make

a very graphic demonstration of some of the problems you have discussed.

Mr. O'Brien, any questions?

Mr. O'BRIEN. No. I just merely join in your remarks, Mr. Chairman. I think we have had a graphic demonstration, and I do think that the legislation that we have before us does not impose too great a burden on the industry.

Mr. ROGERS of Florida. Mr. Gilligan?

Mr. GILLIGAN. Thank you, Mr. Chairman.

I join in expressing my appreciation of the presentation made. I was interested, Doctor, in the containers of children's aspirin that were passed up here. Do these caps that are on here now constitute what are referred to in this bill as safety closures?

Dr. GODDARD. This is one such safety closure; yes. They are working to improve these because—I don't know if you have tried to remove that cap.

Mr. GILLIGAN. Yes; I have.

Dr. GODDARD. Children are successful in removing those caps.

Mr. GILLIGAN. Do safety closures in your definition include, for instance, metal caps with a reverse screw? I mean one that unscrews in the reverse order?

Dr. GODDARD. The evaluation that I am aware of on the reverse screw metal cap would lead me not to include that as a safety closure.

Mr. GILLIGAN. You mean children don't know the right way to open it?

Dr. GODDARD. That is right. They will experiment and find the way.

Mr. GILLIGAN. As I understand section 3, it would authorize the requirement of putting safety closures on certain containers of drugs if the Secretary believes that to be in the interest of protecting the health and safety of children, but in your opinion that safety closure is not a sufficient protection?

You would still want the smaller containers required?

Dr. GODDARD. Yes. In the case of flavored children's aspirin, we believe that both would help in reducing the incidence of both nonfatal and fatal cases.

Mr. GILLIGAN. Would the requirement for the retail packaging of these drugs in small containers extend just to things like flavored aspirin which might attract children, or would it be applied generally across the board to any kind of dangerous drug to attempt to keep each package below the level of a lethal dosage?

Dr. GODDARD. Just the aspirin on the reduction and the total dosage available in package form.

Mr. GILLIGAN. Is there any reason why you have not considered extending it to other drugs and materials on the market?

My experience, I might say, with our children, is that they find out after they have tasted something that it is flavored aspirin; and their instincts are to taste, smell, feel, and so forth and then arrive at a judgment as to what they are dealing with, and it seems to me there are a number of drugs around that are in the normal family medicine chest which could fall within this dangerous category.

Dr. GODDARD. It is true there are a number of medicines in almost every household which are potentially toxic, but by all odds the greatest danger is posed by the flavored children's aspirin.

I mentioned there were 16,000-plus cases of accidental poisoning involving aspirin and other salicylate products in 1965, and the vast majority of these were children's aspirin.

When we analyzed the other statistics from the National Clearing House for Poison Control Centers, we found the frequency of occurrence of these other forms of poisoning drops off rather markedly and we think the safety closure principle applied to the more serious of these problems would suffice.

If it does not in experience suffice, then we may of necessity have to ask for other remedies, but there are other action programs that are aimed at helping reduce the incidence of posisonings, attempting to educate the family, the mother in particular, through the pediatricians.

The American Academy of Pediatrics has been particularly concerned about this problem for the past decade and has effectively worked with educational organizations, through their own membership and through the medical profession in general.

In addition, I know of several industry-sponsored activities. So it is my feeling that we should at this time limit the reduction of the quantity to the children's aspirin.

Mr. GILLIGAN. The language of the proposed act then would limit the authority of the Secretary in the field of package sizes to the single product of children's aspirin or aspirin?

Dr. GODDARD. Salicylates in general, intended for children.

Mr. GILLIGAN. One other brief question, Doctor.

In reference to the second bill, you provide for a number of things, including the authorization to the Secretary to pay for certain services rendered by private institutions or governmental agencies of one type or another in this general field.

In my quick glance at the bill I don't see any specific sums authorized for this purpose. It is your thought that whatever expenses are involved in this program can be absorbed within the existing departmental budget without the necessity of——

Dr. GODDARD. Yes; that is correct.

Mr. GILLIGAN. Thank you, sir.

No further questions, Mr. Chairman.

Mr. ROGERS of Florida. Mr. Mackay.

Mr. MACKAY. Mr. Chairman, I want to thank the Commissioner for this very fine testimony, and I wonder if you are prepared to react to the testimony which will follow from the Chemical Specialties Manufacturers Association, Inc., and particularly their discussion of preemption.

Perhaps I can state my question in this manner.

The manufacturer always says that he wants to avoid a multiplicity of regulation, and could you or any of your associates state to what extent the State laws now deal with this specific problem?

Mr. GOODRICH. There are several State laws in this area, but the Hazardous Substances Labeling Act was enacted in 1960 and the pattern since that time has been relatively consistent.

There were a few States that were ahead of us—Indiana for one had a law before we did—and so there were some differences.

In general, the labeling patterns have been consistent, but our position over the years, as the chairman will well remember, has been that if the States want to impose an additional warning we have not felt that we wanted to stand in the way of it.

Remember in the Drug Amendments of 1962 the Congress wrote in a specific provision that it did not preempt State laws and in 1965, on drug abuse, the same thing, so we would want to support in every way possible uniformity of the labeling patterns and the States would not be authorized under the constitutional cases to forbid the sale of a product in a lawfully labeled Federal container, but they would not be prohibited from adding additional warnings consistent with the Federal.

Mr. MACKAY. Also I would like to ask, since this Child Safety Act has been under discussion in the press and magazines a good bit, whether or not you have encountered any opposition to the thrust of this measure?

Dr. GODDARD. I haven't been made aware of any opposition to this proposal. There may be some that I am not aware of. I don't mean to imply that we have knowledge of all that goes on.

Mr. MACKAY. Do you have any other statistics on deaths? Have you undertaken to bring in all of the statistics on the deaths from this type of injury?

Dr. GODDARD. These are statistics, sir, from the National Clearinghouse for Poison Control Centers and the accident prevention program of the Public Health Service. The 1965 figures were just recently made available to us. We can provide for the record a more detailed breakdown as rapidly as these are provided to us.

You realize, as Mr. Goodrich points out, this does not represent the entire universe of accidental poisonings. Not all hospitals record and report these events. Those places where there are poison control centers as part of the hospitals do regularly channel, monthly I believe, their reports to the National Clearinghouse for compilation. So this represents a portion of the total universe of poisonings that occur each year, but I think its magnitude is sufficient for us to be truly concerned about taking whatever steps are available.

Now, we don't suggest that what we propose here will be the final solution. It is we think an important contribution to the final solution, however.

Mr. MACKAY. No further questions.

Thank you, Mr. Chairman.

Mr. ROGERS of Florida. Dr. Goddard, I notice, too, in a statement that will be put in the record by the Chemical Specialties Manufacturers Association (see p. 302), that they suggest another amendment to the bill.

Amendment No. 1 is set forth in their statement. Would you care to comment on this?

Dr. GODDARD. May I ask Mr. Goodrich to comment. He has a quicker grasp of the legal terminology than I do.

Mr. ROGERS of Florida. Yes, certainly.

Mr. GOODRICH. The first one to add "on the container" I am in question about because we are recommending that this law be extended to unpackaged materials, like the beads and things, so I would want to take this back to the office and look at it.

Mr. ROGERS of Florida. Would you let the committee have your thinking on that?

Mr. GOODRICH. Yes, sir. In the second one about warning which if complied with, there is the problem on the one hand a warning says

"Keep out of the reach of children" and it is a children's explosive, so——

Mr. ROGERS of Florida. Is a little inconsistent.

Mr. GOODRICH. Would you give us an opportunity to react to this more carefully after we have had a chance to study the proposals in detail?

(The information requested follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., August 28, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: At his appearance of June 24 on H.R. 13886 (the proposed "Child Safety Act") on behalf of this Department, before the Subcommittee on Public Health and Welfare, Dr. Goddard, the Commissioner of Food and Drugs, was asked to obtain for the Committee the Department's views on amendments to the bill proposed in a statement of the Chemical Specialties Manufacturers Association. These amendments are concerned with title II of the bill, relating to the Federal Hazardous Substances Labeling Act. Amendment No. 1 proposed by CSMA would insert certain language in clause (B) of the bill's definition of the term "banned hazardous substance" (page 10, beginning on line 14). Amendment No. 2 would add to the bill a limited preemption section, discussed below.

Dr. Goddard has also referred to us for reply your letter of July 11, which asks for comment on a letter from the Union Carbide Corporation favoring the bill but supporting the preemption provision proposed by the Chemical Specialties Manufacturers Association.

1. DEFINITION OF "BANNED HAZARDOUS SUBSTANCE"

Clause (B) of the definition

A key provision of H.R. 13886 is the proposed definition of "banned hazardous subsrance". Clause (A), discussed later in this letter, is specifically concerned with toys and other articles intended for use by children. Clause (B), to which the CSMA's proposed Amendment No. 1 is addressed, is aimed at those "hazardous substances" (as defined in present law) that, regardless of their labeling, are too dangerous for use in households. Amendment No. 1, as submitted to the Subcommittee by the Association, would make two changes in clause (B) so as to define a "banned hazardous substance", for the purpose of that clause, as—

"(B) any hazardous substance intended or offered for household use, or so packaged as to be suitable for such use, which the Secretary by regulation classifies as a 'banned hazardous substance' on the basis of a finding that the hazard involved in the use of such substance in housholds is such that cautionary labeling *on the container* would not *if complied with* be an adequate safeguard against substantial personal injury or substantial illness occurring during or as a proximate result of any customary or reasonably foreseeable handling or use of such substance." (Language proposed to be inserted by Amendment No. 1 is italicized.)

The first proposed change, i.e., insertion of the words "on the container", is inconsistent with another provision of the bill (§ 201) that would broaden the scope of the Federal Hazardous Substances Labeling Act so as to apply to *unpackaged* articles intended for use in the household or by children, as well as to hazardous substances packaged in a form suitable for such use. This change would, therefore, be inappropriate.

The second change, i.e., to insert the phrase "if complied with" as above shown, would also be unacceptable to us. The objective of the proposed § 202 of the Act is to authorize this Department—under appropriate safeguards and subject to the standard opportunity for judicial review on the basis of the administrative hearing record—to rule a product off the market for household use when the substance is so dangerous that no amount of reasonable cautionary labeling would serve the purpose of this Act.

The example we have given is X33, an extremely volatile substance intended for waterproofing basement walls, which has resulted in many explosions with consequent death, serious injury, and property damage merely because of the presence of the ordinary pilot light in the basement water heater or because of the striking of a match or spark in the basement. In this instance even if it were

possible to devise directions which, if complied with to the letter, would prevent an explosion—such as a direction not to have a pilot light going in the basement, not to light a match in basement, and to prevent the generation of a spark in the basement such as might occur from the discharge of static electricity or a spark from walking across the basement floor—it would obviously be unreasonable to expect compliance with such stringent directions by the ordinary user. Moreover, children and others who have not seen the label directions, including strangers such as meter readers, might enter the basement without being aware of the danger, and cause a spark.

Again, there might be offered for household use a hazardous substance which only a skilled operator could be expected to use competently and safely, and the necessary instructions for the safe use of which could not be expected to be understood and followed by the householder. Obviously, therefore, the words "if complied with" would tend to frustrate the purpose of the bill as applied to such substances.

Counsel for the CSMA has since indicated to our staff that his concern with clause (B) is his fear that the language of clause (B) would somehow be read to mean that the mere occurrence of injury or illness, without more, would automatically justify banning the article from the market, even when there is no indication that the cautionary labeling is inadequate or that improved labeling could not adequately serve the purpose. While we believe that such a reading of clause (B) is unwarranted, we would not object to the following alternative version, which is no less suited to the purpose and which, we understand, would meet CSMA's reservations:

"(B) any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Secertary by regulation classifies as a 'banned hazardous substance' on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under this Act for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce."

Clause (A) of the definition

This provision (page 10, 10–14) would, with certain exceptions, deem an article to be a "banned hazardous substance" if it is a "toy, or other article intended for use by children, which is or bears a hazardous substance, or which contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted". Counsel for CSMA has suggested to us that the criterion of accessibility to the child be extended to cases in which the article bears, and does not merely contain, the hazardous substance. We have no objection, though it seems unlikely that an article will ever "bear" a hazardous substance in such manner as not to be susceptible of access to the child. As thus changed, clause (A) would read: "(A) any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted".

Counsel has further suggested to us, and we agree, that the parenthetical phrase in the definition of "misbranded hazardous substance" on page 7, lines 22–24, of the bill should be brought into correspondence with this change, so as to read: "(including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted)".

2. PROVISION AS TO STATE OR LOCAL LABELING REQUIREMENTS

The Federal Hazardous Substances Labeling Act contains no provision as to the effect of the labeling requirements of the Act, and of regulations issued pursuant thereto, on labeling requirements established by or pursuant to State or local law for articles covered by the Act. Amendment No. 2 proposed by the CSMA to the Subcommittee would add to H.R. 13886 the following new section:

"SEC. 203. It is hereby expressly declared that it is the intent of the Congress to supersede any and all laws of the States and political subdivisions thereof insofar as they may now or hereafter provide for the precautionary labeling of any substance or article intended or suitable for household use (except for those substances defined in Sec. 2(f) (2) and (3) of this Act) which differs from the requirements or exemptions of this Act or the Regulations or Interpretations

promulgated pursuant thereto. Any law, regulation or ordinance purporting to establish such a labeling requirement shall be null and void."

(If favorably considered by the Committee, this amendment should be perfected by being cast in the form of an amendment to the basic Act itself. Moreover, the words "a container of" should be deleted, since the bill, as above mentioned, would broaden the Act so as to apply to unpackaged containers. The section number (203) indicates that the draftsman intended to renumber the present § 203 of the bill, which is the last section.)

This provision applies solely to labeling requirements. It would not preclude States and localities from prohibiting altogether the sale, for household use or for use by children, of articles, such as fireworks, covered by the Federal Act which State or local authorities consider too dangerous, or too great a public nuisance, for such use regardless of cautionary labeling, even if, after enactment of the bill, we should not feel warranted in imposing such a ban.

It is important to note, further, that, unlike the pervasive preemption provision contained in § 5 of the Federal Cigarette Labeling and Advertising Act, the CSMA's proposed amendment to H.R. 13886 would in effect recognize State and local power to require cautionary labeling but would require that labeling requirements imposed on articles covered by the Federal Act be uniform with requirements established by or pursuant to the latter. This approach is in line with that proposed in § 12 of the Fair Packaging and Labeling bills (H.R. 15440 and S. 985 (as passed by Senate)) with respect to the detailed requirements for label declaration of the net quantity of contents envisioned by those bills, and with the approach of the applicable provision in the proposed Traffic Safety Act of 1966 (S. 3005) in both the House and Senate versions.

a. Safety considerations bearing on the proposal.

The Congressional purpose in enacting the Federal Hazardous Substances Labeling Act was to prevent so far as possible the occurrence of accidental injury or illness resulting from the presence or use of hazardous substances (within its coverage) in households. The principal means chosen to that end was, and will continue to be, effective cautionary labeling, though H.R. 13886 contemplates that a substance be barred from household use altogether where cautionary labeling cannot reasonably be expected to accomplish its purpose. Cautionary labeling cannot, of course, in any event prevent accidents by itself; to do so, it must be read, understood, and followed. From this standpoint, it is highly desirable that such labeling have signal words that stand out and attract attention; that the information not be crowded on the label, and be easy to read and understand; and that for like articles, or articles involving a like hazard, the label warning be uniform, especially in view of the mobility of our population.

The need for uniformity was recognized by the Congressional Committees reporting on the bill (S. 1283, 86th Cong.) that became the HSL Act (P.L. 86–613). Your Committee, in its report, summarized this need as follows:

"The nationwide uniformity in the labeling of potentially hazardous chemicals would be advantageous to everybody. Such a labeling program would facilitate the education of the public in the cautionary use of these products. Informative, uniform labeling would enable physicians to administer antidotes immediately rather than waste precious time in determining the active ingredients of the product.

"The committee hopes that this legislation will help toward the establishment of uniform, adequate, modern labeling requirements by the various States. Such uniformity now exists to a certain degree in some States which have labeling laws and regulations. In the absence of a Federal law, there is a possibility that diverse labeling regulations will be adopted by the States, leading to a multiplicity of requirements and creating unnecessary confusion in labeling, to the detriment of the public." (H.R. Rept. No. 1861, p. 4.)

The Senate Committee, in reporting earlier on the bill, dealt with this point as follows:

"In recent years legislation has been enacted in several States—Colorado, Connecticut, Illinois, Indiana, Kansas, Ohio, Texas, and Vermont—regulating the labeling of hazardous substances suitable or intended for household use, many of which are shipped in interstate commerce. It is desirable that labeling of these substances be regulated when shipped in interstate commerce and that the standards and requirements of such labels be uniform. Thus, Federal legislation on this subject is needed to require uniform labeling of hazardous substances for household use to require that the labels of such substances: First, warn the user of any hazard in the customary use of the product; and, second, in case of an accident

identify the hazardous ingredient for the attending physician." (S. Rept. No. 1158, p. 3.)

And the American Medical Association had expressed the hope that the Federal legislation would "serve as a model for drafting uniform State laws across the country requiring a declaration of hazardous ingredients and warning statements on labels * * *." Accordingly, in order to stimulate the States in taking uniform action, we developed, and the Council of State Governments published as part of its Program of Suggested State Legislation for 1964 (pp. 13–22), a proposed model State Hazardous Substances Labeling Act, which is patterned after the Federal law. Section 9(b) provides that the administrator of the State law "shall cause the regulations promulgated under this act to conform, insofar as practicable, with the regulations established pursuant to the Federal Hazardous Substances Labeling Act;" however, according to a summary comparison of comparable State laws with the model law, prepared by the Food and Drug Administration in January 1966, only 6 of the 19 laws there listed contain this provision, though it should be noted that the laws of several of the States omitting this provision antedate the Federal Act. (A copy of the table is enclosed herewith as attachment A.)

This is not to suggest that States or localities are free to require labeling incompatible with Federal requirements; it is clear that they are not. However, the potential of nonuniformity (as distinguished from incompatibility) as between Federal and State or local labeling requirements, with consequent detriment to the effectiveness of the Federally required warnings, in real and substantial.

b. Economic considerations bearing on the proposal

We are not sufficiently conversant with the economic aspects of this problem to advise to what extent they should enter into the Committee's decision on this matter. The Committee may wish to consult the Commerce Department and perhaps the Small Business Administration in this connection.

c. Consideration of duplication of effort

Should the principle of nationwide uniformity of cautionary labeling be embodied in the Federal Act, this would not foreclose States and localities from passing on to the Federal agency their experience and views as to the need for, or desirability of, changes in Federal requirements. It would, however, enable them to concentrate their resources in areas of activity in which they can be most effective, to the mutual advantage of both State and Federal law enforcement. In this connection, what was said last year on this point in a report of the Public Administration Service to the Commissioner of Food and Drugs may be of interest:

"*Hazardous household substances.*—Like so many of our consumption goods, hazardous household substances are predominantly a part of interstate commerce. However, the variety of such products is potentially so great and the manufacture of some of them relatively so simple that they will doubtlessly continue to be produced in considerable quantity for essentially local distribution. It is questionable whether the states should attempt to register and review and approve the labels of all hazardous household products offered for sale within their boundaries; these tasks may divert state resources that probably could be put to better use. The state effort should instead be directed towards the assurance of proper labeling, in conformance with federal standards, of products of local manufacture and distribution, and the surveillance of these products at retail." (*A Study of State and Local Food and Drug Programs.* Report of Public Administration Service to Commissioner of Food and Drugs, p. 246. Wash. 1965.)

d. Conclusion

The arguments advanced by the proponents of a limited labeling preemption provision in this field, which is in line with the approach taken in recent bills, are reasonable, and we therefore believe that the proposed amendment—with the technical language changes we have suggested—would be desirable. It would express in the Act itself the original Congressional intent to achieve uniformity in the cautionary labeling of hazardous substances within the scope of the Act. However, we do not believe that consideration of this proposal should be permitted to result in delaying action on H.R. 13886, which is urgent and pressing.

Sincerely,

RALPH K. HUITT,
Assistant Secretary.

ATTACHMENT A

Comparison of State Hazardous Substances Labeling Acts with Council of State Government's recommended Uniform State Hazardous Substances Labeling Act (1964)

State	Statute reference, enactment date, and enforcement agency	Definitions section	Authority to—		Prohibited acts section
			Promulgate regulations declaring hazardous substances	Establish exemptions	
California	Art. 12, title 17, secs. 28740, 28755, 28779, 28799; 1961; health.	Essentially uniform	No	Yes	Essentially uniform, also prohibits manufacturing of misbranded product.
Colorado [1]	1960; Health	No definition for radioactive substance	Yes	Yes	Do.
Connecticut	Public Act 271; 1958; department of consumer protection.	No definition for strong sensitizers, extremely flammable-radioactive substance; labeling requirements less stringent.	No	No	Limited, not uniform.
Illinois	Ch. 111.5; 1960; health	Essentially uniform	Yes	Yes	Uniform, also prohibits manufacturing of misbranded products.
Indiana [2]	Ch. 211; 1958, health	do	No	No	Do.
Kansas	Ch. 341; 1957; health	Essentially uniform; definitions of hazardous substances includes toys.	No	Yes	Limited, not uniform.
Kentucky	KRS 217.650-217.710; 1960; health	No definition for highly toxic, extremely flammable.	No	No	Do.
Maine	Ch. 101, subch. IV; 1965; agriculture.	Uniform	Yes	Yes	Essentially uniform, also prohibits manufacturing of hazardous substances.
Massachusetts	Ch. 943; 1960; health	do	Yes	Yes	Uniform, also prohibits manufacturing hazardous substances.
Minnesota [1]	1962; agriculture	No definition for radioactive substance	No	Yes	Essentially uniform.
Michigan	Act No. 188; 1965; Agriculture	Uniform	Yes	Yes	Uniform.
North Dakota	Ch. 190; 1964; State laboratory	No definition for radioactive material	No	Yes	Essentially uniform.
Ohio	3716.01 to 3716.07; 1961; health	do	No	Yes	Do.
Oklahoma	Art. 16, sec. 1601	Essentially uniform	Yes	Yes	Uniform.
Tennessee	Ch. 104; 1965; agriculture	Uniform	Yes	Yes	Do.
Texas	Art. 726-1; 1958; health	No definition for radioactive substance, other variations from uniform bill.	No	Yes	Essentially uniform.
Vermont	Title 18, ch. 82; 1959; health	Extremely flammable, strong sensitizer not defined.	No	No	Limited, not uniform.
Virginia	Title 3, ch. 12.1; 1964; agriculture and immigration.	Uniform	Yes	Yes	Uniform.
Wisconsin	Ch. 320; 1965; agriculture	Essentially uniform	Yes	Yes	Do.

State	Legal procedures				Authority to—		
	Penalties	Injunction	Stop sale order	Hearing	Promulgate regulations for efficient enforcement	Check records	Conform insofar as practical to Federal act
California	1st offense, $25 to $500 or 6 months; 2d offense, up to $1,000, 1 year or both.	No	Yes	Yes	Yes	No	No.
Colorado [1]	1st offense, $500; 2d offense, $1,000 and 90 days	No	Yes	No	Yes	Yes; carriers and persons	No.
Connecticut	1st offense, $500, 6 months or both	No	Yes	Yes	Yes	No	No.
Illinois	1st offense, $100 to $1,000, 1 year or both	Yes	Yes	Yes	Yes	Yes; carriers and persons	No.
Indiana [2]	1st offense, $500; for willful disregard, $3,000, 1 year or both.	No	Yes	Yes	Yes	Yes	No.
Kansas	1st, $300, 60 days or both; 2d $1,000, 1 year or both	No	No	No	Yes	No	No.
Kentucky	$100 to $500, 30 days or both	No	Yes	Yes	Yes	do	No.
Maine	$10 to $100, 11 months or both	Yes	Yes	No	Yes	Yes; carriers and persons	Yes.
Massachusetts	$2,000, 6 months or both	No	Yes	No	Yes	Yes	No.
Minnesota [1]	Misdemeanor	No	Yes	Yes	Yes	Yes; persons and carriers	No.
Michigan	do	Yes	Yes	Yes	Yes	do	Yes.
North Dakota	do	No	Yes	Yes	Yes	do	Yes.
Ohio	1st, $300, 90 days; 2d, $3,000 or 90 days	No	Yes	Yes	Yes	do	No.
Oklahoma	1st, $500, 90 days or both; 2d, $3,000, 1 year or both	Yes	Yes	No	Yes	Yes; persons and carriers	Yes.
Tennessee	1st, $500, 90 days or both; 2d, $1,000, 1 year or both	No	Yes	Yes	Yes	No	Yes.
Texas	$1,000, 1 year or both	No	No	No	Yes	do	No.
Vermont	$1,000, up to 1 year or both	No	No	Yes	Yes	do	Yes.
Virginia	Misdemeanor	Yes	Yes	Yes	Yes	Yes; persons and carriers	No.
Wisconsin	No provision in law	Yes	Yes	Yes	No	No	No.

[1] Information in our files does not give statute references.
[2] Law requires product registration.

Source: Prepared by the U.S. Food and Drug Administration, Office of Federal-State Relations, January 1966.

Mr. ROGERS of Florida. Yes.

Now let me ask you just a few questions. You specifically say that in the warnings for aspirin there would be no hearings given and no procedure that is normally given in this situation.

Dr. GODDARD. That is correct.

Mr. ROGERS of Florida. You might comment on that and tell us why.

Mr. GOODRICH. Our reasoning on that was that this would be done through the Administrative Procedure Act of giving notice of proposed rulemaking and inviting comments. This is strictly a scientific issue of how many 1¼-grain aspirins can safely be allowed in a container below the lethal dose.

We think that is not a matter that would involve great controversy, and it would involve delay to call for hearings under those circumstances.

We do the same sort of thing in other areas where you are fixing what is a level of harm here. On the safety closures, we didn't provide for a hearing there because this is a practical matter that involves inspection and tests which have never really been subject to hearing procedures and have been, under the history of the Administrative Procedure Act itself, exempt from hearings, so we didn't provide hearings there.

We did not provide for hearings under 502(f)(1), page 3 of the bill, for the cautions on drug labeling.

We have been dealing with regulations under that section since 1938 without provision for hearing. We are regulating the entire range of drug labeling under that section without any problem without a hearing, so we didn't think it called for one to add this additional thing.

In the case of cosmetics where we were issuing additional cautionary warnings on those products, this was something new and we did provide there for full hearing under section 701 with judicial review, and in the case of the banning of hazardous household substances, again we provided for full review, so we have tried to make the type of selection in our proposals that Congress itself has made over the years in dealing with various provisions under this act.

Where a hearing is needed, serves a purpose, we are for it. Where it serves no purpose other than delay we have generally asked not to have it.

Mr. ROGERS of Florida. Do they have judicial review of the setting of the limitation of aspirin?

Mr. GOODRICH. If we were arbitrary and capricious. We have a case in the Supreme Court now involving this problem and we will have better guidance on that next term, as to the extent to which the Administrative Procedure Act or the Declaratory Judgments Act provides for review where the administrative action is not under one of the sections where Congress itself has specified the route of review.

Mr. ROGERS of Florida. Is there any thinking as to how many aspirins would be allowed in the bottle, Dr. Goddard?

Dr. GODDARD. I have with me Dr. Palmisano of the Bureau of Medicine who is a pediatrician.

Dr. Palmisano, would you care to comment on this?

Dr. PALMISANO. Yes.

In this area of where to draw the fine line on how many of these tablets to put in one package, that was discussed before, there is a range

involved because you have to remember that children are all sizes and shapes.

You have to figure out what type and what age of children are going to be able to do this. I jotted down some numbers in my experience with kids.

The deadly age for this type of thing runs around the age of 2. The babies start off very oral and they continue this for a long time. Everything goes right in the mouth. As a pediatrician I always wore bow ties because the end of the four-in-hand tie—this is one of these little things we learn—it goes in the mouth.

At the age of 2, I just checked, pulled out one of my little cards, and the average child, the child that fits in the 50 percentile of 100 children on their second birthday, the average of 50 percentile, the one in the middle will weigh about 28 pounds.

From other data we come to realize that about 1 grain of aspirin per pound is an acute dose if given in one dose; not if you stretch it out over a long period of time, but taken in one fell swoop, is a toxic dose. I am not saying it is necessarily a lethal dose. It would depend on a lot of factors, hydration of the child, and if he has an illness at the same time, so on and so forth.

This is a toxic dose. This is a dose that will require hospitalization at least for a short time and violent measures, like putting a tube down the stomach, and so on.

Many injuries require secondary treatment, by the way, but at 28 pounds for a 2-year-old child, 28 grains is a toxic dose.

Now, the number of baby aspirin for 28 grains is about 22. They are 1¼-grain aspirin, which is the small type, flavored aspirin. This gives you something to shoot at.

Twenty-two tablets taken by this 50 percentile 2-year-old child in one fell swoop, if the whole bottle is filled, down they go. He will get into trouble probably. A few won't and a few can be very sick.

You have to remember there will be a few kids that are age 2 that weigh 30 or 35 pounds and there are some that weigh less.

Somewhere in the neighborhood of 20 to 25 tablets of 1¼-grain aspirin flavored would seem to be the place where you have to cut it off if you want to do what we are talking about. I think this is important relative to what Mr. Gilligan said a little bit earlier.

There are two factors here. One is to put something on the bottle opening to try and cut down the ability to get at them, and with kids you always have to get the second, and third, and fourth line of defense.

I might point out that no matter how good these tops are, a kid has a built-in bottle opener; namely, his teeth. I have just thrown a few empty bottles to a batch of kids in a hospital and it takes a few seconds for them to realize they can pull that top off or bite through it.

It will prevent some, but when you add the limiting of the amount in each bottle I think this will answer most of our problems. We will still get some damage though.

Mr. ROGERS of Florida. Did you say they package 50 in a bottle now?

Dr. GODDARD. Yes. This is the usual number.

Mr. ROGERS of Florida. Suppose a child has a cold. What is a normal prescription for aspirin? How often do they have to take them? One an hour, every 2 hours, or how many?

Dr. PALMISANO. There are all sorts of schedules that physicians use. It is not a critical thing.

In general we feel that the therapeutic dose for aspirin, not the toxic dose, the dose that does what we want generally for fever or for pain, but in general for this age group for fever, is about a half a grain per pound per day. So a 28-pound 2-year-old child would get somewhere in the neighborhood of 14 or 15 grains of aspirin total in a day, but not in one dose, and the average of the time space is about 4 hours.

Aspirin of this type which is more or less pure aspirin has an effect of about 3 to 4 hours and blood level eventually falls off at the end of the next hour. You have to give the next dose if it is needed for fever.

If that would maintain for several days, or even longer if a child has measles or something of this sort, generally we don't get into trouble with it, but we have even gotten into trouble with therapeutic doses.

Mr. ROGERS of Florida. I just wonder now if a parent goes to buy a small bottle that has only 20 aspirin, that is really just about enough for 1 day's dosage.

Dr. GODDARD. About 2 days, Mr. Chairman.

Dr. PALMISANO. I would say 1 to 2 days for a persistent fever; that is correct.

Mr. ROGERS of Florida. Maybe they will just buy a lot of smaller bottles. Would they, do you think?

Dr. PALMISANO. I would expect they would.

Dr. GODDARD. This still, however, could contribute to reduction of the hazard, because the unopened bottles, unused bottles, would be more apt to be stored in the medicine chest out of the reach of the child of the age that Dr. Palmisano is referring to.

The problem often develops because the medicine is being used and is left on the bedside stand or is available to the child because of improper storage and handling, and so we recognize that although some parents might buy multiple containers, we still feel that having the total dosage in the single bottle reduced to less than a lethal level offers an opportunity for improvement in the current situation.

Mr. ROGERS of Florida. I was somewhat surprised at the statistics you gave of the recorded cases of aspirin poisoning, 12,000; 10,000 were actually from baby aspirin and not from the adult aspirin that we sometimes would think, and how is this accounted for? Because the baby aspirin has more of a candy flavor?

Dr. GODDARD. We think that that is one of the factors of course. They are attractive to children, also the way in which they are used by the mother is important. She says this tastes like candy, tastes good, and the child does take the aspirin, and indeed it doesn't have an unpleasant taste. One also must relate this to the increased use of this product in the marketplace.

It is being used much more widely today than it was 10 years ago when I worked in the accident prevention field. We were concerned about it even then, but we did not have this type of statistical information at that time to pin it down.

We knew of cases involving flavored baby aspirin, but we didn't have any grasp of the magnitude. These data on total ingestions in 1965 have just become available to us this week.

Mr. ROGERS of Florida. These are for children under 5 as I understand?

Dr. GODDARD. Yes, sir.

Mr. ROGERS of Florida. What is the history with respect to children above 5?

Dr. GODDARD. The accidental poisonings drop off rather sharply after 5. They still occur, but the magnitude of them is greatly diminished as the child approaches the preschool age and has had some experience and he gets out of this oral stage that Dr. Palmisano mentioned earlier.

He is much more busy getting into things, climbing, and other activities that remove him by and large from this type of risk.

Mr. ROGERS of Florida. And then the second most dangerous preparations are the iron preparations I believe you stated?

Dr. GODDARD. Vitamin and iron preparations.

Mr. ROGERS of Florida. I see.

Dr. GODDARD. Let us see. We will get the list out.

Yes; 2,248 involving accidental ingestion of vitamin and iron preparations.

Mr. ROGERS of Florida. I see. And this authority that would be given by this legislation would apply to over-the-counter drugs as well as drugs dispensed by prescription?

Dr. GODDARD. That is correct.

Mr. GOODRICH. With this point: That the drug as it moved in interstate commerce would have to have this warning on it and if it was a prescription drug or over the counter it would be subject to the safety closure, but the labeling on the actual prescription that goes to the patient only has to have on it such warning as the physician orders.

This was a part of the Durham-Humphery amendments back in 1951 and we are not proposing a change in that at this time. We would apply the safety closure to a drug dispensed——

Mr. ROGERS of Florida. To all?

Mr. GOODRICH. Yes, sir.

Mr. ROGERS of Florida. Let me ask you about the cautionary labeling.

This would go now to cosmetics and drugs?

Mr. GOODRICH. Right.

Dr. GODDARD. That is correct.

Mr. ROGERS of Florida. And against accidental misuse? Is that right?

Dr. GODDARD. That is correct.

Mr. ROGERS of Florida. What is the present authority in this area?

Mr. GOODRICH. The present authority is section 502(f)(1) which we mentioned which says that we have the right to require on drugs such warnings against misuse and against use in unsafe dosage, and against use by children as necessary to protect the public health.

Now, what Congress had in mind there was an intentional use of the article. When the methyl salicylate problem came up, that death was so tragic that we decided to put out a policy statement calling for warning in the case of salicylates against accidental poisoning, and the industry in general went along with that, it has not been challenged.

A year later, 1955, under that same authority we extended that to aspirin. Now, there is, of course, the issue of whether or not under this section requiring warnings against use by children, our authority includes accidental warnings, and this point we are trying to have

clarified by this bill and extended to give us meaningful authority to specify in detail what kind of warning should be there.

All we thought we could do before was say keep out of the reach of children or keep this and other medicines out of the reach of children, and in the case of methyl salicylate, to say that it was dangerous if ingested.

Mr. ROGERS of Florida. What about cosmetics?

Mr. GOODRICH. For cosmetics it would require that if from the nature, composition, or packaging the product involves a substantial risk of causing injury to health during or as the result of reasonably foreseeable handling, storage, or use, whether intentional or otherwise, the cosmetic is misbranded unless it bears cautionary labeling necessary for protection of the public and first aid warnings where appropriate. We would be given limited authority here by regulations to deal only with those areas where there was reason to resolve uncertainty or to carry out the purposes of the act. It wouldn't be an issue of regulation each time, but to take a hold of a situation where a particular cosmetic was causing injuries, to declare that that cosmetic was subject to the new provisions and would therefore have to bear a warning statement.

Mr. ROGERS of Florida. You mean what kind of injuries? Injuries to an adult person?

Mr. GOODRICH. No; accidental ingestion. We would get that same sort of information from the poison control centers.

If cologne, for example, had this aspiration hazard and it should be warned against because it was around the household, then it ought to be put on there.

Mr. ROGERS of Florida. What about hair dye?

Mr. GOODRICH. I don't know whether hair dye is involved in accidental poisonings or not.

Dr. GODDARD. Yes, it has been.

Mr. GOODRICH. Then it would have to have a warning that it would be dangerous if ingested.

Mr. ROGERS of Florida. Also lipsticks. Have you had any cases of poisoning from lipsticks?

Dr. GODDARD. There have been reports of cases where children have tried to eat lipstick. I don't know what toxicity may result. My impression is that it is generally harmless under those circumstances.

Dr. PALMISANO. Yes. There have been a few reports that I know about of lipstick actually having been eaten, but I don't know of any damage that has resulted to my knowledge.

Mr. ROGERS of Florida. In the last part of the bill, the "exclusion, from interstate commerce, of toys and other children's articles containing hazardous substances, and of other substances so dangerous that cautionary labeling is not adequate," this doesn't go to ingestion necessarily, does it?

Dr. GODDARD. No, It may include ingestion.

Mr. ROGERS of Florida. It may, but it goes beyond that as I would interpret it.

Mr. GOODRICH. This would be any toy that contains a hazardous substance which is defined as any substance toxic, corrosive, irritant, strong sensitize, flammable, or which generates pressure through percussion explosion.

The proposal would be nailed down to the types of hazardous substances that are defined in the Hazardous Substances Act which is Public Law 86–613. It is not an across-the-board toy bill.

Mr. ROGERS of Florida. Under this proposal it doesn't have to be packaged?

Dr. GODDARD. That is correct, it does not have to be.

Mr. ROGERS of Florida. And this is to get at the problem like——

Dr. GODDARD. The toy duckling, Jequirity beans, cracker balls, these kinds of toys.

Mr. ROGERS of Florida. Which the courts have held, at least in the *Houston* case, the cracker ball case, that it was not packaged. It was not a package as such, the individual one.

Dr. GODDARD. The individual container was not a package itself.

Mr. ROGERS of Florida. Under this provision if this is passed you could act against such items?

Dr. GODDARD. We could ban these from interstate commerce.

Mr. ROGERS of Florida. And from actual use?

Dr. GODDARD. That is correct.

Mr. ROGERS of Florida. Not require just labeling, but say they should not even be used.

Dr. GODDARD. As inherently too dangerous.

Mr. ROGERS of Florida. Also in the bill I think it is proposed for not only toys and other children's articles, but other substances so dangerous.

Dr. GODDARD. That is the X–33 type of substance.

Mr. ROGERS of Florida. Also, what about cosmetics there? Would they be covered?

Mr. GOODRICH. No.

Mr. ROGERS of Florida. If they were hazardous?

Mr. GOODRICH. They wouldn't come under the Hazardous Substances Act at all. They are exempt, and all we are proposing to do with cosmetics is to require warnings against accidental hazards under the other part of the bill.

Mr. ROGERS of Florida. I remember when we went through this before we had great concern all over the beauty industry about whether women were still going to be able to dye their hair or not. Remember?

Mr. GOODRICH. They are.

Mr. ROGERS of Florida. Even under this?

Mr. GOODRICH. Yes, sir; in spite of this.

Mr. ROGERS of Florida. I don't think we can prevent it, anyhow. This would also allow you to require a warning or an actual banning if there was such a thing as pressure built up in a cooking utensil? Would you require a label on that?

Mr. GOODRICH. No.

Mr. ROGERS of Florida. If it were so hazardous that you had experience that it blew up something you would ban it?

Mr. GOODRICH. We haven't classified that as a hazardous substance. It is not toxic, corrosive, irritant, nor does it generate pressure through decomposition, heat, or other means.

Mr. ROGERS of Florida. Well, it could do it by heat, couldn't it?

Dr. GODDARD. You could with a pressure cooker perhaps do that.

Mr. ROGERS of Florida. This is what I want to know, how far does this authority go.

Mr. GOODRICH. I wouldn't classify that as a "hazardous substance" myself.

Mr. ROGERS of Florida. You mentioned pressurized food containers on page 5 of your statement requiring a cautionary warning to reduce the hazards against accidental injuries.

Dr. GODDARD. Yes.

Mr. GOODRICH. Those containers are known to have a hazardous explosion if they are incinerated or punctured.

Mr. ROGERS of Florida. I want to know where the overlap is on just requiring labeling or actually classifying it as a "hazardous substance" to be prevented from use in interstate commerce.

Mr. GOODRICH. In order to ban it from use we would have to reach the conclusion that no form of labeling would adequtely safeguard.

Mr. ROGERS of Florida. In other words, if there were such a pressure cooker that blew up too often, then you could in effect ban it.

Mr. GOODRICH. That is right, but this is an alternate to labeling. First, labeling is tried and if the labeling does protect the public that is adequate, but we have to make a finding that no form of labeling is enough for this circumstance.

Mr. ROGERS of Florida. Is a hearing given here?

Mr. GOODRICH. Yes.

Mr. ROGERS of Florida. And judicial review?

Mr. GOODRICH. Yes, sir.

Mr. ROGERS of Florida. Now, on H.R. 13884, to strengthen the mutual cooperation and assistance, including training of personnel, in the administration and enforcement of the act and of State and local laws relating to food, drugs, devices, and cosmetics, is there any money authorized to be spent for this?

Dr. GODDARD. Not in this bill, of course. We are carrying out training activities in limited areas as part of our responsibilities today and to the extent that States do have funds available to send their personnel. This is quite frequently, as you know, a serious limitation in their obtaining the training they need to carry out their responsibilities, but to the extent that they can do it today some of them do participate.

We view the job ahead as being one that will require even greater participation by State and local food and drug officials, and one of the most significant contributions we can make at this point in time is the provision of scientific training because the technology is advancing so rapidly that adequate training is a requirement if they are to do their job effectively.

Mr. ROGERS of Florida. What funds will be used by the Department to carry out the provisions of this?

Dr. GODDARD. Our regular appropriations, sir.

Mr. ROGERS of Florida. How much would be anticipated to be used?

Dr. GODDARD. We have about $985,000 total training money at the present time for all purposes and I can't give you a firm estimate in the first year.

We first would have to determine which training courses are most badly needed at this time and set some priorities, and after that is done I can give you a firm estimate on the total cost.

Mr. ROGERS of Florida. Would you let the committee have an estimate of what you anticipate in the first year?

Mr. GODDARD. We will be happy to.

(The estimate requested when supplied, will be found in the committee files.)

Mr. ROGERS of Florida. Is there any limitation of time?

Dr. GODDARD. No, sir.

Mr. ROGERS of Florida. This would be an amendment to——

Mr. GOODRICH. To the Food, Drug, and Cosmetic Act itself.

Mr. ROGERS of Florida. I think we would like to know the amounts of money involved. I think your idea of bringing in the States to help enforce and carry out some of these duties is a very good one and I know you are doing this in the drug field as well, which I think is a very forward step.

Dr. GODDARD. Yes.

Mr. ROGERS of Florida. And I would think would be an economical way to approach the problem because it will reduce the requirement for additional Federal employees to get into the field and simply using existing State authorities that are already in their jobs now.

Dr. GODDARD. Yes, sir.

Mr. ROGERS of Florida. In your professional judgment, do you anticipate that you will need additional personnel to carry out the provisions of either of these bills?

Dr. GODDARD. If additional personnel are needed we believe any such increase can be absorbed within our present budget. Insofar as staff for training purposes is concerned we will draw upon our scientific staff that is now working in this area to constitute the faculties.

We have a training branch which sets up these training programs and in part this will be determined by the speed with which we intend to move the training programs forward.

Mr. ROGERS of Florida. Is there any provision in the law that presently requires a physician to report a poisoned child case to your clearing center?

Dr. GODDARD. There is no legal provision, if that is your question, sir.

Mr. ROGERS of Florida. Yes.

Dr. GODDARD. This is a voluntary effort that the National Academy of Pediatrics, the American Medical Association, and other groups were instrumental in establishing. I believe it was in 1957 we held the meeting in Chicago at the Academy of Pediatrics annual meeting and actually set up the national clearinghouse at that time.

There were in existence then some 10 or 12 poison control centers. Since then we have seen great growth in the establishment of additional poison control centers in hospital emergency rooms throughout the country. But there is no mandatory reporting requirement of these kinds of cases.

Mr. ROGERS of Florida. Do you feel the present setup is sufficient to give you the necessary information?

Dr. GODDARD. I think it gives us a good feel, if you will, for what is happening in accidental poisoning in childhood. I don't believe we need 100 percent reporting to determine that a serious problem exists with children's aspirin and some of these other compounds.

Mr. ROGERS of Florida. I suppose there is no authority at all to tie in the reporting of child cruelty by any stretch of the imagination in your particular department?

Dr. GODDARD. No; not in our agency. The Public Health Service is, however, along with the Academy of Pediatrics and others, concerned about this particular problem. If I remember correctly, Dr. Palmisano can check me on this, hasn't the academy attempted to gather statistics on the frequency of these episodes, and to stimulate better State laws in this field, and to make aware the local coroners, the medical examiners, of this as a possibility to be kept in mind when a young child is found dead or brought in in serious condition to emergency rooms?

Mr. ROGERS of Florida. Because I think that the committee itself, not on this particular legislation, would be interested in getting some facts on this. This is an area I would be very much interested in, and I think the committee would, to see what needs to be done in this area.

Dr. GODDARD. Mr. Ellenbogen.

Mr. ELLENBOGEN. Mr. Chairman, the Children's Bureau of our Department has developed, and published, and the Council of State Governments has endorsed, a uniform State law on this subject.

Mr. ROGERS of Florida. Good.

Are there any other questions?

Mr. GILLIGAN. Mr. Chairman, this isn't a question, but rather a comment.

I know that comparisons are odious but since Mr. Mackay pointed out the wisdom of Dr. Goddard in having chosen the Fourth District of Georgia as his domicile I think it is only fair to point out the wisdom of his lieutenant, Dr. Palmisano, in having Cincinnati, in the First District of Ohio, as his home and domicile.

I might say further that I think he was once a student of mine. If he survived that I dare say he can go on to greater things.

Mr. ROGERS of Florida. Maybe he took aspirin.

Dr. PALMISANO. If the record shows any mistakes in English and/or syntax we know where the blame lies.

Mr. GILLIGAN. I will clean up the record.

Mr. ROGERS of Florida. Mr. O'Brien, do you see anybody you recognize?

Mr. O'BRIEN. No; I am afraid to after this discussion.

Mr. ROGERS of Flodida. Are there any other questions?

This has been most helpful. You have brought to the committee information that will be a basis for us taking action in a very important field and we believe that the suggestions that you have given us will be helpful in trying to reduce the child accidents from poisoning.

This will conclude the hearing.

Dr. GODDARD. Thank you.

(Whereupon, at 11:30 a.m., the hearing adjourned subject to call of the Chair.)

CHILD SAFETY ACT AND PERSONNEL TRAINING

MONDAY, AUGUST 15, 1966

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met on 10 a.m., pursuant to recess, in room 2123, Rayburn House Office Building, Hon. Paul G. Rogers presiding.

Mr. ROGERS of Florida. The committee will come to order, please.

We are continuing our hearings on H.R. 13886 and we have with us this morning one of our distinguished colleagues who has been the forerunner in this field and the committee is very pleased to see the Honorable Lee Sullivan, a Member of Congress from Missouri, and our distinguished colleague.

We would be delighted to hear from you now and have the benefit of your advice for this committee.

STATEMENT OF HON. LEONOR K. SULLIVAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mrs. SULLIVAN. Thank you, Mr. Chairman and members of the committee.

Unlike most of your witnesses this morning, I am not here to oppose the proposed Child Safety Act. The fact is that most of its provisions are similar to, and, in specific instances, I believe, taken in whole or part from, my omnibus bill to rewrite the Food, Drug, and Cosmetic Act, H.R. 1235.

My complaint is that the Department of Health, Education, and Welfare failed to adopt enough of H.R. 1235 in this legislation.

For the past 5 years, I have pleaded unsuccessfully with that Department to get behind H.R. 1235 as a single package, with or without changes or amendments or deletions, in view of the fact that Presidents Kennedy and Johnson, and Secretaries Ribicoff and Celebrezze and Gardner, and Commissioners Larrick and Goddard at various times have endorsed and called ringingly for passage of nearly every single important item contained in my omnibus bill.

It has been called to my attention by the legislative strategists in the Department of Health, Education, and Welfare, however, that I do not serve on the committee which handles this legislation, and that the members of this committee might be miffed if the Department were to endorse H.R. 1235 by number, even if supporting most of the things in it.

Mr. ROGERS of Florida. May I interrupt the gentlewoman there and say she may advise the Department that the members of this

committee would not be miffed, but would be delighted to see any endorsement they make of the gentlewoman's bill.

Mrs. SULLIVAN. Thank you very much, Mr. Chairman. I appreciate that. The Department also appears to fear an omnibus bill approach; it seems to feel that if it goes along on the same petty pace which has been followed for the last dozen years in amending the basic act a little at a time, in piece-meal fashion, it will add up eventually to a solid and loophole-free statute.

In the meantime, however, we have limped along with a law which its administrators admit is woefully inadequate in coping with the dangers to our health and safety from foods, drugs, and cosmetics—and this bill before you today is just one illustration of how weak the present law is when it comes to protecting the lives of children.

Be that as it may, I am not at all pleased that when it took whole sections out of H.R. 1235 to form this truncated bill in one limited area of inadequacy in the basic statute, the Department went only half way toward protecting children from poisoning from candied or flavored aspirin.

The Department has requested legislation merely to limit the number of such attractive menaces to child safety that can be packaged in a single container. The theory is that if a child swallows the whole bottle of pills—as many of them frequently do—the probable dosage in a small container will not kill the child, even though it will undoubtedly make him very, very sick.

But why permit these pills to be sold at all?

Dr. James Goddard, the Commissioner of the Food and Drug Administration, has testified before you that every third day a child dies from an overdose of candied aspirin. At least 12,500 documented cases were recorded at poison control centers in 1965 of child poisoning from flavored aspirin—90 percent of all cases where the type of aspirin involved in a child poisoning case could be ascertained.

Children don't like plain aspirin—who does? They are seldom tempted to eat the unflavored tablets, which they could hardly mistake for candy once they tasted them. They love the candied type. They think it is candy. Some parents perhaps contribute to this tragic misconception by luring the child into taking medicine on the fraudulent claim that it is candy.

It tastes like candy and looks like candy, and the child—particularly a toddler who can't read the warnings on the label—can hardly be blamed for grabbing the bottle at the first opportunity and downing the contents.

The child may or may not die—125 of them died last year from this cause and in some years it has been a higher toll—but even when the child does not die, the parents are put through the most agonizing kind of unnecessary torture as the child's life hangs in the balance.

Almost every family has known the tragedy of a child death or the torture of a near tragedy from this cause. I have received many letters from families which have undergone this torture. They plead for the outlawing of this dangerous drug which takes the lives of so many young children, a drug whose dangerous nature they hadn't realized until a near tragedy occurred in their own households. They point out that you can easily crush a 1¼ grain aspirin, or part of a regular 5-grain tablet, on a spoon with jelly or sugar and get the dose down without any real difficulty.

I am disappointed in the timidity of the HEW position on this matter because, as I said, the administration proposal to do anything at all about children's flavored aspirin was prompted originally by the provision in section 14 of H.R. 1235, as introduced by me on the opening day of this Congress, January 4, 1965.

It was the first time any piece of legislation had ever been introduced in the Congress on the subject of flavored aspirin. It grew out of two paragraphs in a letter I received from a woman in St. Louis who had written to me in very general terms about the need for a central registry for all products in interstate commerce which had caused injury or disease for man or animal.

Her letter prompted me to write some inquiries to a number of different departments and agencies of the Federal Government—Food and Drug, Public Health, Agriculture, the Children's Bureau—about the feasibility of the idea.

Interestingly enough, nearly every agency I contacted referred me to the poison control program of Public Health and that agency, in turn, sent me some material on their operations.

I was appalled at what the statistics they sent me revealed about the horrible toll of accidents and death from candied aspirin for children. This was in 1964, and so when I reshaped my omnibus bill for introduction in the 89th Congress that December, I decided to include as section 14 a prohibition against the sale in interstate commerce of flavored aspirin.

Mr. Chairman, I would like to submit for the printed record of your hearing, the background of this idea, including the original letter to me and my followup on it, and the material I obtained on this subject.

Mr. ROGERS of Florida. Without objection, it will be made a part of the record.

(The material referred to follows:)

WEBSTER GROVES, MO., *April 29, 1964.*

Re our conversation on April 16, 1964, about accident reporting.

Hon. LEONOR SULLIVAN,
Congresswoman, Third District, Missouri,
Old House Office Building, Washington, D.C.

DEAR MRS. SULLIVAN: It should be mandatory for all persons responsible for the health of the public to report to a central agency all accidents or diseases clearly related to some product which has been shipped in interstate commerce.

The average person, including many public health officials and doctors, does not know what to do when such a product causes an accident. Usually each incident "dies" with the patient, or is forgotten if recovery is made. Many such accidents may happen before someone who cares takes action and brings a report to the proper authority. Therefore, the U.S. Public Health Service, or other designated agency should place in the hands of all doctors, etc. mandatory reporting forms with adequate provision for the gathering of sample material, and information necessary for the tracing of the source of the material. Such reports should cover accidents to non-human life as well as human. Such reporting could be provided for under laws now being administered without further Congressional action.

I have talked about this to Loretta Vrooman, and may have said something to Tom Curtis. However, to the best of my knowledge, nothing has been done about this.

The Consummer Conference was highly interesting. However, such conferences seem to bring out only those already interested and knowledgeable about the problems. It seems to me the problem is to reach groups which are new in the field.

Am enclosing an article from the Saturday Review which should interest you. I am becoming such a pest that I pulled it out to send to Tom before I read the last paragraph. My favorite building in Washington after the Rotunda of the Capital is the Library of Congress. I worked in the stacks on my MA Thesis, and almost became the Curator of Municipal Reports.

Sincerely,

Mrs. FLORIS R. MILLS.

HOUSE OF REPRESENTATIVES,
Washington, D.C., May 12, 1964.

Mrs. FLORIS R. MILLS,
Webster Groves, Mo.

DEAR MRS. MILLS: Thank you very much for your letter and the material you sent me on the Library of Congress and its needs. I have always supported the Library on appropriations and I will certainly do my best to improve their space situation as well as personnel.

On the other matter, I have referred your suggestion to the heads of a number of agencies and have asked them for comments and advice. It is very possible that the kind of thing you recommended can be carried out without the need for special legislation, but I am going to let them tell me so.

With best wishes, I am,

Sincerely yours,

LEONOR K. (MRS. JOHN B.) SULLIVAN,
Member of Congress,
Third District, Missouri.

HOUSE OF REPRESENTATIVES,
Washington, D.C., May 12, 1964.

Hon. LUTHER L. TERRY,
Surgeon General,
U.S. Public Health Service, Washington, D.C.

DEAR DR. TERRY: I would like to have your comments and suggestions and advice in connection with a recommendation made to me by a resident of the St. Louis Area who is active in consumers affairs. She writes as follows:

"It should be mandatory for all persons responsible for the health of the public to report to a central agency all accidents or diseases clearly related to some product which has been shipped in interstate commerce.

"The average person, including many public health officials and doctors, does not know what to do when such a product causes an accident. Usually each incident 'dies' with the patient, or is forgotten if recovery is made. Many such accidents may happen before someone who cares takes action and brings a report to the proper authority. Therefore, the U.S. Public Health Service, or other designated agency should place in the hands of all doctors, etc. mandatory reporting forms with adequate provision for the gathering of sample material, and information necessary for the tracing of the source of the material. Such reports should cover accidents to non-human life as well as human. Such reporting could be provided for under laws now being administered without further Congressional action."

Sincerely yours,

LEONOR K. (MRS. JOHN B.) SULLIVAN,
Member of Congress,
Third District, Missouri.

NOTE.—Similar letters also addressed to Commissioner George P. Larrick, Food and Drug Administration; Administrator Byron T. Shaw, Agricultural Research Service; Chief Katherine B. Oettinger, Children's Bureau.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., May 21, 1964.

Hon. LEONOR K. SULLIVAN,
House of Representatives,
Washington, D.C.

DEAR MRS. SULLIVAN: This replies to your letter of May 12, 1964, requesting our comment on a suggestion that all persons responsible for the health of the public be required to report to a central agency all accidents or diseases clearly related to some product which has been shipped in interstate commerce.

We believe there is no Federal law under which such a requirement could be made at this time. Legislation would be required in order to put this suggestion into effect.

We will discuss this matter with the Public Health Service and the Department and will let you have our further comments at a later date.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

DEPARTMENT OF AGRICULTURE,
AGRICULTURAL RESEARCH SERVICE,
OFFICE OF ADMINISTRATOR,
Washington, D.C., June 3, 1964.

Hon. LEONOR K. SULLIVAN,
House of Representatives.

DEAR MRS. SULLIVAN: This is in reply to your letter of May 12, addressed to Dr. Byron T. Shaw, regarding recommendations which you received from a constituent who feels some mandatory nationwide system should be established for reporting accidental poisoning cases.

Approximately 500 local Poison Control Centers are now operating throughout the continental United States. Many of these centers are manned by volunteers who keep the records and furnish needed information to doctors requesting it. Of the 500 Poison Control Centers, about half submit their accident records to a National Clearing House established by the U.S. Public Health Service. In turn, the National Clearing House disperses the information which it receives to all the participating centers and to all other interested agencies, including the Department of Agriculture. This is not a compulsory program, however, and only a small percentage of actual cases of poisoning reach the National Clearing House. Nevertheless, the whole program has been very popular with practicing physicians and is very helpful to the Pesticides Regulation Division of this Service in carrying out its responsibilities.

In addition to this program of the U.S. Public Health Service which is limited to human accidents, the Department of Agriculture investigates accidents which are brought directly to its attention. The Pesticides Regulation Division and the Plant Pest Control Division of this Service attempt to establish the facts on reported cases of injury both to man and animals if they are related to pesticide use.

The U.S. Public Health Service also maintains a record on deaths from all causes in its Bureau of Vital Statistics. Accidental deaths related to pesticides as well as those from drugs or other solid and liquid substances are recorded by that agency. A Public Health Service handbook entitled "Clinical Handbook on Economic Poisons" is a useful guide for physicians in the diagnosis and treatment of poisoning by pesticides, and has been distributed quite widely to interested doctors.

You may wish to write to the National Clearing House for Poison Control Centers in the Public Health Service for information regarding details on how the Poison Control Centers operate.

If we can be of further assistance to you in this matter, please feel free to call on us.

Sincerely yours,

R. J. ANDERSON, *Deputy Administrator.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
PUBLIC HEALTH SERVICE,
BUREAU OF STATE SERVICES,
Washington, D.C., May 20, 1964.

Hon. LEONOR K. SULLIVAN,
House of Representatives,
Washington, D.C.

DEAR MRS. SULLIVAN: Your letters of May 12, 1964 to Mrs. Oettinger, Chief of the Children's Bureau, and the Surgoen General, on reporting of injuries and disease associated with a product, have been referred to this Division for reply.

Your correspondent in the St. Louis area has identified a major opportunity for improved health protection services for the consumer.

I am pleased to report that this Division is taking positive action in our area of program responsibility—accidental injuries and accidental poisonings.

Our National Clearinghouse for Poison Control Centers receives reports on accidental poisonings from approximately 300 local poison control centers throughout the country. These reports are analyzed to identify the product involved and the circumstances surrounding the poisoning. On the basis of these reports, corrective action is brought about and prevention programs are developed. The clearinghouse also provides to the local centers, information on the diagnosis and treatment of poisoning cases. Attached is a summary report on poisoning cases and a copy of our Bulletin which is distributed to all State and local centers.

A number of special studies have been done on accidental injuries. These studies usually begin with the voluntary cooperative reporting of injuries by hospitals in a community and are followed up with interviews and investigations to identify the cause of the injury. From these studies corrective actions can be taken or programs to inform the public of hazards can be carried out. One such project is being carried out in cooperation with the health department in St. Louis. Other projects are being or have been carried out in Mississippi County, Arkansas and Robeson County, North Carolina on burn injuries; in Albany, New York on injuries to elderly people; and in Iowa on injuries associated with machinery. This Division has taken the lead on other problems which are national in scope. For example, a defective trailer heater, after being associated with two deaths, brought about a joint intensive effort on the part of the manufacturer, health departments, police departments and others to identify and trace all trailers having this type of heater and warning the owners. This was accomplished, but still 18 deaths resulted before all could be found and corrected.

Other steps to improve consumer protection from injuries are being planned by this Division. We hope to identify and establish certain cities or counties as special surveillance areas for injury reporting. These would be areas representing various sections of the country. From these areas we would have rapid reporting and investigation of injuries which would bring about a reduction of the "lag time" between the identification of an injury cause and its correction.

We feel that the central reporting of all accidental injuries and diseases related to a product would be impractical and perhaps unnecessary. We feel that a carefully selected and efficiently operated network of reporting areas such as proposed above would bring about the benefits suggested for a central reporting service.

Your correspondent in the St. Louis area may find it helpful to discuss her ideas with Dr. C. Howe Eller, Commissioner of Health, St. Louis County Health Department. Dr. Eller is a member of the Surgeon General's Advisory Committee on Accident Prevention and is especially interested in injury control.

We appreciate your bringing to our attention the services that would benefit your constituent. We hope the above information will be helpful to you.

Sincerely yours,

PAUL V. JOLIET, M.D.,
Chief, Division of Accident Prevention.

NATIONAL CLEARINGHOUSE FOR POISON CONTROL CENTERS, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, PUBLIC HEALTH SERVICE, WASHINGTON, D.C.

(A service of the Division of Accident Prevention, Bureau of State Services)

SEPTEMBER-OCTOBER 1963.

SURVEY OF THE MOST-FREQUENTLY ACCIDENTALLY INGESTED PRODUCTS

A primary function of the National Clearinghouse for Poison Control Centers is analysis of the data reported by the centers. Currently, about half of the 511 centers throughout the country are using our standard report form (PHS–2805). In 1961 42,000 cases were submitted for statistical processing. Approximately 90 percent were reports of ingestions among children under 5 years of age. Summaries of our tabulations were distributed to the participating centers. Consolidated summaries were sent to the State Health Departments concerned and Public Health Service Regional Offices.

After coding and tabulation, the individual case histories are filed by category (such as laxatives, bleaches, tranquilizers, etc.) and then subdivided by trade name. This file serves to provide clinical information both on categories of products and on individual trade name items that make up each category.

An analysis of the accidental ingestions among children under 5 years of age shows that 10 categories out of the 80 currently used accounted for approximately half the cases. The following table lists the relative frequencies of such ingestions during 1961.

Types of substances:	*Percent of total*
1. Aspirin	21. 8
2. Insecticides (exclusive of mothballs)	5. 3
3. Bleach	4. 4
4. Detergents, soaps, cleaners	4. 3
5. Furniture polish	2. 4
6. Kerosene	2. 2
7. Vitamins and iron preparations	2. 2
8. Disinfectants, deodorizers	2. 1
9. Lye, corrosives	2. 1
10. Laxatives	1. 9

If suicides and accidental ingestions in persons 5 years and over were also considered, sedatives-barbiturates (4.5% of all ingestions) and tranquilizers (2.8% of all ingestions) would be included in the "top 10." However, since poison control centers are concerned primarily with accidental posioning, the following observations will be confied to those categories of substances most frequently ingested by small children.

Individual case reports are on file for those ingestions reported to us since July 1959, a 30-month study period in which approximately 90,000 reports were analyzed. Within each of the "top 10" categories, the number of different products and the frequency of each were tabulated. Information concerning hospitalization was tabulated on the 10 most-frequently-ingested products within each of the "top 10." This report, then, would cover 100 individual products except that the kerosene category is not broken down by trade names.

On further review of the cases accumulated in this 30-month period, it was found that 34,651 reports identified the name of the ingested product in these "top 10" categories. Of 1722 different trade name products represented, 15 were reported 200 or more times, and 16 others were reported 100 or more times.

Products among "Top 10" substances which were reported 100 or more times, July 1959 to December 1961

Product	Cases	Percent [1] hospitalized	Product	Cases	Percent [1] hospitalized
1. Aspirin	15,546	13.9	19. "Comet"	169	0.0
2. "Clorox"	1,855	14.3	20. "Harris Famous" roach tablets	168	5.6
3. Kerosene	1,656	39.5	21. "6-12" insect repellent	168	8.5
4. "Ex-Lax"	1,021	6.0	22. "Poly-Vi-Sol"	166	0.0
5. "Drano"	989	50.9	23. "Mr. Clean"	162	13.8
6. Ammonia	420	40.8	24. "Sani-Flush"	161	22.5
7. "Pride" furniture polish	360	32.6	25. "Carter's Little Pills"	161	7.5
8. "Lysol"	356	29.0	26. "Roman" cleanser bleach	158	6.5
9. "Old English" polishes	303	50.3	27. "Joy"	145	5.7
10. "Gator Roach Hives"	275	21.3	28. "Chocks" vitamins	127	0.0
11. "Lestoil"	262	27.9	29. "Ajax"	121	13.6
12. Lye	245	55.1	30. "Lilly's" ant cup	119	27.3
13. "Purex"	240	13.0	31. "Easy-Off" oven cleaner	101	29.8
14. "Pine-Sol" disinfectant	212	31.5			
15. "Black Flag"	200	25.5	Total "31"	26,425	20.1
16. "Real-Kill"	194	26.3			
17. "Raid"	192	22.7	Total cases with trade name specified	34,653	20.0
18. "Windex"	173	3.1			

[1] Based on cases with known information regarding hospitalization.

It was found that 15 products (acetyl salicylic acid, kerosene, and ammonia each counted as a single product) accounted for 0.9 percent of the individually identified products, but for 69.1 percent (23,940) of the cases. When the 31 products named 100 or more times were analyzed, 1.8 percent of the individually identified products accounted for 76.3 percent (26,425) of the ingestion cases. The remaining 1,691 products represented 98.2 percent of the identified substances but only 23.7 percent of the cases. Aspirin, of course, led the 10 most-frequently ingested products with almost half of the cases, followed by "Clorox" (5.4%), kerosene (4.8%) "Ex-Lax" (2.9%), and "Drano" (2.9%).

Children hospitalized from these ingestions ranged from 6.0 percent to as high as 55 percent, with figures based on the number of cases for which data concerning hospitalization were available. The criteria for hospitalizing an ingestion case vary from hospital to hospital. Many of the cases were admitted either because of a hospital policy or for 24-hour observation. The average hospitalization for the 15 products was 20.6 percent, and 20.0 percent for the combined products in all of the selected groups of substances.

In analyzing ingestions among children under 5 years of age, the identification of the trade-name products most-frequently encountered was included for a number of reasons. When relatively few products account for the majority of ingestions, the necessity is clear for having the information on the ingredients, symptoms, and treatment for these cases instantly available. Because information is generally available on the more common products (whether by reason of volume of sales or popularity of the product), the less-frequently-mentioned products probably cause the poison control center the most difficulty. In the latter case, the formulations are less likely to be readily available, causing delay in the disposition of the child. In brief, the 15 products that are mentioned 200 times or more should be familiar to the doctors in the poison control centers, whereas the 5,000 to 6,000 products that have been ingested a fewer number of times will present greater problems.

On several occasions in these tabulations, the trade name mentioned on the report fails to specify the individual product of a company. Thus, several similar products with a familiar company trade name may be grouped together; examples of this are "Black Flag," "Real-Kill," "Raid," and "Old English" Furniture Polish. Other tables include merely a chemical identification, since this was the principal method of identifying the products when these cases were reported. Therefore, in one table both potash and lye are mentioned individually, although several of the products in the table might have contained either or both of these substances. Similarly, ferrous sulfate and ammonia are listed in their appropriate categories. The tables, therefore, reflect the named products that were identified by the individual poison control centers and, although some of the lists might not be mutually exclusive, there are still many interesting and informative conclusions that might be made.

ASPIRIN

Aspirins, all types combined, whether identified by brand name or not, constituted about one-fourth of all ingestions with a total of 51 brand names listed. Among reports listing brand names, "St. Joseph's" (54%), "Bayer's" (32%), and "Bufferin" (6%) comprised 92 percent of all ingestions. The next seven brands made up another 6 percent and 41 brands the remaining 2 percent of the cases. Two-thirds of the case reports failed to note a trade name.

Even though aspirin accounts for nearly a third of the poisoning deaths among children under 5 reported yearly, most of the reported ingestions do not require hospitalization. Only 13.9 percent of the cases known as to hospitalization were treated on an in-patient basis, and only 0.6 percent were hospitalized for four or more days.

The following table indicates the 10 most-frequently-ingested brands of aspirin of the 51 brands reported and known as to "baby" or "adult" type. It might be pointed out that, although the frequencies of these categories are based on 1961 figures, the aspirin table was the only one in the group that does not contain the accumulated data for the 30-month study period.

Aspirin most frequently ingested by all ages, by trade name, 1961 only

Trade name	Total		Type of aspirin					
			Baby		Adult		Unknown	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
1. "St. Joseph's"	1,515	54.0	949	61.6	16	4.8	550	58.5
2. "Bayer"	891	31.8	435	28.2	103	30.8	353	37.6
3. "Bufferin"	171	6.1			171	51.2		
4. "Rexall"	60	2.1	41	2.7	7	2.1	12	1.3
5. "Abbott"	36	1.3	31	2.0	1	.3	4	.4
6. "Johnson's"	23	.8	23	1.5				
7. "McKesson"	22	.8	13	.8	4	1.2	5	.5
8. "Aspergum"	20	.7			20	6.0		
9. "Squibb"	9	.3	5	.3	1	.3	3	.3
10. "Norwich"	7	.2	4	.3	2	.6	1	.1
Other	50	1.8	29	1.9	9	2.7	12	1.3
Total	2,804	99.9	1,530	100.0	334	100.0	940	100.0

INSECTICIDES

Insecticides (excluding mothballs) accounted for 5 percent of all the ingestions among small children. During the study period, 467 trade-name products were designated among the 3,368 cases which were reviewed. The 10 most frequently named constituted 47 percent of the cases and, as might be expected, were the types of insecticides that might be found in and around the house, the environment of the small and unaware child.

Insecticides most frequently ingested by all ages, by trade name and hospitalization, July 1959 to December 1961

	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
1. "Gator Roach Hives"	275	225	21.3	78.7
2. "Black Flag"	200	102	25.5	74.5
3. "Real-Kill"	194	118	26.3	73.7
4. "Raid"	192	75	22.7	77.3
5. "Harris Famous" roach tablets	168	125	5.6	94.4
6. "6-12" insect repellent	168	71	8.5	91.5
7. "Lilly's" ant cup	119	33	27.3	72.7
8. "Antrol" ant killer	88	48	31.2	68.8
9. "Terro" ant killer	84	62	37.1	62.9
10. "Off!" insect repellent	77	20	0	100.0
Total	1,565	879	20.7	79.3

BLEACHES

Bleaches are responsible for 4.4 percent of the ingestions among children under 5 years of age. In 2,886 cases in which the trade names were identified, there were 155 products and the 10 most frequently mentioned accounted for 2509 reports. "Clorox" accounted for 64 percent of the cases in which the trade names were known. Following this was "Purex" (8.3%), "Roman" Cleanser (5.5%), "Dazzle" (2.3%), and "Fleecy White" (1.8%). The remaining 150 trade names identified constituted only 18 percent of the bleach ingestions reported. In those cases where hopsitalization was known, it was found that 14.1 percent of the children were admitted. However, no breakdown was made to determine if a greater majority were hospitalized in the earlier part of the study, when less was known about the effects of hypochlorite ingestions. Some were admitted only for observation.

Bleaches most frequently ingested by all ages, by trade name and hospitalization, July 1959 to December 1961

Trade name	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
1. "Clorox"	1,855	1,121	14.3	85.7
2. "Purex"	240	162	13.0	87.0
3. "Roman" cleanser	158	107	6.5	93.5
4. "Dazzle"	65	17	41.2	58.8
5. "Fleecy White"	51	19	26.3	73.7
6. "Lestaire"	43	16	12.5	87.5
5. "Hi-lex"	34	21	28.6	71.4
8. "Savol"	22	14	7.1	92.9
9. "Hood 33"	21	19	5.3	94.7
10. "White Monday"	20	10	30.0	70.0
Total	2,509	1,506	14.1	85.9

DETERGENTS, SOAPS, AND CLEANERS

This heterogeneous class of products was named in 4.3 percent of the cases reported to the National Clearinghouse in 1961. Listed on the reports as the agent in the ingestion, in the 3496 cases in which a product was identified, were 413 different trade names. Again, the 10 most frequently ingested from this group contributed 1712 cases, or 49 percent of the total. Ammonia led the list with 420 cases, but it is a generic name and seldom identified by individual label. However, it accounted for a greater percentage of hospitaliztion than the other products listed.

Detergents, soaps, and cleaners most frequently ingested by all ages, by trade name and hospitalization, July 1959 to December 1961

Trade name	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
1. Ammonia	420	213	40.8	59.2
2. "Lestoil"	262	86	27.9	72.1
3. "Windex"	173	32	3.1	96.9
4. "Comet"	169	37	.0	100.0
5. "Mr. Clean"	162	58	13.8	86.2
6. "Joy"	145	35	5.7	94.3
7. "Ajax"	121	22	13.6	86.4
8. "Trend"	93	23	4.3	95.7
9. "Glass Wax"	84	12	16.7	83.3
10. "Texize"	83	47	10.6	89.4
Total	1,712	565	23.5	76.5

FURNITURE POLISH AND WAX

The furniture polish and wax category contained 148 trade names among 1670 identified products. The 10 most-frequently-ingested trade-named items contributed 1097 cases, 66 percent of the total, while the other 138 trade-named products were distributed among 573 cases. Two products, "Pride" (360 cases) and "Old English" Polish (303 cases) were the most frequently ingested. In the 527 cases where information concerning hospitalization was available, 5.1 percent were hospitalized for 1 day, 4.9 percent for 2 to 3 days, and 6.5 percent for 4 or more days. Nineteen percent of the children were hospitalized for an unknown number of days. This group of substances had a percentage of hospitalization (35.5%) that was roughly equivalent to that for kerosene (39.5%), undoubtedly because the main ingredient of many of the polishes is a petroleum distillate.

Furniture polish and wax most frequently ingested by all ages, by trade name and hospitalization, July 1959 to December 1961

Trade name	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
1. "Pride" furniture polish	360	175	32.6	67.4
2. "Old English" polishes	303	179	50.3	49.7
3. "Jubilee"	79	24	16.7	83.3
4. "O'Cedar" polishes	79	45	28.9	71.1
5. "Bruce" floor cleaner	66	35	28.6	71.4
6. "Hi Lite" furniture polish	56	30	30.0	70.0
7. "Pledge"	40	6	33.3	66.7
8. "Stanley's" furniture creme	39	12	.0	100.0
9. "Klear" floor wax	38	7	14.3	85.7
10. "AerOwax"	37	14	7.1	92.9
Total	1,097	527	35.5	64.5

KEROSENE

During this study, 1,656 reports of kerosene ingestion were submitted, making it the third leading substance ingested. Although kerosene or petroleum distillate, is a vehicle in many other products, it has been classified by itself; this category does not include products in which it is present in high concentration. In 1,371 cases with information on hospitalization, it was found that 541 (or 39.5%) were admitted. In 52 cases (3.8%) the victims were in the hospital one day; in 105 cases (7.7%), from two to three days; and in 92 cases (6.7%) for four or more days. There were 292 cases (21.3%) in which the children were hospitalized, but the number of hospital days was not specified.

Kerosene ingested by all ages, by hospitalization, July 1959 to December 1961

	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
Kerosene	1,656	1,371	39.5	60.5

VITAMINS AND MINERALS

In the review of the 1184 vitamin and mineral ingestions with known trade names, there were 706 cases from the first 10 preparations listed. A total of 172 trade names was reported in this group. In the 218 reports in which hospitalization was known, it was significant that the preparations that contained iron (ferrous sulfate) accounted for the greater percentage of hospital admissions.

Vitamins and minerals most frequently ingested by all ages, by trade name and hospitalization, July 1959 to December 1961

Trade name	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
1. "Poly-Vi-Sol"	166	32	0	100.0
2. "Chocks"	127	22	0	100.0
3. "Tri-Vi-Sol"	80	12	0	100.0
4. "One-a-Day"	78	18	5.6	94.4
5. "Mol-Iron"	67	51	60.8	39.2
6. Ferrous sulfate	63	34	55.9	44.1
7. "Deca-Vi-Sol"	51	13	7.7	92.3
8. "Feosol"	36	27	29.6	70.4
9. "Mulvidren"	21	4	0	100.0
10. "Unicap"	17	5	0	100.0
Total	706	218	27.5	72.5

DISINFECTANTS AND DEODORIZERS

The 10-most-frequently-ingested disinfectants made up 64.4 percent of all ingestions involving this type of product. A total of 185 trade names was mentioned on the reports in this category, but "Lysol" accounted for nearly one-fourth of the cases and was followed by "Pine-Sol" with 14 percent.

Disinfectants and deodorizers most frequently ingested by all ages, by trade name and hospitalization, July 1959 to December 1961

Trade name	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
1. "Lysol"	356	214	29.0	71.0
2. "Pine-Sol"	212	108	31.5	68.5
3. "Wizard" deodorizers	72	23	4.3	95.7
4. "Breath O'Pine"	57	23	34.8	65.2
5. "Germ-trol"	56	25	20.0	80.0
6. "Red Cap Refresh-R"	53			
7. "Air-Wick"	43	5	0	100.0
8. "CN" disinfectant	33	24	16.7	83.3
9. "Sylpho-nathol"	31	4	25.0	75.0
10. Formaldehyde	26	17	35.5	64.7
Total	939	443	27.3	72.7

LYE AND CORROSIVES

Whereas lye and corrosives constitute only 2 percent of the cases of ingestion for children, they show a significantly higher proportion of hospitalizations and days of hospitalization. The 10 products listed are not mutually exclusive, since some of these trade-named products do contain lye or potash. But because this was the principal means of identification of the ingested item, they have been tabulated as they were reported; 127 brand names were listed in the 1871 cases in which the brand name was known. Approximately one-half of the patients ingesting these products were hospitalized, making the percentage of this group higher than for any other type of substance. There were 1197 records containing data on hospitalization. Where the number of hospital days was reported, it was found that 10.1 percent were hospitalized for four or more days. "Drano" was the most-frequently-identified item, accounting for 989 cases, or 52.9 percent of the reports, with lye (13.1%), "Sani-Flush" (8.6%), "Easy-Off" Oven Cleaner (5.4%), and "Vanish" Bowl Cleaner (4.8%), the next most frequent.

Lye and corrosives most frequently ingested by all ages, by trade name and hospitalization, July 1959 to December 1961

Trade name	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
1. "Drano"	989	757	50.9	49.1
2. Lye	245	205	55.1	44.9
3. "Sani-Flush"	161	80	22.5	77.5
4. "Easy-Off" oven cleaner	101	47	29.8	70.2
5. "Vanish"	90	29	24.1	75.9
6. Potash	38	35	65.7	34.3
7. "Whink" rust stain remover	20	9	22.2	77.8
8. "Plumite"	18	15	46.7	53.3
9. "Sno Bol"	15	11	27.3	72.7
10. "Bowlene"	14	9	22.2	77.8
Total	1,691	1,197	48.0	52.0

LAXATIVES

The 10 most-frequently-ingested laxatives contributed 93.6 percent of all the cases involving this type of product. "Ex-Lax," heading the list of the top 10, was mentioned 1,021 times; followed by "Carter's Little Pills," 161; "Feen-A-Mint," 95. The seven other trade-named products together accounted for 142 cases, bringing the total to 1,419. There were 43 other trade names mentioned in 97 case reports. The 6.6 percent hospitalized, when there was knowledge as to hospitalization, were probably children who were admitted for observation.

Laxatives most frequently ingested by all ages, by trade name and hospitalization, July 1959 to December 1961

	Total cases	Total with known hospitalization data	Percent hospitalized	Percent not hospitalized
1. "Ex-Lax"	1,021	502	6.0	94.0
2. "Carter's Little Pills"	161	106	7.5	92.5
3. "Feen-A-Mint"	95	37	2.7	97.3
4. "Alophen"	30	22	0	100.0
5. Milk of magnesia	29	12	16.7	83.3
6. Castoria	26	5	20.0	80.0
7. "Phenolax"	15	9	0	100.0
8. "Dulcolax"	15	8	25.0	75.0
9. "Hinkle's Pills"	14	6	16.7	83.3
10. "Modane"	13	4	50.0	50.0
Total	1,419	711	6.6	93.4

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Type of substance ingested by quarter of year in 47,180 accidental ingestions among all ages, 1962

Type of substance	Total		Quarter of year							
			January–March		April–June		July–September		October–December	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Per cent
Medicines	23,317	49.4	5,830	56.9	5,290	46.3	5,685	43.8	6,512	51.9
Internal	20,203	42.8	5,109	49.9	4,498	39.4	4,866	37.5	5,730	45.7
Aspirin	9,447	20.0	2,513	24.5	2,039	17.8	2,113	16.3	2,782	22.2
Other	10,756	22.8	2,596	25.4	2,459	21.5	2,753	21.2	2,948	23.5
External	3,114	6.6	721	7.0	792	6.9	819	6.3	782	6.2
Cleaning and polishing agents	7,969	17.0	1,673	16.3	2,003	17.5	2,225	17.2	2,068	16.5
Petroleum products	2,312	4.9	394	3.8	685	6.0	744	5.7	489	3.9
Cosmetics	2,368	5.0	554	5.4	566	5.0	596	4.6	652	5.2
Pesticides	3,528	7.5	502	4.9	1,033	9.0	1,234	9.5	759	6.0
Gases and vapors	653	1.4	169	1.6	157	1.4	155	1.2	172	1.4
Plants	1,423	3.0	81	.8	298	2.6	646	5.0	398	3.2
Turpentine, paints, etc	2,235	4.7	364	3.6	531	4.6	696	5.4	644	5.1
Miscellaneous	2,933	6.2	601	5.9	736	6.4	846	6.5	750	6.0
Not specified	442	.9	69	.8	131	1.1	146	1.1	96	.8
Total	47,180	100.0	10,237	100.0	11,430	100.0	12,973	100.0	12,540	100.0

Source: Individual poison reports (phone inquiries and treated cases) submitted to the National Clearinghouse for Poison Control Centers by 279 centers in 40 States.

Accidental ingestions among children under 5 years of age—Type of substance by year of report, reported by poison control centers,[1] 1960–62

Type of substance	1960–62		1962		1961		1960	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	50,662	49.8	20,563	50.4	16,119	50.3	13,980	48.3
Internal	44,011	43.2	17,964	44.1	13,984	43.7	12,063	41.7
Aspirin	21,666	21.3	8,799	21.6	6,938	21.7	5,929	20.5
Other	22,345	22.0	9,165	22.5	7,046	22.0	6,134	21.2
External	6,651	6.5	2,599	6.4	2,135	6.7	1,917	6.6
Cleaning and polishing agents	17,563	17.3	7,085	17.4	5,473	17.1	5,005	17.3
Petroleum products	5,345	5.3	2,098	5.1	1,726	5.4	1,521	5.3
Cosmetics	5,586	5.5	2,179	5.3	1,694	5.3	1,713	5.9
Pesticides	8,202	8.0	3,030	7.4	2,709	8.5	2,463	8.5
Gases and vapors	146	.1	78	.2	46	.1	22	.1
Plants	2,599	2.5	1,135	2.8	721	2.3	653	2.3
Turpentine, paints, etc	4,886	4.8	2,017	4.9	1,424	4.4	1,445	5.0
Miscellaneous	6,055	5.9	2,246	5.5	1,860	5.8	1,949	6.7
Unknown	811	.8	344	.9	262	.8	205	.7
Total	101,765	100.0	40,775	100.0	32,034	100.0	28,956	100.0

[1] Includes 73 treatment centers in 1962; 74, in 1961; 50, in 1960.

Source: Individual case reports submitted to the National Clearinghouse for Poison Control Centers. (1962: 40,775 reports from 279 centers in 40 States; [a] 1961: 32,034 reports from 243 centers in 38 States; [a] 1960: 28,956 reports from 213 centers in 38 States. [a])

[a] Includes District of Columbia, Canal Zone, and 2 military bases abroad.

Substances most frequently ingested by children under 5 years of age, reported by poison control centers,[1] 1959–62

Type of substance	1962		1961		1960		1959	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Aspirin	8,799	21.6	6,968	21.8	5,930	20.5	2,901	19.0
Bleach	2,155	5.3	1,417	4.4	1,055	3.6	527	3.4
Soaps, detergents, cleaners	1,727	4.2	1,384	4.3	1,417	4.9	728	4.8
Insecticides (excluding mothballs)	1,678	4.1	1,687	5.3	1,413	4.9	941	6.1
Vitamins, iron preparations	1,153	2.8	704	2.2	549	1.9	265	1.7
Furniture polish	991	2.4	780	2.4	676	2.3	385	2.5
Disinfectants, deodorizers	840	2.1	662	2.1	639	2.2	340	2.2
Other analgesics	773	1.9	578	1.8	502	1.7	209	1.4
Kerosene	759	1.9	710	2.2	696	2.4	395	2.6
Laxatives	757	1.9	622	1.9	606	2.1	372	2.4
Perfumes, toilet water	714	1.8	547	1.7	596	2.1	272	1.8
Cough medicine	680	1.7	527	1.6	492	1.7	266	1.7
Lye, corrosives	679	1.7	660	2.1	642	2.2	368	2.4
Tranquilizers	677	1.7	549	1.7	425	1.5	258	1.7
Rodenticides	654	1.6	505	1.6	515	1.8	265	1.7
Antihistamines	623	1.5	517	1.6	388	1.3	260	1.7
Antiseptics	610	1.5	493	1.5	385	1.3	186	1.2
Mothballs	608	1.5	462	1.4	450	1.6	317	2.1
Hormones	593	1.5	377	1.2	315	1.1	185	1.2
Lighter fluid	578	1.4	459	1.4	323	1.1	148	1.0
Berries, beans	545	1.3	283	.9	303	1.0	101	.7
Airplane dope	491	1.2	323	1.0	279	1.0	156	1.0
Amphetamines	490	1.2	455	1.4	384	1.3	179	1.2
Turpentine	487	1.2	372	1.2	381	1.3	213	1.4
Paints (lead and nonlead pigment)	482	1.2	292	.9	399	1.4	133	.9
Solvents, thinners	463	1.1	361	1.1	296	1.0	149	1.0
Liniment, rubbing alcohol	455	1.1	424	1.3	350	1.2	201	1.3
Sedatives, barbiturates	417	1.0	422	1.3	346	1.2	174	1.1
Gasoline	357	.9	273	.9	216	.7	104	.7
Lotions, creams	341	.8	247	.8	210	.7	34	.2

[1] Includes 73 treatment centers in 1962; 74, in 1961; 50, in 1960; 0 in 1959.

Source: Individual case reports submitted to the National Clearinghouse for Poison Control Centers. (1962: 40,775 reports from 279 centers in 40 States;[a] 1961: 32,034 reports from 243 centers in 38 States; [a] 1960: 28,956 reports from 213 centers in 38 States; [a] 1959: 15,303 reports from 59 centers in 20 States [a].)

[a] Includes District of Columbia, Canal Zone, and 2 military bases abroad.

Type of products as a percentage of all ingestions—Accidental ingestions among children under 5 years of age, 1962

Type of substance	Total[1]		Age in years									
			Under 1		1		2		3		4	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	20,563	50.4	461	31.1	3,651	30.6	9,028	56.6	5,542	66.9	1,819	61.5
Internal	17,964	44.1	248	16.7	2,703	22.7	8,078	50.7	5,198	62.7	1,691	58.2
Aspirin	8,799	21.6	78	5.3	1,041	8.7	3,780	23.7	2,965	35.8	923	31.2
Other	9,165	22.5	170	11.4	1,662	13.9	4,298	27.0	2,233	26.9	768	26.0
External	2,599	6.3	213	14.4	948	7.0	950	5.9	344	4.2	128	4.3
Cleaning and polishing	7,085	17.4	317	21.4	3,022	25.3	2,501	15.7	877	10.6	328	11.1
Petroleum products	2,098	5.1	53	3.6	1,063	9.0	693	4.3	213	2.6	68	2.3
Cosmetics	2,179	5.3	92	6.2	804	6.8	955	6.0	257	3.1	60	2.0
Pesticides	3,030	7.4	199	13.4	1,240	10.4	968	6.1	425	5.1	176	6.0
Gases and vapors	78	.2	14	.9	11	.1	20	.1	14	.2	15	.5
Plants	1,135	2.8	49	3.3	327	2.7	315	2.0	261	3.1	171	5.8
Turpentine, paints, etc.	2,017	5.0	95	6.4	912	7.6	651	4.1	249	3.0	102	3.5
Miscellaneous	2,246	5.5	193	13.0	816	6.8	671	4.2	375	4.5	178	6.0
Not specified	344	.8	11	.7	79	.7	138	.9	76	.9	37	1.3
Total	40,775	99.9	1,484	100.0	11,925	100.0	15,940	100.0	8,289	100.0	2,954	100.0

[1] Includes 183 cases under 5 unknown years.

Source: Individual poison reports (phone inquiries and treated cases) submitted to the National Clearinghouse for Poison Control Centers by 279 centers in 40 States.

Accidental ingestions among children under 5 years of age—Treated cases, by type of substance and days of hospitalization, reported by 279 poison control centers [1] in 40 States,[2] 1962

Type of substance	Days of hospitalization [3]									
	Total		No days		1 to 3 [4]		4 or more		Unknown days	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	11,006	100	9,438	85.3	572	5.2	72	0.7	984	8.9
Internal	10,209	100	8,727	85.5	522	5.1	61	.6	899	8.8
Aspirin	5,917	100	5,118	86.5	271	4.6	26	.4	502	8.5
Other	4,292	100	3,609	84.1	251	5.8	35	.8	397	9.2
External	857	100	711	83.0	50	5.8	11	1.3	85	9.9
Cleaning and polishing agents	2,913	100	2,384	81.8	145	5.0	55	1.9	329	11.3
Petroleum products	1,319	100	830	62.9	144	10.9	50	3.8	295	22.4
Cosmetics	410	100	381	92.9	10	2.4	2	.5	17	4.1
Pesticides	1,556	100	1,273	81.8	103	6.6	13	.8	167	10.7
Gases and vapors	17	100	9	52.9	2	11.8	2	11.8	4	23.5
Plants	361	100	320	88.6	12	3.3	2	.6	27	7.5
Turpentine, paints, etc	776	100	591	76.2	46	5.9	22	2.8	117	15.1
Miscellaneous	475	100	413	86.9	26	5.5	1	.2	35	7.4
Not specified	213	100	175	82.2	10	4.7	3	1.4	25	11.7
Total	19,106	100	15,814	82.8	1,070	5.6	222	1.2	2,000	10.5

[1] Includes 73 poison treatment centers.
[2] Includes District of Columbia, Canal Zone, and 2 military bases abroad.
[3] Excludes 4,014 cases unknown as to hospitalization.
[4] Includes some patients who are hospitalized for 1 day for purpose of observation only.

Source: Individual case reports submitted to the National Clearinghouse for Poison Control Centers.

Number of deaths due to accidental poisoning, by type of solid and liquid substances for children under 5 years of age, United States,[1] 1953–62 (excludes Armed Forces overseas)

Type of substances	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962
Morphine and other derivatives	5	3	4	2	4	3	3	6	1	1
Barbituric acid and derivatives	8	13	8	11	10	9	7	7	14	5
Aspirin and salicylates	69	84	72	69	90	91	106	144	128	122
Bromides	1	1	----	1	2	----	----	----	----	----
Other analgesic and soporific drugs	13	3	8	9	11	6	11	13	14	17
Sulfonamides	----	----	----	----	----	----	----	----	----	----
Strychnine	13	6	6	3	2	5	4	2	3	3
Belladonna, hyoscine and atropine	4	2	1	1	1	3	1	1	----	----
Other and unspecified drugs	42	47	36	32	36	33	48	38	39	46
Total drugs	155	159	135	128	156	150	180	211	199	194
Noxious foodstuffs	----	1	1	----	2	3	1	----	1	----
Alcohol	6	4	3	2	2	6	3	4	5	3
Petroleum products	100	83	69	84	66	75	57	37	46	39
Industrial solvents	11	9	10	7	10	8	5	11	13	18
Corrosive aromatics, acids and caustic alkalies	29	19	14	16	10	24	19	23	25	15
Mercury and its compounds	----	----	----	1	1	2	2	2	1	2
Lead and its compounds	52	34	47	33	37	61	81	78	56	73
Arsenic and antimony, and their compounds	25	22	20	39	20	23	25	14	17	25
Fluorides	----	----	1	----	2	2	1	----	3	3
Other and unspecified solid and liquid substances	67	59	58	84	68	68	82	65	82	53
Total substances	445	390	358	394	374	422	456	445	448	425

[1] 1959 includes Alaska; 1960–62 includes Alaska and Hawaii.

Source: Vital Statistics—Special Reports, Accident Fatalities. National Vital Statistics Division, years indicated.

Number of deaths due to accidental poisoning, by type of solid and liquid substances, all ages, United States,[1] 1953–62 (excludes Armed Forces overseas)

Type of substances	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962
Morphine and other opium derivatives	31	33	40	56	41	28	69	60	56	73
Barbituric acid and derivatives	337	345	411	323	326	220	298	289	339	401
Aspirin and salicylates	98	117	105	108	124	119	149	188	182	174
Bromides	16	13	6	5	10	3	7	7	4	6
Other analgesic and soporific drugs	82	91	100	125	111	86	117	160	169	267
Sulfonamides						1			1	
Strychnine	21	14	17	7	16	9	5	6	6	8
Belladonna, hyoscine and atropine	4	3	2	1	1	4	2	1	3	1
Other and unspecified drugs	75	85	75	71	79	79	130	125	122	164
Total drugs	664	701	756	696	708	549	768	836	882	1,094
Noxious foodstuffs	4	8	7	4	8	5	4	7	6	10
Alcohol	221	199	223	226	265	322	360	357	409	235
Petroleum products	116	94	76	98	72	83	64	43	53	47
Industrial solvents	47	45	44	43	46	41	37	35	40	51
Corrosive aromatics, acids, and caustic alkalies	63	47	51	60	30	57	55	56	50	47
Mercury and its compounds	9	7	10	7	11	8	11	9	8	3
Lead and its compounds	65	41	64	47	51	70	93	98	77	90
Arsenic and antimony, and their compounds	52	37	41	58	37	39	47	31	32	49
Fluorides	6	2	6	1	5	3	2	7	8	5
Other and unspecified solid and liquid substances	144	158	153	182	157	252	220	200	239	202
Total substances	1,391	1,339	1,431	1,422	1,390	1,429	1,661	1,679	1,804	1,833

[1] 1959 includes Alaska; 1960–62 includes Alaska and Hawaii.

Source: Vital Statistics—Special Reports, Accident Fatalities, National Vital Statistics Division, years indicated.

Deaths due to accidental poisoning by solid and liquid substances, all ages and children under 5 years of age, United States,[1] 1952–61

Year	All ages		Children under 5 years	
	Number	Rate per 100,000 population	Number	Rate per 100,000 population
1952	1,440	0.93	443	2.58
1953	1,391	.88	445	2.55
1954	1,339	.83	390	2.19
1955	1,431	.87	358	1.96
1956	1,422	.85	394	2.11
1957	1,390	.82	374	1.95
1958	1,429	.82	422	2.16
1959	1,661	.94	456	2.30
1960	1,679	.93	445	2.18
1961	1,804	.99	448	2.17

[1] 1959 includes Alaska; 1960–61 includes Alaska and Hawaii.

Source: Deaths from National Vital Statistics Division. Rates based on estimated population data from Current Population Reports, U.S. Bureau of Census.

NATIONAL CLEARINGHOUSE FOR POISON CONTROL CENTERS, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, PUBLIC HEALTH SERVICE, WASHINGTON, D.C.

(A service of the Division of Accident Prevention, Bureau of State Services)

SEPTEMBER–OCTOBER 1964.

POISONING REPORT DATA FOR CHILDREN UNDER 5 YEARS OF AGE

The National Clearinghouse for Poison Control Centers during the period of 1961–62 received 96,000 reports of ingestion incidents. Eighty-seven percent were classified as accidents, and 86 percent involved children under 5 years of age. Although many of these reports did not contain all the information that was requested on the standard reporting form, the volume of reports provided sufficient completed forms to make epidemiological deductions. It is assumed, therefore, that the more complete forms were randomly filled out without regard to the type of product ingested.

When the broad classes of substances are subdivided to determine the relative frequency of occurrence among children under 5 years, the following categories constitute the top five: aspirin, bleach, soaps and detergents, insecticides, and vitamins and iron preparations. When each year of life is studied the same five substances appear in the same order of frequency for the 2 year olds as for the total of those under 5 years. However, the 2 year olds account for 39 percent of the total accidents.

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TABLE 1.—*Substances most frequently ingested by children under 5 years of age, 1962*

Age (in years)	Substance	Percent [1]	Substance	Percent [1]	Substance	Percent [1]	Substance	Percent [1]	Substance	Percent [1]	Total number of cases
Under 1	Insecticides	8.4	Soaps, detergents	5.5	Aspirin	5.3	Baby preparations	5.1	Disinfectants	4.6	1,484
1	Aspirin	8.7	do	6.8	Bleach	6.2	Insecticides	5.8	Furniture polish	4.9	11,925
2	do	23.7	Bleach	5.5	Soaps, detergents	3.7	do	3.2	Vitamins and iron preparations.	3.0	15,940
3	do	35.8	do	4.2	Vitamins and iron	4.1	Laxatives	3.1	Insecticides	3.0	8,289
4	do	31.2	Plants, other than mushrooms.	5.2	Bleach	4.6	Vitamins and iron	4.6	do	3.8	2,954
Total under 5 [2]	do	21.6	Bleach	5.3	Soaps, detergents	4.2	Insecticides	4.1	Vitamins and iron preparations.	2.8	40,775

[1] Represents percentage that specifies substance is of each age group.
[2] Includes cases under 5 years, but unknown age.

Source: Individual case reports submitted to the National Clearinghouse for coding and tabulating.

In children under 1 year of age insecticides were ingested more frequently than any other category of substances. However, they dropped below aspirin, bleach, and soaps and detergents in the older age groups. Baby preparations were fourth and disinfectants were fifth in frequency of occurrence, but were far down on the list in the older age groups.

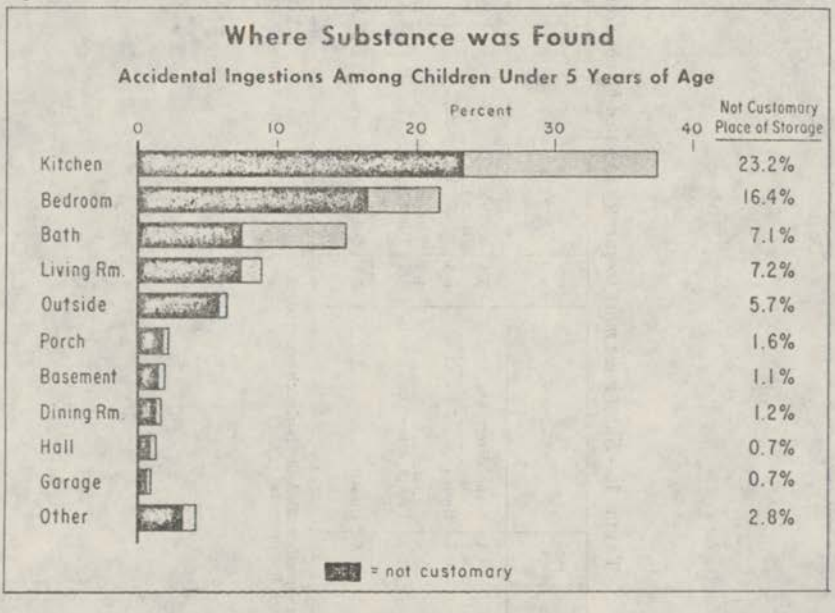
In the one year old age group, aspirin was the most frequently ingested substance and the proportion of aspirin ingested increased with the older age groups. With the exception of furniture polish, which appears fifth in the frequency of ingestion for 1 year olds but does not appear in any other age group, the top ingestion categories for children under 5 were the same for 1 year olds differing only in their order of frequency.

In the 3 year old group, laxatives were fourth in the frequency of ingestion but did not appear at all in the other age groups. The exception for the 4 year olds was found to be plants which were the second most frequently ingested category for this age group.

The room in the house in which ingestion accidents occurred most frequently was the kitchen (37 percent), and in 62 percent of these accidents the offending substances were not in their customary place of storage. Accidents occurred next most frequently in the bedroom (22 percent), and in 72 percent of these accidents the substances were not in their customary place of storage. In the bathroom (15 percent) ingested substances were not in their customary place of storage 46 percent of the time.

Although fewer accidents occurred in the living room, dining room, bathroom, hall, basement, and other areas, the substances were not in their customary storage place almost two-thirds of the time. (Figure I.)

Figure I



In most ingestion cases, absorbtion of the potentially poisonous substance is prevented by induction of emesis or by gastric lavage. In the 1961–1962 data, when it was known whether or not the patient vomited, it was found that almost 60 percent of the children did vomit, either spontaneously or after induction. Approximately 60 percent of the vomiting occurred within one hour of the ingestion. In those cases in which it was known as to whether or not lavage was done, it was found that approximately 55 percent were lavaged within 1 hour of the ingestion.

In accidental ingestions among children under 5 years of age, symptoms were reported present in 28 percent of the cases in 1961 as compared to 26 percent of the cases in 1962. Symptoms were present most frequently in petroleum prod-

ucts, 1962—55 percent; 1961—52 percent; and cleaning and polishing agents, 1962—42 percent; 1961—43 percent.

Although there are probably many reasons influencing ingestions in children under 5 years of age, easy accessability pre-empts motivational factors. In the cases that were adequately followed up it was found that over two-thirds of the ingestions involved substances that were not in their customary places of storage: petroleum products (87 percent), paints and paint solvents (80 percent), and cleaning and polishing agents (76 percent), led the list of offending substances but were only percentage points above such items as aspirin, internal medicines, external medicines, and pesticides. Although the customary place of storage is presumed to be a safe place, adequate prevention measures are necessary.

The transference of products from their original containers to soda bottles, cups, glasses, etc., which are usually the vehicles of edible substances, also contributes to the numbers of accidental ingestions. Kerosene (91 percent), bleach (41 percent), pesticides (52 percent), were the substances most frequently not in their original container. Kerosene (91 percent), bleach (81 percent), and pesticides (75 percent) were among the substances most frequently not in their customary place of storage at the time of ingestion. These three substances rank second, third, and fourth, after aspirin, as the most frequently ingested by children under 5 years of age. On the other hand, furniture polish and medicines were seldom transferred to other containers, indicating that the substance not being *in* its customary place of storage and its transference from its original containers were both prominent factors.

Because of the work of Dr. Rogers Myers in Boston relating accidents to unusual environmental conditions, an attempt was made to find correlations between illness in the family and type of substance ingested. When there was illness in the family internal medicines were the most frequently ingested substances by children under 5 years of age, accounting for over two-thirds (68 percent) of the ingestions, with aspirin comprising 40 percent of medicines. When there was no illness in the family, internal medicines were ingested less frequently so that cleaning and polishing agents, pesticides, and petroleum products were proportionally higher. This still leaves unanswered the question of whether the higher incidence of medicine ingestion was due to environmental conditions or improper storage of medicines during a period when they would be used more frequently, or both.

Figure II shows the percent of ingestion accidents according to the hour of the day. In both the telephone calls and the hospital treated cases the peak time was seen to be between 10 and 11 in the morning with a secondary smaller peak at 4 in the afternoon. There has been much speculation about this curve. One theory relates its peaks to the periods immediately preceding the average mealtime. Whether these peaks represent periods of increased hunger, or decreased parental supervision, or some other reason, is not known.

In the under 5 age group, 56 percent of the ingestion accidents involved males. In the age group 5–9 males also predominated, but in the 10–14 groups males and females were equally involved, except for 1 year. Over 15 years of age the pattern reversed and females (55 percent) exceeded males in the ingestion incidents. (See figure III.)

In the children under 5 years of age, the 2 year olds accounted for 39 percent of the accidents. As Figure III indicates, the 1 year olds accounted for 29 percent; 3 year olds 20 percent, and the 4 year olds 7 percent. Two-thirds of the accidents, (68 percent) under 5 years of age involve the 1 and 2 year old children. In 1962 approximately 94 percent of children had no previous history of poisoning as compared to 85 percent in 1961. Only 13 percent of the cases reported a history of pica (abnormal appetite for inedible substances) in 1961.

In the accidental ingestions among children under 5 years of age there was reported to be no warning label on the original container of almost half (48 percent of the substances ingested. Cosmetics (89 percent,) petroleum products (76 percent), paints and paint solvents (66 percent) were most frequently reported as having no warning label on the original container.

In 1961, it was reported that in 20 percent of the aspirin ingestions and in 27 percent of the pesticide ingestions there was no warning label on the original container. However, since both of these products were required to have a warning label it might be concluded that it was not read. Since August 1962, the Federal Hazardous Substances Labeling Act has required warning labels on the petroleum products and paints and paint solvents, as well as many other products. These labeling laws should stimulate proper storage of potentially toxic substances, but the laws will not deter the under 5 age group from ingestion if the substances are readily available.

Figure II

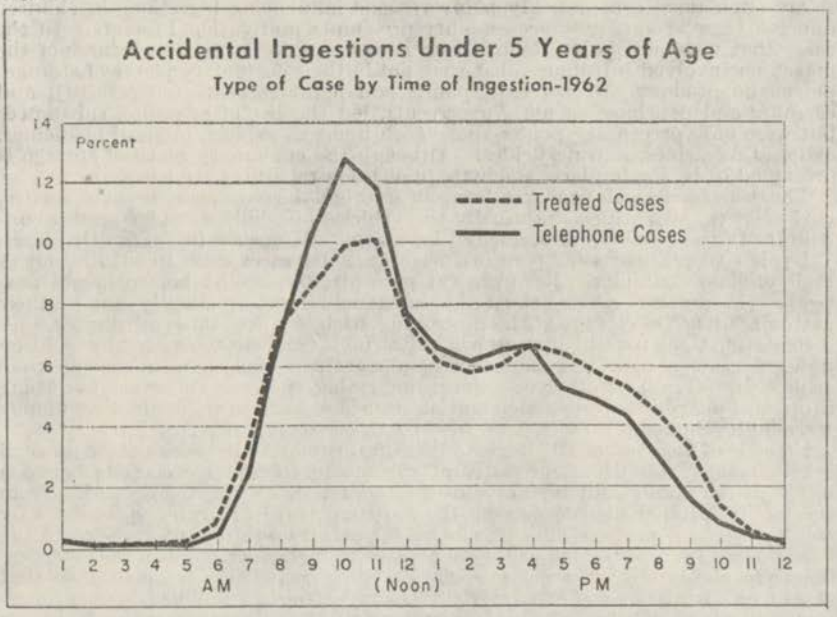
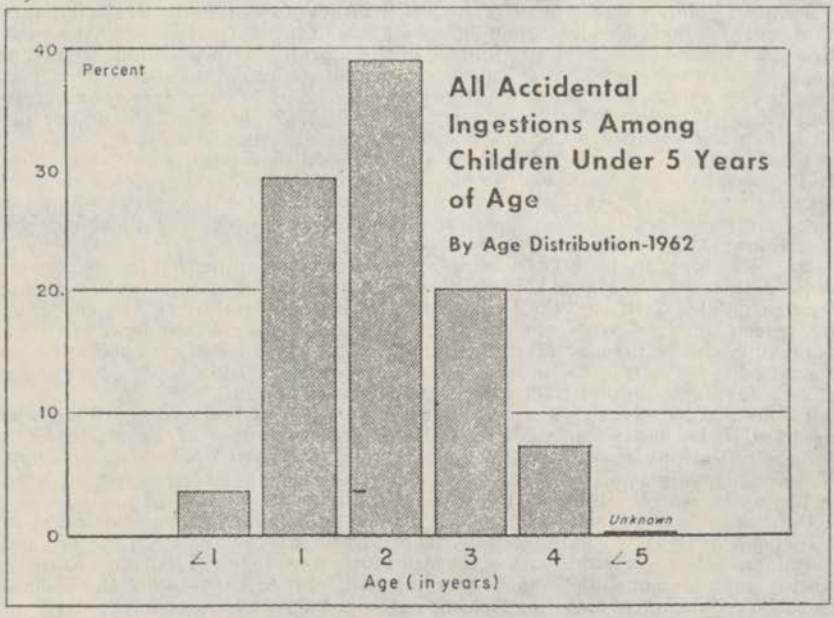


Figure III



ACCIDENTAL POISONING FROM CAMPHOR PRODUCTS

The November 1960 Bulletin of the National Clearinghouse for Poison Control Centers contained an article, later printed in the *American Journal of Disease of Children*, 15:535, April 1961, on poisonings from camphor compounds, particularly Camphorated Oil.

To determine the current status of poisonings from these preparations, the National Clearinghouse for Poison Control Centers has reviewed the reports received from poison control centers for the years 1962 and 1963. The data indicates that the number of reported cases continues to increase, although there was some decrease in reports of serious illness. Twenty-eight percent of the patients involved in these accidents were symptomatic with over 10 percent having convulsions. One reported fatality in 1964 was an adult who ingested 2 ounces of camphorated oil, mistakenly believing it to be castor oil.

In reviewing these reports an attempt was made to learn more about the circumstances of these accidents. A great many involved small children who obtained the preparations because of improper storage. Another group occurred while the parent was medicating the child. The children in this group reached for the container and swallowed the contents when the bottle was placed down momentarily while the parent performed some other task.

Of more serious consequence, are the large number of cases in which the Camphorated Oil was mistakenly administered in belief that it was Castor Oil. However, in one instance it was confused for cough medicine and in another for a nose drop. Of 194 reports of ingestion of Camphorated Oil for 1962, 22 cases of mistaken identity were reported; of 308 reports in 1963, 31 involved mistaken identity. Of special interest is the report that in several cases the product was purchased from a grocery store or pharmacy when the product desired was Castor Oil. These figures represent the minimum number of poisonings due to mistaken identity since some reports did not contain information on how the accident occurred. In some instances, there are remarks on the report which would make one believe that in many cases there was unfamiliarity with the use of Camphorated Oil. We urge physicians, pharmacists, nurses, and public health workers to stress the hazards of self-medication as exemplified by the use of Camphorated Oil for Castor Oil. Because of the seriousness of the symptoms displayed from this particular product, all personnel employed by pharmacies should be instructed to make inquiries as to the expected use of Camphorated Oil when it is sold. They also should advise purchasers of its poisonous nature.

HONORS

Recently, the National Clearinghouse for Poison Control Centers has been informed of honors upon State Coordinators for Poison Control Centers because of their outstanding service. In the spring, Dr. Joseph Karas of the Providence Poison Control Center, Rhode Island Hospital, and Dr. Heber Youngken, Dean of the College of Pharmacy, University of Rhode Island, were given awards by the Rhode Island Pharmaceutical Association testifying to their public service in service in poison control activities. Both men have been extremely active in preventive, as well as treatment programs.

Mr. Arthur Blank was recognized by John Dempsey, the Governor of Connecticut, for his outstanding job as Technical Director of the Connecticut Poison Information Center. He was commended for his excellent service and the invaluable assistance that he rendered to the people of the State of Connecticut. Mr. Blank has served as the Secretary of the American Association of Poison Control Centers for five years.

SEVENTH ANNUAL MEETING OF THE AMERICAN ASSOCIATION FOR POISON CONTROL CENTERS

The annual meeting of the American Association for Poison Control Centers will be held Monday, October 26, 1964, simultaneously with the annual meeting of the American Academy of Pediatrics. It will be held in the Le Petit Trianon Ballroom on the Ballroom Floor at the New York Hilton Hotel, 54th St. and 6th Avenue, New York City.

The morning session which will commence at 9:00 a.m., will be comprised of a business meeting for election of officers and presentation of reports from the standing committees. The liaison personnel to the Food and Drug Administration, the National Clearinghouse for Poison Control Centers, and other organizations will also present their reports.

The afternoon session, as in previous years, will be a scientific program consisting of the presentation of original papers.

All members of the Association are requested to attend. There is no registration fee. All guests and visitors will be welcome.

HENRY L. VERHULST, *Director.*
JOHN J. CROTTY, M.D., *Associate Director.*

Type of substance ingested by quarter of year in 54,886 accidental ingestions among all ages, 1963

Type of substance	Total		Quarter of year							
			January–March		April–June		July–September		October–December	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	28,022	51.1	7,111	56.9	6,044	46.5	6,686	45.7	8,181	55.4
Internal	24,705	45.0	6,293	50.4	5,263	40.5	5,822	39.8	7,327	49.6
Aspirin	11,620	21.2	2,987	23.9	2,291	17.6	2,586	17.7	3,756	25.4
Other	13,085	23.8	3,306	26.5	2,972	22.9	3,236	22.1	3,571	24.2
External	3,317	6.0	818	6.5	781	6.0	864	5.9	854	5.8
Cleaning and polishing agents	8,579	15.6	1,992	15.9	2,248	17.3	2,193	15.0	2,146	14.5
Petroleum products	2,849	5.2	442	3.5	771	5.9	962	6.6	674	4.6
Cosmetics	2,655	4.8	666	5.3	607	4.7	690	4.7	692	4.7
Pesticides	4,102	7.5	644	5.2	1,188	9.1	1,367	9.3	903	6.1
Gases and vapors	498	.9	150	1.2	129	1.0	105	.7	114	.8
Plants	1,693	3.1	96	.8	336	2.6	794	5.4	467	3.2
Turpentine, paints, etc	2,674	4.9	506	4.1	670	5.2	812	5.6	686	4.6
Miscellaneous	3,369	6.1	795	6.4	881	6.8	884	6.0	809	5.5
Not specified	445	.8	91	.7	111	.9	107	.9	106	.7
Total	54,886	100.0	12,493	100.0	12,985	100.0	14,630	100.0	14,778	100.0

Source: Individual poison reports (phone inquiries and treated cases) submitted to the National Clearinghouse for Poison Control Centers by 335 centers in 40 States.

Accidental ingestions among children under 5 years of age, type of substance by year of report, reported by poison control centers,[1] 1961–63

Type of substance	1961–63		1963		1962		1961	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	61,017	50.9	24,335	51.8	20,563	50.4	16,119	50.3
Internal	53,536	44.7	21,588	46.0	17,964	44.1	13,984	43.7
Aspirin	26,545	22.2	10,808	23.0	8,799	21.6	6,938	21.7
Other	26,991	22.5	10,780	23.0	9,165	22.5	7,046	22.0
External	7,481	6.2	2,747	5.9	2,599	6.4	2,135	6.7
Cleaning and polishing agents	20,078	16.8	7,520	16.0	7,085	17.4	5,473	17.1
Petroleum products	6,425	5.4	2,601	5.5	2,098	5.1	1,726	5.4
Cosmetics	6,332	5.3	2,459	5.2	2,179	5.3	1,694	5.3
Pesticides	9,109	7.6	3,370	7.2	3,030	7.4	2,709	8.5
Gases and vapors	188	.2	64	.1	78	.2	46	.1
Plants	3,206	2.7	1,350	2.9	1,135	2.8	721	2.3
Turpentine, paints, etc	5,814	4.9	2,373	5.1	2,017	4.9	1,424	4.4
Miscellaneous	6,647	5.5	2,541	5.4	2,246	5.5	1,860	5.8
Not specified	947	.8	341	.7	344	.9	262	.8
Total	119,763	100.0	46,954	100.0	40,775	100.0	32,034	100.0

[1] Includes 102 cooperating hospitals in 1963; 73, in 1962; 74, in 1961.

Source: Individual case reports submitted to the National Clearinghouse for Poison Control Centers (1963: 46,954 reports from 335 centers in 40 States;[a] 1962: 40,775 reports from 279 centers in 40 States;[a] 1961: 32,034 reports from 243 centers in 38 States.[a])

[a] Includes District of Columbia, Canal Zone, and military bases abroad.

Substances most frequently ingested by children under 5 years of age, reported by poison control centers [1], 1960–63

Type of substance	1963		1962		1961		1960	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Aspirin	10,808	23.0	8,799	21.6	6,968	21.8	5,930	20.5
Bleach	2,214	4.7	2,155	5.3	1,417	4.4	1,055	3.6
Insecticides (excluding mothballs)	1,884	4.0	1,678	4.1	1,687	5.3	1,413	4.9
Soaps, detergents, cleaners	1,797	3.8	1,727	4.2	1,384	4.3	1,417	4.9
Vitamins, iron preparations	1,380	2.9	1,153	2.8	704	2.2	549	1.9
Furniture polish	1,121	2.4	991	2.4	780	2.4	676	2.3
Plants (excluding mushrooms and toadstools)	1,054	2.2	873	2.1	506	1.6	463	1.6
Other analgesics	974	2.1	773	1.9	578	1.8	502	1.7
Disinfectants, deodorizer	869	1.9	840	2.1	662	2.1	639	2.2
Lighter fluid	851	1.8	578	1.4	459	1.4	323	1.1
Perfumes, toilet water	840	1.8	714	1.8	547	1.7	596	2.1
Tranquilizers	836	1.8	677	1.7	549	1.7	425	1.5
Hormones	820	1.7	593	1.5	377	1.2	315	1.1
Kerosene	775	1.7	759	1.9	710	2.2	696	2.4
Lye, corrosives	772	1.6	679	1.7	660	2.1	642	2.2
Laxatives	769	1.6	757	1.9	622	1.9	606	2.1
Rosenticides	728	1.6	654	1.6	505	1.6	515	1.8
Antihistamines	721	1.5	623	1.5	517	1.6	388	1.3
Airplance dope	678	1.4	491	1.2	323	1.0	279	1.0
Cough medicine	673	1.4	680	1.7	527	1.6	492	1.7
Mothballs	625	1.3	608	1.5	462	1.4	450	1.6
Amphetamines	601	1.3	490	1.2	455	1.4	384	1.3
Antiseptics	579	1.2	610	1.5	493	1.5	385	1.3
Paints (lead and nonlead)	556	1.2	482	1.2	292	.9	399	1.4
Sedatives, barbiturates	534	1.1	417	1.0	422	1.3	346	1.2
Turpentine	526	1.1	487	1.2	372	1.2	381	1.3
Solvents, thinners	507	1.1	463	1.1	361	1.1	296	1.0
Liniment, rubbing alcohol	505	1.1	455	1.1	424	1.3	350	1.2
Gasoline	482	1.0	357	.9	273	.9	216	.7
Lotion, creams	404	.9	341	.8	247	.8	10	.7

[1] Includes 102 cooperating hospitals in 1963; 73, in 1962; 74, in 1961; 50 in 1960.

Source: Individual case reports submitted to the National Clearinghouse for Poison Control Centers (1963: 46,954 reports from 335 centers in 40 States;[a] 1962: 40,775 reports from 279 centers in 40 States;[a] 1961: 32,034 reports from 243 centers in 38 States;[a] 1960: 28,956 reports from 213 centers in 38 States.[a])

[a] Includes District of Columbia, Canal Zone, and military bases abroad.

Type of products as a percentage of all ingestions—Accidental ingestions among children under 5 years of age, 1963

Type of substance	Total [1]		Age in years									
			Under 1		1		2		3		4	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	24,335	51.9	486	28.3	4,272	32.1	10,678	57.4	6,577	69.4	2,188	62.6
Internal	21,588	46.0	268	15.6	3,265	24.5	9,682	52.0	6,219	65.6	2,056	58.9
Aspirin	10,808	23.0	98	5.7	1,256	9.4	4,625	24.9	3,634	38.3	1,163	33.3
Other	10,780	23.0	170	9.9	2,009	15.1	5,057	27.2	2,585	27.3	893	25.6
External	2,747	5.9	218	12.7	1,007	7.6	996	5.4	358	3.8	132	3.8
Cleaning and polishing	7,520	16.0	364	21.2	3,205	24.1	2,622	14.1	886	9.3	373	10.7
Petroleum products	2,601	5.5	47	2.7	1,180	8.9	952	5.1	290	3.1	113	3.2
Cosmetics	2,459	5.2	124	7.2	915	6.9	1,053	5.7	268	2.8	81	2.3
Pesticides	3,370	7.2	262	15.3	1,326	10.0	1,095	5.9	439	4.6	212	6.1
Gases and vapors	64	.1	6	.3	23	.2	13	.1	14	.1	7	.2
Plants	1,350	2.9	64	3.7	340	2.6	460	2.5	285	3.0	179	5.1
Turpentine, paints, etc	2,373	5.1	118	6.9	1,124	8.4	794	4.3	227	2.4	88	2.5
Miscellaneous	2,541	5.4	230	13.4	825	6.2	821	4.4	419	1.7	218	6.2
Not specified	341	.7	16	.9	93	.7	114	.6	79	3.5	34	1.0
Total	46,954	100.0	1,717	100.0	13,303	100.0	18,602	100.0	9,484	100.0	3,493	100.0

[1] Includes 355 cases under 5 unknown years.

Source: Individual poison reports (phone inquiries and treated cases) submitted to the National Clearinghouse for Poison Control Centers by 335 centers in 40 States.

Accidental ingestions among children under 5 years of age—Treated cases, by type of substance and days of hospitalization, reported by 335 poison control centers [1] in 40 States,[2] 1963

Type of substance	Days of hospitalization [3]									
	Total		No days		1 to 3 [4]		4 or more		Unknown days	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	14,290	100	12,337	86.3	786	5.5	97	0.7	1,070	7.5
Internal	13,300	100	11,483	86.3	738	5.5	92	.7	987	7.4
Aspirin	7,718	100	6,734	87.3	404	5.2	48	.6	532	6.9
Other	5,582	100	4,749	85.1	334	6.0	44	.8	455	8.2
External	990	100	854	86.3	48	4.8	5	.5	83	8.4
Cleaning and polishing agents	3,411	100	2,766	81.1	189	5.5	85	2.5	371	10.9
Petroleum products	1,773	100	1,149	64.8	233	13.1	86	4.9	305	17.2
Cosmetics	566	100	539	95.2	4	.7	4	.7	19	3.4
Pesticides	1,960	100	1,613	82.3	135	6.9	27	1.4	185	9.4
Gases and vapors	25	100	18	72.0	1	4.0	1	4.0	5	20.0
Plants	490	100	424	86.5	28	5.7	4	.8	34	6.9
Turpentine, paints, etc	1,004	100	775	77.2	85	8.5	30	3.0	114	11.4
Miscellaneous	603	100	520	86.2	31	5.1	12	2.0	40	6.6
Not specified	202	100	165	81.7	16	7.9	2	1.0	19	9.4
Total	24,324	100	20,306	83.5	1,508	6.2	348	1.4	2,162	8.9

[1] Includes 102 cooperating hospitals.
[2] Includes District of Columbia, Canal Zone, and military bases abroad.
[3] Excludes 3,941 cases unknown as to hospitalization.
[4] Includes some patients who are hospitalized for 1 day for purpose of observation only.

Source: Individual case reports submitted to the National Clearinghouse for Poison Control Centers.

Number of deaths due to accidental poisoning, by type of solid and liquid substances, for children under 5 years of age, United States,[1] 1953–62 (excludes Armed Forces overseas)

Type of substances	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962
Morphine and other derivatives	5	3	4	2	4	3	3	6	1	1
Barbituric acid and derivatives	8	13	8	11	10	9	7	7	14	5
Aspirin and salicylates	69	84	72	69	90	91	106	144	128	122
Bromides	1	1	------	1	2	------	------	------	------	------
Other analgesic and soporific drugs	13	3	8	9	11	6	11	13	14	17
Sulfonamides	------	------	------	------	------	------	------	------	------	------
Strychnine	13	6	6	3	2	5	4	2	3	3
Belladonna, hyoscine and atropine	4	2	1	1	1	3	1	1	------	------
Other and unspecified drugs	42	47	36	32	36	33	48	38	39	46
Total drugs	155	159	135	128	156	150	180	211	199	194
Noxious foodstuffs	------	1	1	------	2	3	1	------	1	------
Alcohol	6	4	3	2	2	6	3	4	5	3
Petroleum products	100	83	69	84	66	75	57	37	46	39
Industrial solvents	11	9	10	7	10	8	5	11	13	18
Corrosive aromatics, acids and caustic alkalies	29	19	14	16	10	24	19	23	25	15
Mercury and its compounds	------	------	------	1	1	2	2	2	1	2
Lead and its compounds	52	34	47	33	37	61	81	78	56	73
Arsenic and antimony, and their compounds	25	22	20	39	20	23	25	14	17	25
Fluorides	------	------	1	------	2	2	1	------	3	3
Other and unspecified solid and liquid substances	67	59	58	84	68	68	82	65	82	53
Total substances	445	390	358	394	374	422	456	445	448	425

[1] 1959 includes Alaska; 1960–62 includes Alaska and Hawaii.

Source: Vital Statistics—Special Reports, Accident Fatalities, National Vital Statistics Division, years indicated.

Number of deaths due to accidental poisoning—By type of solid and liquid substances, all ages, United States,[1] 1953–62 (excludes Armed Forces overseas)

Type of substances	1953	1954	1955	1956	1957	1958	1959	1960	1961	1962
Morphine and other opium derivatives	31	33	40	56	41	28	60	60	56	73
Barbituric acid and derivatives	337	345	411	323	326	220	298	289	339	401
Aspirin and salicylates	98	117	105	108	124	119	149	188	182	174
Bromides	16	13	6	5	10	3	7	7	4	6
Other analgesic and soporific drugs	82	91	100	125	111	86	117	160	169	267
Sulfonamides						1			1	
Strychnine	21	14	17	7	16	9	5	6	6	8
Belladonna, hyoscine and atropine	4	3	2	1	1	4	2	1	3	1
Other and unspecified drugs	75	85	75	71	79	79	130	125	122	164
Total drugs	664	701	756	696	708	549	768	836	882	1,094
Noxious foodstuffs	4	8	7	4	8	5	4	7	6	10
Alcohol	221	199	223	226	265	322	360	357	409	235
Petroleum products	116	94	76	98	72	83	64	43	53	47
Industrial solvents	47	45	44	43	46	41	37	35	40	51
Corrosive aromatics, acids, and caustic alkalies	63	47	51	60	30	57	55	56	50	47
Mercury and its compounds	9	7	10	7	11	8	11	9	8	3
Lead and its compounds	65	41	64	47	51	70	93	98	77	90
Arsenic and antimony, and their compounds	52	37	41	58	37	39	47	31	32	49
Fluorides	6	2	6	1	5	3	2	7	8	5
Other and unspecified solid and liquid substances	144	158	153	182	157	252	220	200	239	202
Total substances	1,391	1,339	1,431	1,422	1,390	1,429	1,661	1,679	1,804	1,833

[1] 1959 includes Alaska; 1960–62 includes Alaska and Hawaii.

Source: Vital Statistics—Special Reports, Accident Fatalities, National Vital Statistics Division, years indicated.

St. Louis City-County Accident Prevention Project, St. Louis, Mo.

Since June 1, 1961 the St. Louis City-County Accident Prevention Project has been collecting information about accidents admitted to 26 hospitals in this area. The project is sponsored by the United States Public Health Service, St. Louis City Health Division, St. Louis County Health Department, St. Louis Safety Council and the Health and Welfare Council of Greater St. Louis.

Data for the first full year, June 1, 1961 to May 31, 1962 have been recorded and analyzed. The attached statistical highlights have been prepared for distribution to organizations or individuals that can use them. The information is made available to serve as a basis for planning and conducting accident prevention programs in the St. Louis area.

Collection of the kind of information contained in this report is made possible through the cooperation and participation of the 26 hospitals listed below:

St. Louis Children's Hospital
Homer G. Phillips Mem. Hospital
St. Louis City Hospital
St. Louis County Hospital
St. Anthony's Hospital
Lutheran Hospital
Alexian Brothers Hospital
St. Mary's Infirmary
Normandy Osteopathic Hospital
Barnes Hospital
Deaconess Hospital
Christian Hospital
DePaul Hospital
St. Mary's Hospital
Bethesda Hospital
Firmin Desloge Hospital
Cardinal Glennon Mem. Hospital
Park Lane Hospital
Missouri Baptist Hospital
Peoples Hospital
Incarnate Word Hospital
St. Joseph's Hosp. of Kirkwood
Faith Hospital
St. John's Hospital
Jewish Hospital
St. Luke's Hospital

GENERAL INFORMATION ABOUT HOSPITALIZED ACCIDENTS

There were 6240 accident cases admitted to the 26 reporting hospitals in St. Louis City and St. Louis County.

The six hospitals reporting the largest number of accidents were—

Hospital	Number of accidents	Percent of total
St. Louis City	1,659	27
St. Joseph's	753	12
Homer G. Phillips	665	11
Deaconess	407	7
Alexian Brothers	318	5
Christian	315	5

An average of 519 accident victims were admitted to hospitals each month. More accidents were reported in March (681) than in any other month.

Accidents which occurred in the home remained numerically consistent from month to month, but accidents outside the home, falls in particular, showed definite seasonal trends. 200 more accidents were reported during the six month period from December 1961 through May 1962 than from June 1961 to November 1961. Falls accounted for almost all of the increase.

Persons injured by falls greatly exceeded the number injured by motor vehicles. Of the total 6,240 accidents reported, falls constituted the largest single cause—2,662 or 43%. Motor vehicles accounted for 1,203 or 19%. Accidents from all other causes combined reached a total of 2,027 or 33%. In 4% of the accident reports the specific cause was listed as "unknown".

In the age group 65 years or over 82% of all accidents were caused by falls. From this age group 838 persons were injured by falls—529 of which occurred inside the home.

191 accidents were reported that involved machinery. Of these, 76 occurred in the home, 76 in industrial plants, 27 were caused by power mowers, and 12 by other types of machinery.

47% of all accidents reported occurred in or around the home, and if motor vehicle were excluded, then 58% were home accidents.

29% of all hospitalized accidents were in the 1–4 and 65 and over age groups.

Poisoning is the major cause of all accidents in the 1–4 age group.

Of the total reported accidents for whom the sex was reported, 3,701 of the cases were male and 2,520 were female.

Among children 5–14 years of age falls occur most frequently in these places: Home, school or school grounds, and places for recreation or sports.

HOSPITALIZED HOME ACCIDENTS, JUNE 1, 1961, TO MAY 31, 1962

In one year a total of 2919 reported accidents occurred in or around the home. This represents 47% of all accidents admitted to the 26 participating hospitals.

Home accidents were broken down into the following categories by number and percent of total:

Cause of accident	Number	Percent of total
Falls	1,645	56
Poisonings [1]	373	13
Burns	112	4
Blow from object	109	4
Machinery	106	4
Others	496	16
Unknown	78	3
Total	2,919	100

[1] Only poison cases that required hospitalization were included in this figure.

56% of all accidents that occurred in or around the home were caused by falls. More females than males had accidents due to falls, especially those occurring on the same level, such as slipping on throw rugs or floors.

Falls in the home occurred most frequently in the age group 65 years and over with 63. The next largest number were in the age groups 5–14 with 278 and 1–4 with 209.

48% of all home accidents happened to persons in the 1–4 and 65 and over age groups.

298, or 37% of the accidents in the 1–4 age group *that were admitted to hospitals* were caused by poison. Poison is the major cause of all accidents among children from 1–4 years.

There were 18 home accidents that involved motor vehicles in the garage or yard. Twelve of these were in the 1–4 and 5–14 age groups.

In children under 1 year of age the two leading causes of accidents were falls from one level to another and hot substances.

The largest number of accidents involving hot substances occured in the 1–4 age group with 50. Reports show that in many of these accidents pot handles were turned out over the edge of the stove where young children could reach them and pull the hot substance down over them.

Accidents that occurred in or around the home were almost as high for males as for females—1422 males and 1482 females.

HOSPITALIZED NONHOME ACCIDENTS, JUNE 1, 1961, TO MAY 31, 1962

There were 3321 hospitalized accident cases reported that occurred in non-home situations.

Non-home accidents were classified under the following categories:

Cause of accident	Number	Percent of total
Motor vehicle	1,185	36
Falls	1,017	31
Blow from object	190	6
Machinery	86	3
Burns	71	2
Poisoning [1]	71	2
Others	536	15
Unknown	165	5
Total	3,321	100

[1] Only poison cases requiring hospitalization were included in this figure.

The largest number of hospitalized motor vehicle accidents occurred in the 25–44 age group with 331 out of 1185.

For the age group 15–24 the largest number of non-home accidents (261) were caused by motor vehicles—85 of the persons injured were drivers of the vehicle.

Persons in the 25–44 age group had the most non-home accidents or 856 as compared with 711 for those 45–64 and 659 for those 5–14 years of age.

69 males and 2 females were injured in non-home fires. The greater number of males injured by non-home fires is accounted for by the firemen and others involved in the Ralston-Purina, and Gaslight Square fires.

TABLE 1.—*Summary of inpatient accidental injury reports by place of occurrence and type of accident, June 1, 1962, through May 31, 1963*

(*a*) Place of occurrence:	
Home accidents	3,075
Non-home accidents	3,136
Place unknown	708
Total	6,919
(*b*) Type of accident:	
Falls	2,955
Home	1,787
Non-home	842
Place unknwon	326
Non-falls other than motor vehicle	2,083
Home	1,168
Non-home	682
Place unknown	233
Motor vehicle	1,673
Home	53
Non-home	1,577
Place unknown	43
Type unknown	208
Home	67
Non-home	35
Place unknown	106
Total	6,919

Source: Accidental injury reports received from participating hospitals during 12-month report period.

TABLE 2.—*Number of inpatient accidental injury reports received from each participating hospital by month of report, June 1, 1962, through May 31, 1963*

Participating hospital, code 37-38	Total	June	July	August	September	October	November	December	January	February	March	April	May
Total, all hospitals	6,919	685	767	662	568	542	520	619	591	418	443	567	537
01 St. Louis Children's Hospital	118	15	4	4	1	2	3	14	10	7	14	19	25
02 Homer G. Phillips Memorial Hospital	916	101	112	72	44	61	82	87	60	50	83	90	74
03 St. Louis City Hospital	1,316	156	116	93	136	141	103	107	129	67	63	95	110
04 St. Louis County Hospital	788	76	102	65	69	49	56	81	74	43	59	67	47
05 St. Anthony's Hospital	90	0	0	0	0	0	0	6	24	28	10	17	5
06 Lutheran Hospital	36	15	2	11	6	0	0	1	1	0	0	0	0
07 Alexian Brothers Hospital	414	42	48	44	44	41	41	31	26	31	31	28	7
08 St. Mary's Infirmary	0	0	0	0	0	0	0	0	0	0	0	0	0
09 Normandy Osteopathic Hospital	285	20	44	34	28	13	26	27	19	14	18	20	22
10 Barnes Hospital	82	24	15	22	10	11	0	0	0	0	0	0	0
11 Deaconess Hospital	404	35	48	27	29	36	28	40	44	30	23	31	33
12 Christian Hospital	301	19	30	22	29	29	22	26	33	15	17	30	29
13 DePaul Hospital	322	36	28	44	26	26	30	36	21	15	17	21	22
14 St. Mary's Hospital	146	11	22	0	0	0	20	14	19	9	23	6	22
15 Bethesda Hospital	6	0	0	0	0	0	0	0	0	0	0	0	6
16 Firmin Desloge Hospital	0	0	0	0	0	0	0	0	0	0	0	0	0
17 Cardinal Glennon Memorial Hospital	265	24	45	57	36	33	19	22	20	9	0	0	0
18 Park Lane Hospital	36	0	3	14	17	1	0	0	0	0	0	1	0
19 Missouri Baptist Hospital	36	0	0	0	0	0	0	19	0	3	1	9	4
20 Peoples Hospital	65	0	8	3	4	2	4	5	8	12	6	6	7
21 Incarnate Word Hospital	268	21	22	30	18	28	25	26	25	22	16	16	19
22 St. Joseph's Hospital of Kirkwood	745	66	83	87	46	47	45	58	57	50	41	76	89
23 Faith Hospital	26	10	6	6	2	0	0	1	0	0	1	0	0
24 St. John's Hospital	154	11	24	26	23	22	14	3	1	1	5	16	8
25 Jewish Hospital	0	0	0	0	0	0	0	0	0	0	0	0	0
26 St. Luke's Hospital	99	2	5	1	0	0	2	15	20	12	15	19	8
RR Unknown or not stated	1	1	0	0	0	0	0	0	0	0	0	0	0

Source: Accidental injury reports received from participating hospitals during 12 month report period.

TABLE 3.—*Number of reported home accidents by type of accident and by age and sex of inpatient, June 1, 1962, through May 31, 1963*

Type of accident, col. 26-27	Total			Under 1	1 to 4	5 to 14	15 to 24	25 to 44	45 to 64	65 plus	Unknown
	Male	Female	Unknown								
Total, all home accidents	1,537	1,533	5	99	783	657	116	287	431	665	37
RR Unknown or not stated	42	25		4	12	21	7	8	3	8	4
Total, motor vehicle	35	18		1	13	21	1	5	9	3	
01 Driver	3								2	1	
02 Other occupant	3	4			2	3		1	1		
03 Pedestrian	14	8			8	4		2	6	2	
04 Cyclist	11	6		1	3	13					
05 Unknown or not stated	4					1	1	2			
Total falls	755	1,032		44	257	332	43	147	327	622	15
20 Same level	198	442		5	37	77	14	45	150	304	8
21 1 level to another	469	445		36	208	230	22	88	146	179	5
22 Fall unknown	88	145		3	12	25	7	14	31	139	2
Total, other types	705	458	5	50	501	283	65	127	92	32	18
10 Other bicycle	15	7			1	21					
11 Machinery	99	37			37	38	7	21	25	6	2
30 Blow from object	50	28	1	2	22	28	7	9	5	5	1
31 Collision with object or person	21	15	1		2	24	3	5	1	2	
32 Cutting or piercing instrument	36	12			7	17	7	6	9	1	1
33 Cut by other object	43	26			14	27	6	13	8		1
34 Caught between 2 objects	38	23		2	31	20	1	2	3	2	
35 Foreign body	44	35		5	26	28	6	7	5	1	1
36 Torsion	17	10			1	1	4	11	8	2	
37 Poisoning, solid or liquid	186	152	1	17	275	11	10	14	5	1	6
38 Poisoning, gas or vapor	15	7		2	6	5	2	2	3	2	
39 Fire or explosion	51	45		3	17	31	9	17	9	8	2
40 Hot substance	58	49	2	19	55	19	1	8	5		2
41 Other	32	12			7	13	2	12	6	2	2

Source: Accidental injury reports received from participating hospitals during 12-month report period.

TABLE 4.—*Number of reported nonhome accidents by type of accident and by age and sex of inpatient, June 1, 1962, through May 31, 1963*

Type of accident, col. 26-27	Total			Under 1	1 to 4	5 to 14	15 to 24	25 to 44	45 to 64	65 plus	Unknown
	Male	Female	Unknown								
Total, all nonhome accidents	2,097	1,036	3	7	147	677	587	796	628	237	57
RR Unknown or not stated	26	9			1	3	5	7	12	5	2
Total, motor vehicle	991	584	2	3	103	248	351	444	301	87	40
01 Driver	348	112	1		2	2	118	177	134	20	8
02 Other occupant	124	215	1	3	19	48	93	88	59	20	10
03 Pedestrian	214	114			66	131	15	29	51	30	6
04 Cyclist	66	18			4	49	19	10	1		1
05 Unknown or not stated	239	125			12	18	106	140	56	17	15
Total falls	497	345		2	25	266	85	145	180	133	6
20 Same level	226	210			3	136	49	83	81	81	3
21 1 level to another	230	102		2	20	103	30	57	82	35	3
27 Fall unknown	41	33			2	27	6	5	17	17	
Total, other types	583	98	1	2	18	160	146	200	135	12	9
10 Other bicycle	28	4			1	27	3	1			
11 Machinery	46	6				1	13	18	18		2
30 Blow from object	154	24			3	47	36	53	33	2	4
31 Collision with object or person	89	24	1		5	46	36	15	7	3	2
32 Cutting or piercing instrument	33	4				3	10	15	8	1	
33 Cut by other object	35	6			2	6	9	15	8	1	
34 Caught between 2 objects	31	3		1	2	3	3	11	12	2	
35 Foreign body	16	3		1		5	5	8			
36 Torsion	78	12				8	15	38	27	2	
37 Poisoning, solid or liquid	3	1			3		1				
38 Poisoning, gas or vapor	6	1					1	2	4		
39 Fire or explosion	26	3			1	4	4	11	9		
40 Hot substance	10	2					4	4	2	1	1
41 Other	28	5			1	10	6	9	7		

Source: Accidental injury reports received from participating hospitals during 12-month report period.

TABLE 5.—*Number of reported accidental falls by place of occurrence and by age and sex of inpatient, June 1, 1962, through May 31, 1963*

Place of occurrence, col. 28	Total			Under 1	1 to 4	5 to 14	15 to 24	25 to 44	45 to 64	65 plus	Unknown
	Male	Female	Unknown								
Total, all places	1,435	1,519	1	46	328	671	143	329	567	840	31
R Unknown or not stated	183	142	1	----	46	73	15	37	60	85	10
1 Home (indoors)	387	763	----	39	148	99	26	95	217	512	14
2 Home (outdoors)	368	269	----	5	109	233	17	52	110	110	1
3 Street or highway	31	39	----	----	3	10	8	12	18	18	1
4 Sidewalk	57	88	----	1	5	30	6	15	41	47	----
5 School or school grounds	109	47	----	----	2	113	29	3	6	2	1
6 Other public building	23	48	----	----	1	8	4	12	20	25	1
7 Industrial place or premise	106	17	----	----	----	2	14	55	41	9	2
8 Place for recreation or sport	109	53	----	----	9	71	21	35	22	3	1
9 Other	62	53	----	1	5	32	3	13	32	29	----

Source: Accidental injury reports received from participating hospitals during 12-month report period.

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TABLE 6.—*Number of reported accidents, excluding motor vehicle accidents and falls, by place of occurrence and by age and sex of inpatient,*[1] *June 1, 1962, through May 31, 1963*

Place of occurrence Col. 28	Total			Under 1	1 to 4	5 to 14	15 to 24	25 to 44	45 to 64	65 plus	Unknown
	Male	Female	Unknown								
Total, all places	1,453	624	6	54	564	497	248	366	264	54	36
R Unknown or not stated	165	68	----	2	45	54	37	39	37	10	9
1 Home (indoors)	530	406	5	49	467	183	45	98	55	27	17
2 Home (outdoors)	175	52	----	1	34	100	20	29	37	5	1
3 Street or highway	54	19	----	----	7	29	8	17	9	2	1
4 Sidewalk	30	5	----	----	2	16	5	8	1	3	----
5 School or school grounds	75	14	----	----	----	46	37	3	----	----	3
6 Other public building	24	10	----	----	1	2	5	13	9	4	----
7 Industrial place or premise	269	19	1	----	----	2	54	125	101	2	5
8 Place for recreation or sport	92	21	----	----	5	46	28	26	8	----	----
9 Other	39	10	----	2	3	19	9	8	7	1	----

[1] Accidents where type was unknown have also been excluded. See table 1 for these figures.

Source: Accidental injury reports received from participating hospitals during 12 month report period.

[From the Consumer Reports, March 1964]

CANDY ASPIRIN

THESE PILLS, DESPITE "SAFETY CAPS," ARE THE LEADING CAUSE OF CHILD POISONINGS

Most major promoters of regular aspirin also sell children's candy aspirin—sweetened, flavored tablets containing one-fourth as much acetylsalicylic acid as a regular aspirin pill. In recent months the drive to develop tihs market seems to have intensified; TV commercials for the children's versions have now become common. CU's medical consultants have long opposed these products on the grounds that medication should not be made attractive to children too small to understand its hazards.

Many kinds of medicins (antibiotics, antiepileptics, antihistamines, barbiturates, sulfonamides, salicylates, laxatives, and vitamins) have been compounded in special forms to make children think they are candy or liquid confections. But no other candy medicine has the unenviable record of children's aspirin—no doubt because none combines a potential lethal effect with such wide availability.

The first candy aspirin, manufactured in 1932, was sold by prescription only, and comparatively little of it was used. Before World War II, only about 20% of total aspirin fatalities were in pre-school children. But then, in 1948, drugstores started selling candy aspirin without a prescription; and by 1951 the proportion of aspirin deaths occurring in pre-schoolers had reached 80%. A review of accidental poisonings for all ages, reported in 1959 by the National Clearinghouse for Poison Control Centers, showed that aspirin accounted for a fourth of the cases, "most of them small children who swallowed candied aspirin."

Although candy aspirins are now generally bottled with some sort of "safety cap," supposedly too difficult for a small child to remove, the records of poison control centers still attribute an overwhelming proportion of accidental aspirin poisoning to the fact that pre-school children have helped themselves to medicated candy.

CU's alternative

Parents can avoid this threat to their small children by simply not having candy aspirin in the house. With a little effort, as CU has pointed out, unflavored aspirin can be made palatable by crushing it into a spoonful of jelly or honey. Any medicinal taste that might linger in the child's mouth can be washed away with at least three or four ounces of water, milk, or fruit juice—an amount of liquid that ought to be taken with every dose of aspirin anyway to prevent possible irritation of the stomach. (Buffered aspirin, frequently advertised as preventing stomach irritation, is no better in this regard than plain aspirin.)

Aspirin deserves far more respect as a potentially hazardous medicine than most people give it. Where children are concerned the margin between an effective dose and an overdose may be rather narrow. In Milwaukee, Wis., early last year, for example, the deaths of two toddlers were attributed to aspirin given to them for relief of respiratory ailments. One child had been given only half a baby aspirin, the mother reported, every three hours for four days, but he had also been taking a cough remedy that contained acetylsalicylic acid (aspirin). The other child was reported to have received half an adult aspirin tablet every three or four hours for four days.

For the safe administration of aspirin both the amount and the frequency of dosage must be taken into consideration. CU's medical consultants agree with the Food and Drug Administration's label requirement recommending that aspirin be administered no more than three times in any 24-hour period, and in doses spaced at least three hours apart.

In setting up the proper size of the dose for children, however, CU's consultants disagreeing with the FDA, consider weight to be a better indication than age. For example, children weighing less than 30 pounds, for whom the dose would be apt to be less than a tablet, should never have aspirin except under a doctor's direction; children weighing 30 to 60 pounds should be able to take one regular aspirin tablet (5 grains); children weighing over 60 pounds should be able to take the typical adult dose of two regular tablets—limiting dosage times, of course, as indicated above.

What about liquid substitutes?

CU's objections to the candy aspirin pill apply even more strongly to flavored substitutes. The chance of taking a dangerous overdose is even greater with an

easily swallowed liquid. Moreover, some of the liquids advertised for use in place of aspirin are of questionable effectiveness.

Liquiprin and *Dropsin*, for example, contain salicylamide as their active ingredient. Although in laboratory studies this substance relieved induced pain as well as aspirin did, it proved no better than a placebo in controlled clinical studies of effectiveness against naturally occurring pain. Aspirin, on the other hand, worked well in the clinical tests. Salicylamide also fared poorly in studies of its effects in lowering fever.

Other flavored liquids, *Tylenol* and *Tempra*, contain acetaminophen as their active ingredient. In pain-relieving and fever-lowering effectiveness, this drug is comparable to aspirin, but there have been reports of kidney damage in people who used it regularly in large doses over a prolonged period. Although there is no reason to suspect such serious side effects from occasional small doses, CU's medical consultants suggest that its chief value for children is as an aspirin substitute for those who are allergic to the more common pain killer. For such special use acetaminophen can be bought in unflavored tablet form.

REPORT ON A CLINICAL CONFERENCE ON ASPIRIN POISONING OF THE PEDIATRIC CONFERENCES FROM THE BABIES' HOSPITAL UNIT, UNITED HOSPITALS OF NEWARK, N.J.

SALICYLATE POISONING

Case I

(By E. Garcia, M.D.[1])

Case I (S.K.) is a 3-month-old Negro male admitted on April 5th, 1964, with twitchings of extremities and dyspnea a few minutes prior to admission.

Two weeks prior to admission, the patient had a cold and began coughing. No medication was given until the night prior to admission when he developed hyperpyrexia. One-half tablet of Anacin and 6 doses of 1¼ grains of aspirin were given every two hours (approximately 10 grains in 14 hours).

Eight hours prior to admission he was seen at Newark City Hospital Emergency Room where he received a penicillin injection. A few minutes before admission, however, he started having non-projectile vomiting and twitchings involving all extremities and dyspnea. He was rushed to Babies' Hospital Emergency Room and admitted to the ward.

For one week he had been having semi-watery, yellowish, non-mucoid, non-bloody stools 6 to 8 times a day, which spontaneously cleared two days prior to admission.

Family History: Non-contributory.

Past Personal History: The first of a set of twins, the boy was born full-term of spontaneous delivery, at City Hospital. The birth weight was 5 lbs. 12 oz. Growth and development were normal, and the patient had no feeding problem, the only allergy being to orange juice. He had one polio shot. On admission the child was found to be fully developed, well fed and nursed. The baby was highly febrile—104° F; the pulse rate was 160, respiratory rate 60 to 80 per minute. He was hyperpneic, with twitchings of all extremities and he had a dry cough. The conjunctiva was pale; there was flaring of the alae nasae, and a slight mucoid nasal discharge noted. The throat was minimally injected. The neck was supple and the cervical nodes very shotty. The heart was tachycardic, and the lungs clear.

Hospital course: This 10½ pound infant was admitted hyperpneic, hyperpyrexic, slightly dehydrated and tachycardic. The lungs were clear upon auscultation at that time, but due to the clinical picture and the infiltration over the right lower lobe on x-ray, a presumptive diagnosis of pneumonia was made.

However, salicylate poisoning was also entertained based on the history of salicylate ingestion of approximately 10 grains within 14 hours, hyperpnea, hyperpyrexia and a strongly positive ferric chloride test for salicylates in the urine. CO_2 was 30 vols.% with slight elevation of sodium chloride. White blood count and differential revealed a shift to the left.

Intravenous fluids in the form of 1/6 M sodium lactate, saline and dextrose water and I.V. penicillin were started. The patient was kept in a croupette under oxygen and high humidity for several days.

[1] Resident in Pediatrics, Babies' Unit, United Hospitals of Newark, Newark, N.J.

About 11 hours after admission, the liver was felt to be three finger breadths below the right costal margin, and the cardiac rate was over 200 per minute. Anticipating an impending heart failure, he was digitalized and placed on the "serious" list. Only two doses of digoxin were given as liver receded and cardiac rate slowed down the following day. At this time, his respiratory rate was between 50 and 70 per minute with a blood salicylate level of 37.3 mg.% and blood pH of 7.3. Electrolytes remained within normal limits and CO_2 continued to rise with administration of 1/6M sodium lactate. Ionosol MB was administered intermittently. Fluids were based on 180 cc./kg. body weight per day. In the afternoon of the second hospital day, the infant had another episode of twitchings, which was controlled with phenobarbital. The twitchings were regarded as due to rapid hydration. A spinal tap was negative.

On the third hospital day, the salicylate level in the blood was 43 mg.%, on the fourth day 30 mg.% and the fifth day 5mg.%. By that time the urine had become negative. Interestingly, the infant was tachypneic with crepitant and subcrepitant rales over both lung fields; chest x-ray revealed a segmental right upper lobe pneumonia. He, likewise, looked shocky with hemoglobin of 10.6 gm. The night before, he had two tarry stools which were strongly positive for occult blood. In view of the pallor and the downhill course of the patient, 100 cc. of whole blood transfusion was given in spite of the 12.3 gm. hemoglobin—a value which could have been due to hemoconcentration since the child still looked dehydrated in spite of continuing I.V. fluids through a cutdown. Since he persistnently refused fluids by mouth, I.V. fluids were administered for one week. At this time he was alert, well hydrated and was sucking vigorously. During the first hospital week, he had 3 to 4 episodes of twitchings, controlled by phenobarbital. Serum calcium was repeatedly cheked and was normal.

On the ninth hospital day, he was found to be in hypotonic dehydration, having had 8 to 10 bouts of loose stools the night before. Sodium chloride 3% was administered, computed according to deficit. Within these days, he had one bout of twitching, but the cause was not determined. Plasmanate 5% was administered three times because of the low protein. Eventually, CO_2 and serum electrolytes became normal.

On the 12th hospital day, examination of the stool revealed *E. coli* type 0110-B14. Coly-Mycin was immediately started and treatment continued for nearly two weeks. A repeat stool culture one week after the Coly-Mycin was started showed persistence of pathogenic *E. coli*. Neomycin was then added to the regimen. Oral alimentation in the form of banana and applesauce was resumed on the 16th hospital day and full strength formula on the 21st hospital day.

The pneumonia cleared on the second hospital week. The patient continued to improve and was discharged on the 16th hospital day still receiving neomycin. The third stool culture taken shortly before discharge was later reported negative.

Case II

(By L. S. Joaquin, M.D.[2])

Case II is a 13-year-old white male who was admitted for the first time because of vomiting. The patient was apparently well and in good health until about 24 hours prior to admission when he vomited about 6 to 7 times. The vomitus consisted of food, and the episodes of vomiting commenced one hour after having ingested ½ cupful of candle wax.

The following morning the private physician was consulted and he noticed that the patient was dizzy, flushed and breathing deeply. Urinalysis done at that time showed a strongly positive acetest and negative tes-tape for glucose. The doctor advised the patient to take 2 oz. of sweetened fluids every 15 minutes, but the parents noticed that he was becoming irrational and drowsy. The physician was again consulted, and this time he advised hospitalization.

Family History: Asthma and other forms of allergy are present on the mother's side, but no other familial illness.

Past History: The patient was born of a 7½ months' gestation with a birth weight of 5½ lbs. in a normal spontaneous delivery. The pattern of growth and development was normal and he had no other serious illness. His height is 5'6''; weight is 132.5 lbs. The patient is known to be allergic to feathers, grassweed, pollen, chocolate, terramycin and sulfas.

Hospital Course: Upon admission, the patient was conscious, coherent, cooperative, afebrile but with a flushed face. The pulse rate was 90, and respiratory rate 20 per minute; the blood pressure 120/70; and temperature 100°F.

[2] Resident in Pediatrics, Babies' Unit, United Hospitals of Newark, Newark, N.J.

The private physician suspected salicylate intoxication although the patient denied having taken any aspirin. A stat urinalysis was strongly positive for salicylate with 2+ for acetone and 1+ for albumin; stat blood salicylate level was 42.5 mg.%. CBC was normal. The blood chemistry showed a BUN of 16.7 mg.; sodium 142; potassium 3.9; chloride 106; CO_2 38 vol.%. Ionosol MB was given intravenously along with sodium bicarbonate in doses of ½ gm. every two hours, as indicated by the urine pH. About 12 hours after treatment, a suicide note was found by the mother and the patient later admitted taking 80 5-grain aspirin tablets (total 400 grains.)

The patient responded well to therapy and, at present, is completely rational, cooperative and alert. He has continued to receive supportive therapy and is now attending school.

Discussion by C. Prentiss Ward, M.D.[3]

These two cases illustrate the problems of salicylate intoxication: 1) in which the salicylate was given for therapy by the parent and 2) an attempt at suicide. In reviewing the literature we find that acetylsalicylic acid, because of its widespread use, attractive taste of the "baby" aspirin, and easy availability, is the most common childhood poison and presents a particular threat of families with young children. A seminar on the subject of salicylism from the University of Colorado revealed that the compounds commonly causing intoxication are sodium salicylate, methyl salicylate (oil of wintergreen) and acetylsalicylic acid (aspirin.) (1) Ease of availability is evidenced by the fact that more aspirin is consumed in the United States than any other drug. Salicylates were responsible for 541 fatalities (7.7% of the deaths due to accidental poisoning) between 1952 and 1956. Of these, 380 fatalities occurred in children under five years of age. (2) Of 3,926 poisonings reported from 29 Poison Control Centers acetylsalicylic acid was listed as the cause in 983 patients and "baby" aspirin accounted for 62 per cent of the ingestions, and "adult" aspirin for 10.9 per cent. (3) Other series of statistics have shown an even higher rate of poisonings due to the "flavored" type of aspirin. (4)

The National Clearinghouse for Poison Control Centers of the U.S. Public Health Service has reported 96,000 cases of ingestion incidents during 1961–1962. Of the cases classified as accidents 86 per cent involved children under five years of age, with aspirin as the most frequently ingested substance. It was noted that the proportion of aspirin ingested increased with the older age groups. (5)

Review of the data collected by the Boston Poison Information Center (6) revealed that 62 of 94 children shared the acetylsalicylic acid with playmates and that "flavored" variety tablets were taken in 84 episodes. In 73 cases ingestion followed the use of acetylsalicylic acid to treat another member of the family. One-third of the involved children were just recovering from or affected by illness, generally an upper respiratory disorder. All children, with but one exception, had previous experience with acetylsalicylic acid, again usually the "flavored" variety. This medication was used for virtually every illness or indisposition suffered by the family members with or without fever. Parents frequently admitted that they encouraged acceptance of the medication by presenting it to the children as "candy." Children often explained that they were "playing doctor," "having a tea party" or "acting just like mommy or daddy when they felt bad," thereby showing that ingestion was not accidental but part of the physical and human environment in which a child is unable to distinguish or remember the difference between candy and medicine. The importance of increasing parental awareness of developmental patterns and abilities and the need for instruction in accident prevention is very clear.

Unfortunately, the toxicity of the salicylates is underestimated both by the laity and the physician in general. Too often proper therapy is delayed because of improper evaluation of the seriousness of the problem.

We should also note here that many cases of salicylism are not due to accidental ingestion but the result of the administration of what were considered to be therapeutic doses. Segar reported 43 cases of salicylism in children under 6 years of age; 11 of these due to accidental ingestion, while 32 were the result of misguided therapeutic efforts by an adult. (7) This places a burden upon the doctors who prescribe salicylates for infants. It seems that a better subtitle for today's discussion could be "Iatrogenic Deaths" because this is what is really happening. Therefore when considering accidental ingestion, one must take into account not only the toddler who has found a bottle of acetylsalicylic acid but also that an overdose may have been administered by an adult. It has been noted that the

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latter was more likely to be the case in the infant, while poisoning in the 2 to 4 year old is usually the result of accidental ingestion.

Clinical manifestations and physiology

The physiology and excretion of salicylate merit reviewing. The excretion of salicylates is slow, the half-life of salicylate in the body being about 20 hours. Eighty per cent is excreted through the kidneys and the remaining 20 per cent is excreted in other ways. This means that if, due to dehydration for example, the urine excretion is decreased, the rate of excretion of salicylate will be even less than 50 per cent in 20 hours.

Since aspirin is routinely given every four hours, it is easy to see how it can accumulate in the body. Therefore, the total dosage that the child has taken over three or four days or a week is the significant amount in making a presumptive diagnosis of salicylism. This is illustrated in Case I. This 10-pound baby had a total of 10 grains or 120 mg. per kg., an amount well up in the toxic range. The toxicity was enhanced by dehydration due to fever, diarrhea and vomiting. These symptoms common in sick children decrease the efficiency of the kidneys, thereby increasing the accumulation of salicylates in the body.

Now it is found that if the urine is alkaline up to a level of pH 7 the excretion of salicylates is ten times as rapid as when the pH of the urine is 6. But due to metabolic acidosis the urine is ordinarily acid. There is an initial respiratory alkalosis and a compensating loss of bicarbonate. This leads to the phase of metabolic acidosis due both to the loss of bicarbonate and to the accumulation of ketones and of metabolites. Another toxic effect of salicylates is an actual increase in the metabolic rate: with toxic doses, the metabolism is increased to the point where a fever may result from the aspirin itself. Therefore, this is a paradoxical effect of overdosage of aspirin and one which might very easily be overlooked. Case II illustrates this. The patient was a 13-year-old boy who had a temperature of over 100° by mouth and, as far as we know now and in retrospect, had no infection at all.

It is claimed that the basal metabolic rate may be increased by as much as 100 per cent by a toxic dose of salicylates. Diarrhea may also be caused by toxic doses of salicylates. When we realize how often babies with diarrhea are dosed with aspirin, it becomes readily apparent how often aspirin adds to their difficulties.

Then there is the factor of dehydration due to additional water loss from the lungs, accompanying the increased metabolism. The effect on the blood-clotting mechanism is demonstrated in attempted suicides by teenagers who occasionally die from a cerebral hemorrhage. This is related to a failure of the clotting mechanism. Aspirin is chemically similar to the coumarins with a similar pharmacologic effect; therefore Vitamin K is considered part of the routine treatment of salicylate intoxication.

Outline of Clinical Management of Silicylate Poisoning

I. Immediate
   1) Evaluation of severity of intoxication
   2) Appraisal of status of dehydration
   3) Determination of acid-base imbalance
      Test urine with Phenistix paper and Nitrazene paper
   4) Determination of electrolyte imbalance
   5) Draw blood for the following laboratory tests:
      salicylate level
      CO_2-combining power
      Plasma CO_2 content
      pH
      serum electrolytes

II. Pending laboratory report
   1) Start intravenous fluids (5 per cent glucose in ⅓ physiologic saline)
   2) If dehydration is severe hydrating solution should be given at the rate of 8cc./sq.m. body surface per minute for 30 to 45 minutes
   3) After that time, slow down hydrating solution to 2 cc./sq.m./min.
   4) Correct bicarbonate and potassium deficits as indicated (average requirement: 5 mEq $NaHCO_3$/kg. and 2 mEq K/kg. for 12 hours)
   5) In presence of clinical acidosis and acid urine—$NaHCO_3$ should be given in *initial* hydrating solution

III. In life-threatening intoxication—consider peritoneal dialysis with 5 per cent albumin solution or dialysis with artificial kidney

IV. Administer vitamin K and B complex, the route of administration depending on the condition of the patient
V. Maintenance management
    1) Test each urine voided with Nitrazene paper
    2) Perodic (frequent) determination of:
        blood CO_2-combining power
        blood CO_2 content
        blood pH

As regards other symptoms which occurred in our case of attempted suicide—the boy complained of deafness, an interesting symptom, inasmuch as ringing in the ears is a frequent sign of excessive aspirin. This boy actually complained of deafness.

On admission we obtained a salicylate level of 44 mg.% in the blood of this patient. Using the extrapolation method of Done (8) it was computed that this level was approximately that reached at 20 hours after his ingestion of the salicylate; we were then able to calculate that he probably had a level close to 100 mg.% at the peak—which would have been 2 hours after he took the salicylates.

The toxic dose is considered to be in the range of 75 to 150 mg./kg., which our first patient had. In the second case, 80 5-grain tablets—roughly 370 mg./kg.—were taken, which is a fatal dose. Vomiting saved his life.

It is of interest to note that in a toxicology text, (9) aspirin is graded No. 4 in a classification of toxicity, where 6 is an extremely toxic substance and 1 is nontoxic. In this scale aspirin is given a rating of 4; in other words, it is very toxic. Surprising is the universal use and availability of a substance that is so highly toxic.

It behooves us all to be aware of the fact that babies are getting sick and dying every day because of aspirin given to them by their parents and, in some cases, as prescribed by doctors.

Laboratory studies by John Stirling, M.D.[4]

The action of aspirin in the body is very complicated. It tends to act on all the systems: on the nervous system, the gastrointestinal tract, the respiratory and genito-urinary systems. Therefore, when the patient (adult or child) is brought into the hospital, he tends to have a variety of symptoms which may make the diagnosis somewhat difficult.

The over-all action at first is one of stimulation, especially in adults. Later, aspirin tends to exert a generalized depression. Once salicylate poisoning is suspected, the diagnosis is comparatively easy from the laboratory finding. This depends upon the reaction of ferric chloride with salicylate, giving a purple-colored compound—ferric salicylate—which can be measured.

In the pediatric office, the phenostix, used for the determination of phenylketonuria, also contains ferric chloride, and can be used as a routine screening test for salicylates. Most children tend to pass, rather rapidly, through the initial stimulatory stage following ingestion of this compound and, therefore, by the time they come to the pediatrician they are usually in a state of generalized depression. It should be borne in mind that children, under three years of age, seem to be much more sensitive to this action of aspirin than adults.

In the early stages of salicylate poisoning there is prolonged hyperventilation, due to stimulation of the respiratory center. This leads to a respiratory alkalosis, which may be aggravated by a metabolic alkalosis because of the vomiting which often occurs. Therefore, there is a real problem in ascertaining and correcting an electrolyte and acid-base imbalance which may shift rapidly.

As the process continues ketone bodies are produced, resulting in an uncompensated metabolic acidosis. Urine pH at this stage is usually acid. Determination of blood pH, PCO_2, CO_2, the carbon dioxide-combining power, and the use of a nomograph make possible an accurate determination of the acid-base balance. If any two of these are determined, the others can always be determined. In other words, if you can pick up a CO_2-combining power and if you have the facilities to do a total CO_2 content, then the pH can be determined. If you can obtain the pH and one of the others, then you will be able to tell whether the child is in a respiratory alkalosis or a metabolic acidosis.

Ideally, the pH should be done on unexposed arterial blood but capillary blood is sufficiently accurate. The reason for this is that as the blood passes through the lungs it throws off carbon dioxide. so that a pH of venous blood would be inaccurate.

[4] Pathologist, Babies' Unit, United Hospitals of Newark, Newark, N.J.

It is also well to determine carbon dioxide content, because this is important with regard to therapy. Thus, administration of bicarbonate would not be advisable when there is a high serum bicarbonate. Ordinarily, we get by with this because a state of metabolic acidosis is usually present by the time the child is hospitalized.

Other laboratory tests of importance are prothrombin determinations if the child shows any hemmorrhagic tendencies, and liver function tests if hepatic damage is suspected. The important thing, however, is determination of the acid-base balance.

Questions and comments

A Voice: Dr. Stirling, you said that early in this case the CO_2 content may be elevated. Then, what would the urine pH be?

Dr. Stirling: Generally, when the child is in a respiratory alkalosis the CO_2 content tends to be low. Also, the pH of the blood will be up, and compensatory biochemical processes coming into play result in an alkaline urine.

A Voice: My reason for asking is this: suppose this happens during the night, and a plasma pH determination cannot be done; and by the time the child is sick enough to need treatment, he is beyond this stage. Would it help to get the pH of the urine, and if the urine were acid, then would it be perfectly safe to go ahead with the bicarbonate therapy?

Dr. Stirling: This has some pitfalls but as a general rule it would apply.

A Voice: Do you think there would be any danger in giving sodium bicarbonate to a child whose urine is acid?

Dr. Stirling: Offhand I would say no, but one must bear in mind that urinary pH does not always reflect plasma pH.

Dr. Barba: I think that some particular cases may have a markedly elevated pH and still have an acid urine with the patient excreting acid metabolites. This is the reason why—due to the complexity of this combination of respiratory alkalosis and metabolic acidosis in any one patient—there is no way one can be really sure what the condition is, by just simple measurement. Fortunately, almost all of the younger children go rather rapidly into a metabolic acidosis. Also, fortunately, since there are two factors at work—a metabolic acidosis and a respiratory alkalosis—the pH is rarely too far from normal in any given patient. It is the exceptional case where the pH goes way down or way up due to the different factors operating. I think that in any one patient you cannot rely on any *one* measure; you have to have all measures.

Chairman: In that respect, how much help will the salicylate level be in determining the status of the patient?

Dr. Barba: I think the salicylate level is of the biggest help with regard to the kind of therapy to institute.

If you use the nomograms in order to extrapolate retrospectively to what the presumed starting level was, and if this is reasonably within limits compatible with life, then you can treat the patient effectively and conservatively with intravenous therapy. However, if you extrapolate back and get an unusually high level, and the level continues to be high, then this might justify using dialysis or transfusion, depending on the age of the child.

Dr. Ward: We might focus on one of the points in the case of the 13-year-old boy: we tested every sample of urine with the pH paper, and found that we were starting off with a level of pH 5.4 at the outset. We were giving him bicarbonate by mouth in what I think is probably a conservative dose (½ grain every two hours). We could have given three or four times as much. It would probably have been better.

We found that it took nearly 24 hours to get his pH up to 7. In other words, from a theoretical point of view, we undertreated him. We could have given him a good deal more bicarbonate; and he probably would have excreted the salicylates even faster, which in this case was not a critical problem. However, if you are dealing with a case which is more toxic, where the child is in coma, you want to achieve a maximum excretion of salicylates with the bicarbonate. You would, therefore, use bicarbonate in the range of 5 mEq/kg., given over a period of 12 hours.

Dr. Barba: One other important point that I would make relates to the occasional case (based on the Henderson equation) where the CO_2: bicarbonate ratio is 1:20. With this hyperventilation, CO_2 is blown off, so that the plasma CO_2 level is reduced, and the kidneys compensate for this by eliminating the bicarbonate. The bicarbonate then goes down, but more slowly. Since this is a slower operating factor, the patient will have an elevated pH.

Due to the toxic effects of salicylates, which will at times cause a depression instead of stimulation, the patient's respiration suddenly may become depressed, and, in that case, he will rapidly reaccumulate the CO_2. The kidneys cannot possibly compensate for this quickly, and severe respiratory acidosis will ensue—in fact, very, very quickly. The only possible remedy in this critical situation is to put the patient on positive pressure therapy so that he is ventilated and thereby helped to blow off the CO_2, combating the respiratory acidosis. I think that in a severe case of salicylate poisoning, you should always have the intermittent positive pressure breathing apparatus available for immediate use.

Chairman: Are there any further comments?

A Voice: Dr. Finberg has advocated the use of diamides, and I would like to find out whether that advocacy has found any fertile ground, and if it has, I would like to speak against it.

Dr. Barba: My comment is based on the few reports I have read about this, though I have never used it: there was one encouraging, and several discouraging reports.

The work conducted at Kings County Hospital in 1954 showed that diamides would alkalinize the urine of dogs poisoned with salicylates and thereby increase the excretion of salicylates. The publication of these results was delayed, until further experimentation proved that this was life-saving.

Rats poisoned with salicylates were then treated with alkali or with alkali plus diamide. The alkali alone worked much better. The diamides produced an acidosis.

So, I believe that while diamides would eliminate the salicylates faster, as Dr. Finberg said, if a child is just between life and death, I think there are reasons to suppose that this treatment might be dangerous. Therefore, I would rather use dialysis, the intermittent positive pressure, and sodium bicarbonate.

Dr. Ward: It might be worth pointing out that in the peritoneal dialysis, 5% albumin is recommended in the solution. I think that would be very sensible because the albumin will bind the salicylates and make their excretion much more effective.

The other thing which has not been brought up is the effect of salicylate poisoning on potassium. The whole process works so as to depress potassium, which was observed in our case.

Chairman: I think that as pediatricians we have tremendous responsibilities to see that such a toxic substance as salicylate is not so easily available, especially those abominable baby-aspirin tablets.

Dr. Stirling: May I ask about the use of Tham (tris hydroxymethyl) aminomethane here?

Dr. Barba: Yes, Tham, has been used; the difficulty with Tham is that it occasionally precipitates a respiratory arrest, so that you have to be able again to maintain adequate prolonged respiratory exchange artificially.

Summary

Two cases of salicylate poisoning are presented in: 1) a 3-month-old infant who received aspirin in therapy; 2) an adolescent boy who attempted suicide.

It has been emphasized that aspirin is highly toxic. The toxic manifestations include respiratory alkalosis, metabolic acidosis, increased basal metabolic rate with resultant fever and dehydration, proteinuria, hypoprothrombinemia, hypokalemia, diarrhea, transient deafness, coma, epistaxis and a tendency to hemorrhage. The toxicity is enhanced by slow excretion, which is further retarded by acidosis or dehydration. Accordingly, on a q 4 h dosage schedule the drug may accumulate to toxic levels, even though individual doses may not have exceeded generally accepted therapeutic amounts. Aspirin is far from innocuous, and the harmful effects must be balanced against the anticipated benefit.

The treatment of salicylate intoxication is discussed, with appropriate emphasis on the correction of electrolyte and acid-base imbalance.

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Mrs. SULLIVAN. Thank you.

After the revised version of H.R. 1235 was introduced containing this new section on flavored aspirin for children, I again went the rounds of the executive department, as I had in previous Congresses, trying to get administration support for the omnibus bill approach to all of the inadequacies of the Food, Drug, and Cosmetic Act.

I failed again—the White House and HEW strategists decided against my approach in favor once again of the piecemeal approach—but I received a great deal of news coverage on the aspirin section and a year or more later, this proposed child safety bill came up, containing several other major provisions of H.R. 1235, on labeling and modification of the exemption of foods, drugs, and cosmetics from the Hazardous Substances Labeling Act, and also including for the first time in an administration bill a provision on flavored aspirin, although, as I said, it is only a halfway adoption of section 14 of my bill.

Naturally, I support this bill as far as it goes. But I am truly distressed at how little the administration has asked for, and how timidly it has asked for it. The witnesses you are going to hear this morning will undoubtedly be eloquent in telling you it goes too far—as they would, I am afraid, of any bill which interfered with them in any way.

I don't think the moderation evidenced in this administration bill will achieve consensus. So why not fight for what is needed, such as a complete ban on flavored aspirin plus the other provisions on H.R. 1235 as listed in the bill's title as follows and I quote the bill:

A bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to amend certain labeling provisions of the food, drug, and cosmetic chapters to assure adequate information for consumers, including cautionary labeling of articles where needed to prevent accidental injury; prohibit worthless ingredients in special dietary foods; require new therapeutic devices to be shown safe and efficacious before they are marketed commercially; require all antibiotics to be certified; require cosmetic to be shown safe before they are marketed commercially; clarify and strengthen existing inspection authority; make additional provisions of the act applicable to carriers; provide for administrative subpenaes, and prohibit the use of carcinogenic color additives in animal feeds.

Mr. Chairman, I have a big file of letters that I received from all over the country after the flavored aspirin ban in my bill was widely publicized, and I will read excerpts from four or five of them to give you an idea of the kind of people who have been writing me on this subject.

One is from the city of New Rochelle, N.Y., from the supervisor of arts in the city schools there. This gentleman, Mr. Mortimer H. Slotnick, says:

How we can tolerate such built-in booby traps is beyond comprehension. As the father of a baby who consumed a bottle of tasty orange-flavored baby aspirins, I can state with the greatest emphasis that dangerous medicines should taste

bitter or sour or just bad. The good Lord smiled on our baby and we discovered the deed in time and pumped her out with no bad effects.

Then Dr. John Ambach of Louisville, Ky., writes:

For several years I have disparaged the use of baby aspirin in the home and this "peculiar" behavior was prompted by case after case of children eating the aspirins, and in some instances rather severe aspirin intoxications that required very strenuous hospital measures to overcome.

And Mr. and Mrs. Clarence L. Hurst of St. Louis write:

I have heard the stories that mothers tell, that is: They were sure the aspirins were on a high shelf, and the child could not reach them, and I have heard that they were sure the baby could not get the safety top off the bottle; of course, other explanations in addition. Despite this, the children were still being poisoned and rather routinely.

We have for the last several years used acetaminophen derivatives and until recently dipyrone derivatives for reducing fever in children and have done beautifully with these products.

Thanks a million for trying to discontinue the baby aspirin. Last week our 3-year-old nephew was taken to the hospital here after eating a number of them. Luckily he just stayed over night and he survived, but many of them don't.

Dr. William B. McIlwaine III, a pediatrician from Petersburg, Va., said:

The enclosure—

A newspaper account of my bill—

interests me a great deal as I am heartily in favor of prohibiting the sale of flavored aspirin for children. At least three or four times a week, I am told, the hospital is engaged in washing out some child's stomach, and I personally feel it is a very dangerous drug in the flavored form.

I have received similar letters from other pediatricians. The chief of pediatrics at the Presbyterian Medical Center in San Francisco, Dr. Lester A. Luz, says:

I have just recently read in the San Francisco Chronicle of your efforts to abolish the distribution of candied aspirin for children. As a pediatrician I wish to commend you for your action. I sincerely hope you will succeed in your project.

On the other side of this issue, I heard from several people, in fact four from mothers who say "How foolish can you get? Aspirin has saved my child. Why would you outlaw it?" Of course I do not wish to ban all aspirin, but I think we should ban the candied flavored aspirin as a leading killer of children under 5, when plain aspirin can be given the child with a little ingenuity and imagination, and with little chance of the child accidentally ingesting any in the mistaken belief it is candy.

Thank you Mr. Chairman.

Mr. ROGERS of Florida. Thank you very much, Mrs. Sullivan, for a very excellent statement. I appreciate very much your thoughts and know that you have given a great deal of time to this subject over the years.

Any questions?

Mr. SATTERFIELD. No questions, Mr. Chairman.

Mr. SPRINGER. Mrs. Sullivan, this is an excellent statement and I know how long you have been very much interested in this subject before the committee and it is important that we do take cognizance of it.

Do you have anything against H.R. 13886?

Mrs. SULLIVAN. Only that it doesn't go far enough.

Mr. SPRINGER. But you are not opposed to anything in the bill at present time?

Mrs. SULLIVAN. No; I am not.

Mr. SPRINGER. You are not opposed to any feature in H.R. 13886.

Mrs. SULLIVAN. That is right.

Mr. SPRINGER. Your only thinking about it is that you believe that it ought to do more or contain more safety features; is that correct?

Mrs. SULLIVAN. That is correct.

Mr. SPRINGER. Would you support the bill if it came to the floor?

Mrs. SULLIVAN. Yes; I would.

Mr. SPRINGER. Thank you, Mr. Chairman.

Mr. FOGERS of Floria. Mr. Mackay.

Mr. MACKAY. No questions

Mr. ROGERS of Florida. Thank you very much, Mrs. Sullivan. We appreciaet your presence here this morning.

Mrs. SULLIVAN. Thank you.

Mr. ROGERS of Florida. Our next witness is Mr. C. Joseph Stetler, who is President of the Pharmaceutical Manufacturers Association.

Mr. Stetler, the committee would be glad to hear you now, and if you would like to please identify those with you for the record.

STATEMENT OF C. JOSEPH STETLER, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY RODNEY MUNSEY, COUNSEL; AND DR. HART VAN RIPER, VICE PRESIDENT FOR MEDICAL AFFAIRS, GEIGY PHARMACEUTICALS

Mr. STETLER. Mr. Chairman, I would like to have with me Dr. Hart Van Riper and Mr. Rodney Munsey.

Mr. ROGERS of Florida. Thank you.

Mr. STETLER. Mr. Chairman and members of the committee, it is a privilege for us to appear before you today to present the views of the Pharmaceutical Manufacturers Association on title I of H.R. 13886, a bill, as you know, entitled, "The Child Safety Act of 1966," and several related measures.

With your permission I would like to file for the record our complete statement that was submitted to the committee and I will present an abbreviated version, if I might.

Mr. ROGERS of Florida. Without objection your complete statement will be made part of the record at this point and we will beglad to have your comments.

(Mr. Stetler's complete statement follows:)

STATEMENT OF C. JOSEPH STETLER, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Mr. Chairman and members of the committee, it is a privilege to appear before you today to present the views of the Pharmaceutical Manufacturers Association on Title I of H.R. 13886, 89th Congress, a bill entitled "The Child Safety Act of 1966," and several related bills.

My name is C. Joseph Stetler. I am the President of the Pharmaceutical Manufacturers Association, a trade association composed of some 140 manufacturers producing about 95 per cent of the drugs sold on prescription or promoted to the medical profession in this country.

Our member firms conduct extensive research and develop, manufacture and distribute products which prolong and save lives. During the past thirty years,

the U.S. pharmaceutical industry has become the world's leader in developing new medicines. Of 604 major new drugs which have been made available since 1941, nearly two-thirds originated in this country with only a relative handful coming from other than private industrial research. New drugs have been a major factor in bringing about an astonishing reduction in morbidity and mortality.

The National Health Education Committee has estimated that the decline in mortality rates since 1937 has added almost nine billion dollars to the national economy each year. More than four million Americans living today would be dead if 1937 death rates had continued. The decline in the number of mental hospital patients in the last nine years has saved approximately $4 billion in institutional construction costs alone. More than half of the hospital beds used for care of tuberculosis patients in 1956 are now available for other purposes, and many tuberculosis facilities have been converted to other uses, for lack of TB patients. Equally important is the role drugs have played in the virtual elimination of poliomyelitis throughout the world.

Although drugs may not be solely responsible for these results, they unquestionably deserve a substantial degree of credit. One statistic alone dramatizes what has happened. Of the more than 775 million prescriptions written in 1964, it is estimated that 70 per cent could not have been filled in 1950, for the simple reason that the drugs prescribed were not then in existence.

This revolution is attributable to many factors. One is the enormous research program of the pharmaceutical industry. Since 1950 its annual research and development expenditure has increased eight-fold. In 1966 alone, it is estimated such expenditures will amount to about $350 million—bringing total industry research to well over $2 billion since 1950.

We appear today to offer our comments concerning the provisions of H.R. 13886, H.R. 14557, H.R. 14632, H.R. 15269 and H.R. 15301 as they relate to limitations on children's aspirin, safety closures on retail drug containers, and cautionary drug labeling. In order to simplify our statement, we have addressed our remarks to H.R. 13886 recognizing, of course, that the other bills have one or more like provisions.

1. LIMITATION ON QUANTITY OF CHILDREN'S ASPIRIN IN RETAIL PACKAGE

Section 2 of the bill would authorize the Secretary of the Department of Health, Education and Welfare to limit by regulation the quantity of aspirin or aspirin-containing products in a retail container if the product was prepared in a dosage form intended for children.

It is presumed from the testimony previously presented on this proposal that this section is intended to apply solely to "children's aspirin." As written, however, the section would embrace not only the specially formulated preparations we think of as "children's aspirin" but would also include all other aspirin-containing products and other forms of salicylic acid which carry children's dosage recommendations on their labels. Present Food and Drug Regulations require, incidentally, that all aspirin tablets include in their labeling dosage directions for children down to three years of age.

To our knowledge no particular problem of child abuse of these other products has been shown to exist, nor did President Johnson in his Consumer Message of March 21, 1966, request action with respect to these preparations. He asked Congress to "Limit the amount of children's aspirin available in retail packages." Commissioner Goddard in his statement before the House Interstate and Foreign Commerce Committee on June 24, 1966, clearly indicated that he considers the problem to be one centered on aspirin that is "colored and flavored to ease the parent's task to give the medicine to a feverish and fretful child."

In order to properly focus the bill, we recommend the following amendment in H.R. 13886: In line 11, page 2,

Strike the word "intended" and insert in place thereof "specifically formulated and labeled."

Further, this section in its present form would give the Secretary power to establish by regulation a limit on the aggregate quantity of "children's aspirin" in each container. As indicated by earlier testimony, scientific opinion is apparently available to establish the quantity of aspirin or salicylic acid which is likely to cause death or serious injury to children of tender age. Thus we believe the limitation, as established by scientific evidence, be written into the statute rather than left to the regulatory discretion of the Secretary of Health, Education, and Welfare.

2. SAFETY CLOSURE ON RETAIL DRUG CONTAINERS

Section 3 of the bill would authorize the Secretary of the Department of Health, Education, and Welfare to require, by regulation, that retail containers for any drug product designated by him be secured by a "safety closure."

Industry is in sympathy with the objectives of this proposal as evidenced by its continued attempts to develop, on its own initiative, closures which would effectively prevent accidental poisoning. However, the criteria of the bill are so broad that they cover every form of container and product, including bottles, tubes, jars, ampules, etc., whether they are for prescription or over-the-counter drugs. Also covered would be the containers which the retail pharmacist uses in dispensing drugs pursuant to a physician's order.

Without some indication of the types of "safety closures" envisioned for the various products and containers marketed, it is not possible to determine how this requirement would affect the pharmaceutical industry in terms of cost of goods and investment in manufacturing equipment. Nor is it possible to estimate how this provision would affect the ultimate cost and availability of products to the consumer. Under the wording of this section, industry could be faced with constant change of equipment and package requirements in order to conform to the opinion of FDA. This prospect is particularly troublesome since at the present time no one in industry or government has been able to devise a really effective or satisfactory closure.

As written, the bill would give the Secretary virtually unlimited authority to impose, by regulation, a safety closure requirement whenever he determines such is necessary without any corresponding determination that the drugs affected have been frequently involved in accidental poisonings.

Finally, and very frankly, we do not believe that our industry, with a high degree of expertise in this field, should be subjected to loose regulatory authority in the Food and Drug Administration, which is not particularly conversant with the subject.

Since there are no completely satisfactory answers available at this time to the "safety closure" question, we would recommend that Congress first require a joint government-industry study with results to be considered by this committee before broad legislation of this type is enacted.

3. DRUG LABELING REGULATION

Section 4(b) of the bill would amend Section 502(f) of the Food, Drug and Cosmetic Act to provide, among other things—

(*a*) That drug labeling be required to bear "adequate warnings" against a "substantial and reasonably foreseeable risk of causing accidental injury";

(*b*) That drug labeling be required to bear instructions for first-aid treatment "when necessary or appropriate"; and

(*c*) The vesting of authority in the Secretary of HEW to promulgate drug labeling regulations regarding specific drugs or classes of drugs (without opportunity for hearing) on "such other information relating to the foregoing matters and to side effects, contraindications, effectiveness and other matters" in order to carry out the purposes of the amendments. The regulations authorized could also include the designation of matters to be included in or omitted from labeling and could relate to specific drugs or classes of drugs.

The preamble to H.R. 13886 states the purpose of the proposed legislation to be "To protect children and others from accidental death or injury by amending * * * with respect to aspirin intended for children, safety closures, on drug containers and cautionary labeling of containers."

In our opinion the regulation promulgating authority regarding side effects, contraindications, effectiveness and other matters included in section 4(b) of the bill is not related to that stated purpose. This is an entirely separate issue with different implications and should be considered in connection with other pending bills. In any event, we oppose the drug labeling provision in Section 4(b) first, because of the extent of control, over all drugs, which this provision would give the Secretary in connection with every piece of printed matter that falls within the broad purview of the term "labeling." The provision is in effect a "blank check" to issue regulations prescribing the exact words that must be used in labeling, and the things that cannot be said, about accidental injury, first-aid. side effects, contraindications, effectiveness "and other matters." Authorization would be granted to prescribe the exact manner and form of statements in labeling on these subjects.

It would appear that this regulation-making authority is broad enough to authorize the Food and Drug Administration to issue a regulation for an entire *class* of drugs, stating precisely the words to use to describe a drug's effectiveness, side effects, contraindications, risk of accidental injury, and first-aid instructions. It would also authorize F.D.A. to say that no other language on any of these subjects could be included in any labeling. All the Secretary would need to do, as a basis for issuing such a regulation, would be to make the broad and vague finding that such a requirement is necessary for the safe and effective use of a drug or class of drugs.

There has been no need established for such a sweeping grant of regulatory authority. The phrase "other matters" could be interpreted to mean whatever the Food and Drug Administration wants it to mean. To make the proposal even more objectionable, affected manufacturers would not even be entitled to an administrative hearing on the merits of any regulations enacted. Even the *Federal Hazardous Substances Labeling Act* which deals with much narrower issues embraces the safeguards of Section 701(e) of the Federal Food, Drug and Cosmetic Act.

Complete information regarding effectiveness, contraindications and side effects is already required by the Food, Drug and Cosmetic Act in the labeling of all drugs. To grant F.D.A. the authority to unilaterally dictate what they are, may grant the power to that agency, at its whim, to require any and all well established drugs to be precleared at any time through the new drug provisions of the Act.

We oppose in its present form the requirement that drug labeling be required to bear adequate warnings against substantial and reasonably foreseeable risk of causing accidental injury as being too vague and uncertain. At the present time, drug manufacturers have a duty imposed by law to warn against known or reasonably foreseeable dangers of a product. The duty does not, in general, however, extend to unknown side effects where the manufacturer has exercised all reasonable efforts to determine the nature and effects of the product. Nor do the courts usually construe the duty to warn to extend to harmful effects to the idiosyncratic or allergenic individual. No cases have found a manufacturer liable for failure to warn of the dangers resulting from missuse.

It certainly could be argued that every untoward incident reported to a manufacturer (whether substantiated or not) is notification of a "reasonably foreseeable risk." Must label warning be included for each such report? Drugs by their very nature have certain propensities for causing untoward effects. A drug manufacturer may do the finest job known to science in the development of a drug, yet it is a fact that some person somewhere, sometime and at some dosage level will suffer some side effect from the drug. The "risk of causing accidental injury" is foreseeable, the type of injury may or may not be foreseeable. We recommend, therefore, that the provision be deleted or, in the alternative, that it be amended to read: "Against a known or reasonably foreseeable injury causing propensity of the drug in a substantial number of users when the drug is used according to the directions for use * * *."

Many of the statements just made apply equally to the requirement for "including instructions for first-aid treatment' even though that requirement is limited to situations "when necessary or appropriate." A new duty would be imposed by this language, a violation of which may constitute negligence *per se*, although the guidelines proposed in the bill are general in character and lack definite standards. There is no requirement that risks for a substantial number of people be involved. In addition, the possible number of permutations or combinations of first-aid instructions for either accidental misuse, or even proper use is vast, and at the very least this requirement would foster litigation.

The contention that has been made that the situation is analogous to the *Federal Hazardous Substances Labeling Act* is erroneous. Hazardous substances are confined to inflammable, corrosive, irritant or toxic chemicals and far more precise treatment, expurgative or antidotal in character, is usually available to avoid continuing injury from contact of the substance with body tissue. Drug side effects on the other hand, are not generally subject to first-aid treatment. Persons should be directed only to contact a physician immediately. Indeed, drugs were included within the Federal Hazardous Substances Labeling Bill when proposed but were deleted prior to passage of the Act.

A need has not been established to grant the authority to the Secretary of Health Education, and Welfare which is set forth in Section 4(b) of this bill. In our opinion, therefore, the provision should be deleted from this bill.

We are grateful for the opportunity to present our views to the Committee on the pending bills. If there are questions we will be happy to attempt to answer them.

Mr. STETLER. As I mentioned, I am accompanied today by Dr. Hart Van Riper and Mr. Rodney Munsey. I would just like to very briefly identify them for the committee.

Dr. Van Riper is a physician. He is a board certified pediatrician. He has had extensive experience in private practice and for many years was medical director of the National Foundation for Infantile Paralysis. He is presently the vice president for medical affairs of Geigy Pharmaceuticals.

Mr. Munsey is an attorney and is a member of the legal staff of the Pharmaceutical Manufacturers Association. He has been very active for many years in work involving the Food, Drug, and Cosmetic Act.

We appear here today to comment, as I said, concerning the provisions of several bills that are before the committee as they relate to limitations on children's aspirin, safety closures on retail drug containers, and cautionary drug labeling.

In order to simplify our statement I will address my remarks to H.R. 13886, recognizing that the other bills have one or more like provisions. First, with respect to the limitation on the quantity of children's aspirin in retail packages, section 2 of the bill would authorize the Secretary of the Department of Health, Education, and Welfare to limit by regulation the quantity of aspirin or aspirin-containing products in a retail container if the product is prepared in a dosage form intended for children.

It is presumed by us from the testimony previously presented on this proposal that this section is intended to apply solely to "children's aspirin." However, as written the section would embrace not only the specifically formulated preparations that we think of as "children's aspirin," but would also include all other aspirin-containing products and other forms of salicylic acid which carry children's dosage recommendations on their labels.

Incidentally, present food and drug regulations require that all aspirin tablets include in their labeling dosage instructions for children down to 3 years of age.

To our knowledge no particular problem of child abuse of these other products has been shown to exist, nor did the President in his consumer message of March 21 request action with respect to these preparations. In that message he asked Congress to "Limit the amount of children's aspirin available in retail packages."

We also noted that when Commissioner Goddard appeared before this committee on June 24 that in his testimony he clearly indicated that he considers the problem to be one centered on aspirins that are "colored and flavored."

Therefore, we would suggest with respect to section 2 of that an amendment is in order to more properly focus that section on children's aspirin. It could be done on line 11, page 2, by striking the word "intended" and inserting in lieu thereof the words "specifically formulated and labeled."

One other thing in this particular section that we would comment on, and that is the proposal to give the Secretary of HEW power to establish by regulation a limit on the aggregate quantity of "children's aspirin" in each container. As indicated in earlier testimony by FDA

scientific opinion is apparently available to establish the quantity of aspirin or salicylic acid which is likely to cause death or serious injury to children of tender age is accidentally ingested.

Thus, we believe the limitation, as established by scientific evidence, could and should be written into the statute rather than left to the regulatory discretion of the Secretary of HEW, who would turn the decision over, I am sure, to the Commissioner of Food and Drug.

Now, then, with respect to the safety closure provisions. Section 3 of the bill would authorize the Secretary of the Department of Health, Education, and Welfare to require by regulation that retail containers for any drug product designated by him be secured by a "safety closure."

I would like to say, and say emphatically, that industry is in sympathy with the objectives of this proposal as evidenced by its continued attempts to develop on its own initiative closures which would effectively prevent accidental poisoning.

However, the criteria of this section of the bill are so broad that they cover every form of container and product, including bottles, tubes, jars, ampoules, et cetera, whether they are for prescription or over-the-counter drug products.

Also covered would be the containers which the retail pharmacist uses in dispensing drugs pursuant to a doctor's order.

Without some indication of the types of "safety closures" that are envisioned for the various products and containers marketed, it is not possible to determine how this requirement would affect the pharmaceutical industry in terms of cost of goods and investment in manufacturing equipment.

Nor is it possible to estimate how this provision would affect the ultimate cost and availability of products to the consumer. Under the wording of this section, industry could be faced with constant change of equipment and package requirements in order to conform to the current opinion of the Food and Drug Administration.

This prospect is particularly troublesome since at the present time no one in industry or Government has been able to devise a generally acceptable or a really effective or satisfactory so-called safety closure.

As written, the bill would give the Secretary virtually unlimited authority to impose by regulation a safety closure requirement whenever he determines such is necessary without any corresponding determination that the drugs affected have been frequently involved in accidental poisonings.

Finally, and very frankly, we do not believe that our industry, which has a high degree of expertise in this field, should be subjected to loose regulatory authority in the Food and Drug Administration, which is not particularly conversant with the subject.

Since there are no completely satisfactory answers available at this time to the "safety closure" question, we would recommend that Congress first require a study, possibly a joint Government-industry study, which we would be happy to participate in, with the results to be considered by this committee before broad legislation of this type is enacted.

Our final comment would be with respect to section 4(b) of the bill dealing with the drug-labeling regulations. This section would amend section 502(f) of the Food, Drug, and Cosmetic Act to provide among other things, that drug labeling be required to bear "adequate

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warnings" against a "substantial and reasonably foreseeable risk of causing accidental injury"; second, that drug labeling be required to bear instructions for first aid treatment "when necessary or appropriate"; and third, the vesting of authority in the Secretary of HEW to promulgate drug-labeling regulations regarding specific drugs or classes of drugs (without an opportunity for hearing) on "such other information relating to the foregoing matters and to side effects, contraindications, effectiveness, and other matters" in order to carry out the purposes of the amendments. The regulations authorized could also include the designation of matters to be included in, or omitted from, labeling and could be related to specific drugs or classes of drugs.

The preamble to H.R. 13886 states the purpose of this proposed bill to be to protect children and others from accidental death or injury by amending the Federal Food, Drug, and Cosmetic Act with respect to aspirin intended for children, safety closures on drug containers, and cautionary labeling on containers.

In our opinion the regulation promulgating authority regarding side effects, contraindications, effectiveness and other matters included in section 4(b) of the bill is not related to that stated purpose.

This is an entirely separate issue with different implications and should be considered in connection with other bills now pending before this committee and which, incidentally, include an identical provision.

In any event, however, commenting on this specific provision at this time, we do oppose the drug labeling provision in section 4(b), first, because of the extent of control over all drugs which this provision would give the Secretary in connection with every piece of printed matter that falls within the broad purview of the term "labeling."

The provision is in effect a blank check to issue regulations prescribing the exact words that must be used in labeling, and the things that cannot be said, about accidental injury, first aid, side effects, contraindications, effectiveness, and other matters. Authorization would be granted to prescribe the exact manner and form of statements in labeling on these subjects.

It would appear that this regulationmaking authority is broad enough to authorize the Food and Drug Administration to issue a regulation for an entire class of drugs, stating precisely the words to be used to describe a drug's effectiveness, side effects, contraindications, risk of accidental injury, and first-aid instructions.

It would also authorize FDA to say that no other language on any of these subjects could be included in any labeling. All the Secretary would need to do as a basis for issuing such a regulation would be to make the broad and vague finding that such a requirement is necessary for the safe and effective use of a drug or class of drugs.

There has been no need established for such a sweeping grant of regulatory authority. The phrase "other matters" could be interpreted to mean whatever the Food and Drug Administration wants it to mean. To make the proposal even more objectionable, affected manufacturers would not even be entitled to an administrative hearing on the merits of any regulations enacted. Even the Federal Hazardous Substances Labeling Act which deals with much narrower issues embraces the safeguards of section 701(e) of the Food, Drug, and Cosmetic Act.

Complete information regarding effectiveness, contraindications, and side effects is already required by the Food, Drug, and Cosmetic Act in the labelings of all drugs. To grant FDA the authority to unilaterally dictate what that wording should be may grant the power to that agency at its whim to require any and all well-established drugs to be precleared at any time through the new drug provisions of the act.

We oppose in its present form the requirement that drug labeling be required to bear adequate warnings against "substantial and reasonably foreseeable risk of causing accidental injury" as being too vague and too uncertain.

At the present time drug manufacturers have a duty imposed by law to warn against known or reasonably foreseeable dangers of a product. The duty does not, in general, however, extend to unknown side effects where the manufacturer has exercised all reasonable efforts to determine the nature and effects of the product.

Nor do the courts usually construe this duty to warn to extend to harmful effects of an idiosyncratic or allergenic individual. No cases have found a manufacturer liable for failure to warn of dangers resulting from misuse of a drug.

It certainly could be argued that every untoward incident reported to a manufacturer (whether substantiated or not) is notification of a "reasonably foreseeable risk." Must label warnings be included for each such report? Drugs by their very nature have certain propensities for causing untoward effects.

A drug manufacturer may do the finest job known to science in the development of a drug. Yet it is a fact that some person somewhere, sometime and at some dosage level will suffer some side effect from the drug. The "risk of causing accidental injury" is foreseeable. The type of injury may or may not be foreseeable. We recommend, therefore, that the provision be deleted or, in the alternative, that it be amended to read: "Against a known or reasonably foreseeable, injury-causing propensity of the drug in a substantial number of users when the drug is used according to the directions for use."

Many of the statements made previously would apply equally to the proposed requirement for "including instructions for first-aid treatment" even though that requirement is limited to situations "when necessary or appropriate."

By this language a new duty would be imposed on the manufacturer, a violation of which may constitute negligence per se, even though the guidelines proposed in the bill are general in character and lack definite standards.

There is no requirement that risk for a substantial number of people be involved. In addition, the possible number of permutations or combinations of first-aid instructions for either accidental misuse, or even proper use, is vast, and at the very least this requirement would foster litigation.

The contention has been made that the situation is analogous to the Federal Hazardous Substances Labeling Act, and that in our opinion is erroneous. Hazardous substances are confined to flammable, corrosive, irritant, or toxic chemicals, and far more precise treatment, expurgative or antidotal in character, is usually available to avoid continuing injury from contact of the substance with body tissue.

Drug side effects, on the other hand, are not generally subject to nonprofessional first-aid treatment. Persons should be directed only to contact a physician immediately. Indeed, drugs were included within the Federal Hazardous Substances Labeling Act when proposed but they were deleted prior to the passage of the act.

Finally, and of obvious practical importance, is the fact that the proposed labeling, insofar as prescription drugs are concerned, would not come to the attention of the consumer and often would not come to the attention of the physician.

Therefore, in our opinion the need has not been established to grant the authority to the Secretary of HEW which is set forth in section 4(b) of the bill, and in our opinion it would not be effective for the purpose intended. We, therefore, would recommend that this provision be deleted.

Mr. Chairman, I say again we are grateful for the opportunity to appear before you and your subcommittee and between the three of us we will try to answer any questions.

Mr. ROGERS of Florida. Thank you very much, Mr. Stetler.

What would be your attitude on the proposed ban of candied-flavored aspirin—recognized baby aspirin, not so many in a bottle, but a ban on it being flavored?

Mr. STETLER. You mean as proposed by the last witness?

Mr. ROGERS of Florida. Mrs. Sullivan.

Mr. STETLER. I would like to speak on that briefly. Then I would like to ask Dr. Van Riper to comment. I think that in considering a proposal of this type the committee should take cognizance of the good which obviously comes from the use of baby aspirin. I think in this connection you would be interested in the attitudes of medical groups such as the American Academy of Pediatrics, the AMA, the Academy of General Practice, and the Food and Drug Administration itself, I think all of these are on record in favor of the continued use of baby aspirin.

Through the use of this product you insure the proper ingestion by children of aspirins. It alleviates a great deal of suffering and pain and is curative. I think that good value and the testimonials in favor of baby aspirin have to be weighed against the occasional bad effects and bad results.

I think also the committee would have to look very carefully at the statistics that have been quoted with respect to aspirins and determination whether they refer to aspirins, salicylic acid, and other types of products; what the deaths are actually caused from; and to get a very specific breakdown on just which of these products are the culprit.

I would like to have Dr. Van Riper comment on that.

Dr. VAN RIPER. Mr. Chairman, as a physician and a parent I would agree with the Congresswoman from Missouri that it is possible to crush an aspirin and give it to a child. At the same time it can be a serious struggle, I assure you.

Aspirin of itself is bitter and, irrespective of how you may mix it with jelly, or preserves, or what not, it is difficult to give to a well child let alone one who is feverish and irritable and difficult to handle.

I have recently been in communication with those of the Academy of Pediatrics and the Pediatrics Research Group who, as a committee, are in favor of the continuation of the availability of flavored aspirin for pediatric usage.

Mr. ROGERS of Florida. As I understand it, Mrs. Sullivan doesn't suggest that there not be dosages of baby aspirin; simply that they not be candy-flavored. That is what I understand is her proposal.

Mr. STETLER. I think our comments would relate themself to the flavored aspirin specifically.

Mr. ROGERS of Florida. Dr. Goddard, who testified at the last hearing, said:

> In 1965, for example, where the type of aspirin involved in accidental ingestion was reported, 90 percent of the cases involved children's aspirin.
>
> In other words, there were approximately 12,500 cases where a differentiation could be made in the dosage form ingested. Of these 12,000 cases where there was knowledge of the dosage form, 10,854 involved the children's aspirin.

I notice that you stated that there was no hearing required in the labeling provisions, I believe, of section 4(b). Do you presently have hearings in these situations?

Mr. STETLER. As a matter of fact, under section 2, 3, or 4(b) there is no provision for hearings, as provided in section 701(e) of the Food, Drug, and Cosmetic Act. At the present time there are opportunities for hearings under 701(e) for interested parties concerning many parts of the Food, Drug, and Cosmetic Act.

We think this is a very appropriate provision. We think it should apply. We should have that opportunity whenever anything as broad as this, in the way of regulatory authority, is proposed for a Federal agency, including FDA.

One instance I noticed in the FDA, June 24 testimony. The comment was made with respect to the proper quantity of children's aspirin in a container that a provision had not been made for a hearing under 701(e) because it was a scientific matter and that under the closure provision it was not provided for because it was a practical matter.

I suppose everything falls within a scientific or a practical category. If that argument is a good one it could apply I suppose to most anything under the Food, Drug, and Cosmetic Act.

Mr. ROGERS of Florida. Does this change the present law in relation to these hearings or similar matters?

Mr. STETLER. No, it would not specifically, but it provides FDA with a greatly expanded authority for labeling on all drugs without hearing. By virtue of this new provision, which would, I presume, supersede the present provisions of the Food and Drug Act, the FDA would be given greater authority without the necessity for providing a 701(e) hearing.

Mr. ROGERS of Florida. Under present authority you are entitled to a hearing under the labeling provisions?

Mr. STETLER. That is correct.

Mr. ROGERS of Florida. And under the Hazardous Substances Labeling Act as well?

Mr. STETLER. That is right, it is provided for in the Hazardous Substances Labeling Act by specific reference to 701(e).

Mr. ROGERS of Florida. Do you have any objection to putting instructions for first aid treatment on drugs where it would affect a substantial number of people, along with the directions that they go ahead and see a doctor, of course call a doctor immediately, but in the meantime until the doctor arrives give some first aid treatment? What would be your feeling on that?

Mr. STETLER. Let me say first of all that in our testimony today we are directing our comments to prescription drugs, to drugs that are provided in accordance with a doctor's order, a doctor's prescription.

The type of drugs we are talking about are not susceptible to having their labeling include antidotal or first-aid instructions. This information for prescription drugs depends on the age, the sex, the condition of the health of the individual. Thus the proposal wouldn't be proper even if you were trying to direct it to a substantial number of people.

Even if it was conceivably possible that you could put this kind of labeling on a prescription drug product, it would not come to the attention of the consumer.

You asked one very specific thing and that is, is there someplace for a warning even to the extent that in the event of misuse or overuse see your physician.

We think that would be about the only type of appropriate, cautionary provision that could be put on a prescription drug product.

Mr. ROGERS of Florida. What about those that are not prescription drugs, such as aspirin.

Mr. STETLER. I think at the present time, and I am not fully conversant with this, that there is a requirement by virtue of a previous food and drug policy provision that there be a cautionary warning statement regarding children, on all aspirin products.

Is that correct?

Mr. MUNSEY. Yes.

Mr. ROGERS of Florida. I am not saying warning. I am saying first-aid treatment, along with the requirement that you say a doctor should be called and advised immediately.

Why would it be bad to have a first-aid treatment set forth on the label there?

For instance, if you have a child and he takes too many aspirin, say, or some other drug that you buy over the counter and you can't get the doctor there for a while. Maybe you are in a place where you can't even get him to a hospital. I would think it would be helpful to the parent to have some idea of how to proceed to give first aid if it were to affect a substantial number of people.

I can understand you can't do it for every individual situation where there may be an allergy involved or something like this, but for an overdosage or for some reason like this. What about that?

Dr. VAN RIPER. Mr. Chairman, I think first of all it would probably be difficult to get an adequate statement on even the average package of, let us say, children's aspirin.

Let us also consider that it is not always the well child that consumes aspirin accidentally. It may be the sick child, and I would venture a guess that there are more children who die of aspiration pneumonia as a result of vomiting and of emesis than are actually killed by overdosages of children's aspirin. This is always a danger.

We have throughout the United States today poison control centers of which the public, I think, are becoming more and more aware so that every health office, every hospital in every community, has a list of drugs and can immediately advise the caller as to the treatment in event of overdosage or suspected overdosage.

Drugs are strange things and what one might give for the treatment of overdosage of a particular product might be contraindicated in another. I think sometimes a little knowledge is a dangerous thing.

Mr. ROGERS of Florida. I would agree to that and I understand that, but now on hazardous substances you put this, don't you?

Dr. VAN RIPER. Yes.

Mr. ROGERS of Florida. How can you do it on that when you couldn't do it on a drug?

Dr. VAN RIPER. Mr. Chairman, those are usually very much larger containers.

Mr. ROGERS of Florida. I don't think it takes that much printing, does it? As I have seen on some of them, they just say give warm water or milk or something to vomit, or something like this.

Dr. VAN RIPER. I don't think that warm milk——

Mr. ROGERS of Florida. I don't know what it is.

Dr. VAN RIPER. We are going to have to do something that produces nausea to make the child vomit.

Mr. ROGERS of Florida. Mustard water or milk, but the point I I am trying to make is that you put it on hazardous substances, don't you, and I don't think it takes up that much of the label, as I can recall.

We can inspect them, but, as I recall, it doesn't take up that much area.

Mr. STETLER. Mr. Chairman.

Mr.ROGERS of Florida. Yes.

Mr. STETLER. I don't think we would like to take a strenuous position on the illustration you gave. We have directed our comments on this really to prescription drugs, which present an entirely different situation.

I think that one of the future witnesses scheduled to testify represents the Proprietary Association and this type of product is exactly what they are concerned with. I think possibly they may be in a position to reflect their views on that more particularly or specifically than we are.

Mr. ROGERS of Florida. Thank you very much.

Any questions?

Mr. SATTERFIELD. No questions.

Mr. SPRINGER. Mr. Stetler, I would like to analyze this bill a little bit because everybody on this committee is not a lawyer.

Let us begin with title I on page 2. Do you have a copy of the bill?

Mr. STETLER. Yes, sir.

Mr. SPRINGER. Section 2, as I understand it, would be a limitation on the number of aspirin in a package. Is that substantially correct?

Mr. STETLER. Yes.

Mr. SPRINGER. Let us go now to section 3. This has to do with safety closures and the authority of the Administrator to fix the size of the closures that go on the bottle?

Mr. STETLER. That is right.

Mr. SPRINGER. Is that true?

Mr. STETLER. That is right.

Mr. SPRINGER. What does section 4 do? I want to take (n) first, 403(n) in section 4.

Mr. STETLER. That deals strictly with——

Mr. SPRINGER. Gaseous propellant.

Mr. STETLER. That is right. We haven't commented on that, incidentally.

Mr. SPRINGER. All right. Have you any objection to that?

Mr. STETLER. It doesn't affect us particularly. We haven't objected to it.

Mr. SPRINGER. Now, let us go on then to 502(f). This has to do with a labeling and this is rather complicated, but it says "Unless its labeling bears (1) adequate directions for use." Now "such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health." That is one.

Second, "against unsafe dosage or methods or duration of administration or application."

Third, "or against a substantial and reasonably foreseeable risk of causing accidental injury, in such manner or form, as are necessary for the protection of users, including instructions for first aid treatment."

Now, over on page 4 I would continue that as a fourth where it says "and (3) such other information relating to the foregoing matters and to side effects, contraindications, effectiveness, and other matters as may be required by or pursuant to regulations (applicable to the labeling of such drug) prescribed by the Secretary."

Now, that would be four instances as I count them where he would give what they call adequate directions. Is that true?

Mr. STETLER. Yes, sir; and if I may just comment on that for one moment. This section does provide for an amendment to section 502(f) of the act. It should be pointed out that some of the wording that is repeated is currently in the Food and Drug Act. This is not all new authority.

In other words, starting with lines 18, 19, 20, 21, and 22 up to where you start "or against a substantial and reasonably foreseeable risk of causing accidental injury," that language is currently in the Food and Drug Act.

Mr. SPRINGER. Beginning then with the words "or against unsafe dosage"?

Mr. STETLER. That is in the act already.

Mr. SPRINGER. All that then, down to the bottom of the page?

Mr. STETLER. What is that?

Mr. SPRINGER. Starting with the words "or against unsafe dosage" is what is in the act?

Mr. STETLER. No; starting with line 18. All of that is in the act. The new verbiage starts on line 22 with the words "or against a substantial and reasonably foreseeable risk of causing accidental injury."

There are then some more words that are in the act. All of the language under (3) on page 4 is new. Everything under (3) there is new, from line 1 down to line 14 beginning with the word "*Provided.*" Then it picks up the present section of the Food and Drug Act.

Mr. SPRINGER. All right. That is new.

Mr. STETLER. That is all new.

Mr. SPRINGER. Your only objection to this is that this is without hearing?

Mr. STETLER. That plus the fact that it would require a manufacturer to include in his labeling some information and material which we think is impossible or impractical. Even if language could be devised it would lay him open to product liability vulnerability, and extend the food and drug authority into an area where there is no need for it, no cause for it, would give that agency the authority to state with specificity what can and cannot be in labeling. At the

present time the manufacturer has some discretion in that regard and has some leeway to negotiate or confer with Food and Drug in this matter. To require labeling against "reasonably foreseeable risks" and the inclusion of antidotal or first aid information is not in our opinion necessary or appropriate.

Mr. SPRINGER. Let us go on to (c) then on line 20. Now, there is a new paragraph.

Mr. STETLER. I might say, sir, that we comment on nothing further in the bill. In other words, our comments really stop with line 19 on page 4. Anything else in the bill we have not directed any of our attention to and have no objection to these other provisions.

Mr. SPRINGER. All right. You say you have no objection from there on.

Mr. STETLER. That is right. Our comments relate strictly to the items ending on line 19, page 4 of the bill.

Mr. SPRINGER. All right.

Now, I would like to come if I may while I am on it to this beginning at line 22 and extending through line 19 on page 4.

Would you have any objection to this language as used if you had hearings?

Mr. STETLER. Yes, sir; we still would for the reasons that I mentioned. Even if a hearing were provided, I doubt that that would make it any easier for a manufacturer to anticipate or predict some untoward result that might come from the misuse of a prescription drug product and to be able adequately to identify that risk in a way which would be helpful or available to a consumer.

Also with respect to the first aid information, as we have said before, even with a hearing I doubt that we would be able to perfect language which would be adequate.

Mr. SPRINGER. I want to be sure the committee understands what you are talking about.

Beginning with line 22 on page 3 let us see if we can find out from a legal point what this means—"or against a substantial and reasonably foreseeable risk of causing accidental injury, in such manner and form, as are necessary for the protection of users, including instructions for first aid treatment when necessary or appropriate; and (3) such other information relating to * * * side effects, contraindications, effectiveness, and other matters as may be required by or pursuant to regulations."

Are you saying in essence that that language is so indefinite that you couldn't abide by the Secretary's regulations? That is in essence what you are saying. Is that correct?

Mr. STETLER. That is the main thing, yes, sir.

Mr. SPRINGER. I just want to be sure we understand what your objection is.

Mr. STETLER. Yes, that is the main point, and, secondarily, if he were to promulgate regulations, even though they are vague and difficult of compliance, merely by virtue of this provision being in the law our product liability vulnerability would be substantially increased.

Mr. SPRINGER. I want to pin this down even closer.

"Against a substantial." That is one.

Mr. STETLER. Right.

Mr. SPRINGER. Second, "and reasonably foresseable risk of causing accidental injury." Those are really the meat of what you are talking about there, isn't that right?

Mr. STETLER. That is right.

Mr. SPRINGER. Those two things, that it first would have to be substantial, and then the second, it would have to be a reasonably foreseeable risk on the part of the company? Is that correct?

Mr. STETLER. That is correct.

Mr. SPRINGER. I take it that that would be a question of judgment. I don't know how the administrator and you are going to get together on this, but he is talking about, first, that injury would have to be substantial, and the second, it would have to be reasonably foreseeable on your part.

Mr. STETLER. And, as we point out on page 9 of our testimony, this language at least lends itself to a very loose decision whereby any report to a manufacturer of an ontoward incident might be interpreted as notice of a reasonably foreseeable risk in the future, whether or not that reported incident was substantiated or not.

Mr. SPRINGER. What you are bothered by here, I take it, is the indefiniteness of this language?

Mr. STETLER. Right, vague and indefinite.

Mr. SPRINGER. Let us just see if we can contrast this.

What is the present law. Define it in a few words if you can, or your attorney can do it, simple enough so that this subcommittee can understand it.

Mr. MUNSEY. If you are referring, sir, to the wording "against reasonably foreseeable risk of causing accidental injury" and first aid there are no provisions directly related to accidental injury except those that are included as contraindications, side effects, and warnings.

It would depend on which class of drugs——

Mr. SPRINGER. I am not trying to find out what the Secretary or the Administrator say, but what is the law.

Mr. MUNSEY. In section 502(f) there is nothing in the current law on this subject. In prescription drug advertising the statute refers to contraindications, side effects, and warning.

Mr. SPRINGER. But there is no law on this subject presently. Am I right?

Mr. MUNSEY. Yes, sir.

Mr. SPRINGER. Whatever there is, is pursuant to regulation of the administrator, is that correct, or does he have any regulation on this?

Mr. MUNSEY. He has regulations on information regarding warnings, contraindications, and side effects, nothing in regulations covering generally warnings of this type.

Mr. ROGERS of Florida. Will the gentleman yield?

Mr. SPRINGER. Yes. I don't want to lose my thought though.

Mr. ROGERS of Florida. As I understood it, you made the statement that presently in the law there is wording something like "against a known or reasonably foreseeable injury causing propensity of the drug in a substantial number of users when the drug is used according to the directions for use."

Mr. STETLER. That is what we have suggested.

Mr. ROGERS of Florida. But that is not in present law?

Mr. STETLER. No, it is not.

Mr. ROGERS of Florida. This is what you suggest.

Mr. SPRINGER. Would you repeat that which you suggest?

Mr. STETLER. This is on the bottom of page 9. It begins with the last line on page 9.

Mr. SPRINGER. What is the suggestion of what I am talking about here? What is your suggestion?

Mr. STETLER. It is that the provision be deleted or, in the alternative, that it be amended to read: "against a known or reasonably foreseeable injury causing propensity of the drug in a substantial number of users when the drug is used according to the directions for use."

Mr. SPRINGER. Let me ask you this.

Suppose on page 3, line 24, we were to add the words "based on actual experience records." Would you still object?

Mr. STETLER. Actual experience records could be a single case, I presume.

Mr. SPRINGER. "Records" isn't one.

Mr. STETLER. Well, depending on how that is interpreted. I think we would be much safer and I really think it would be more appropriate if it related itself to a situation where there was a substantial number of cases documented and where it is not an overt or an obvious misuse of the drug.

Mr. SPRINGER. Let me ask you this.

You are using language here and I want to see if we can pin it down so that the committee can get an idea. You use the words "against a known or reasonably foreseeable injury causing propensity of the drug in a substantial number of users when the drug is used according to the directions for use."

Let us ask this. We had 125 young children, under 5, die last year. Is that substantial?

Mr. STETLER. Of course that statistic relates to aspirin, but just using the same statistic, I suppose it would be substantial depending upon the extent of the usage of the drug product that we are concerning ourself with.

Mr. SPRINGER. Suppose that it was used—I don't know—say 5 million times. Is that a substantial number?

Mr. STETLER. It could be interpreted to be substantial, yes.

Mr. SPRINGER. It seems to me that 125 deaths would be substantial, but I am just thinking as a judge, which I was once. I would be inclined to believe that 125 was a substantial number of deaths regardless of what drug you used. If you had 125 people die it would be substantial. Anyway, I think I got what you are talking about.

Now, if I may just run very rapidly through the rest, the exemptions provided from lines 14 through 19 are in the present law; is that right?

Mr. STETLER. This is on page 3.

Mr. SPRINGER. Page 4, line 14 through 19.

Mr. STETLER. That is correct.

Mr. SPRINGER. That is correct; so there is no change in that?

Mr. STETLER. No; that is starting with "provided" on line 14.

Mr. SPRINGER. Let me ask you this. I know you are thinking in terms here of his power to suspend immediately any drug that he so saw fit to do. This is one of your problems that bothers you, isn't it?

Mr. STETLER. Yes, sir.

Mr. SPRINGER. And without a hearing. I don't know whether this is comparable or not, but we had thalidomide here a few years ago and I guess that had not already been marketed in this country. It had been marketed in a good many other countries, but had not been

marketed in this country. Suppose it had been marketed. Are you objecting to taking it off the market without a hearing?

Mr. STETLER. No; he has the authority under present law in that situation.

Mr. SPRINGER. In that situation already to take it off?

Mr. STETLER. That is right.

Mr. SPRINGER. You are talking about these instances where you have an accepted drug, an accepted drug, and removing it without a hearing.

Is that your point?

Mr. STETLER. That is right, because of deficiencies in labeling which would now be required by this verbiage.

Mr. SPRINGER. Let me ask you this, and this has always bothered this committee.

Any time you get anybody off in a hearing we think due process operates someplace. We have to make up our minds when does due process begin and when we deal with these drugs this is a touchy matter on what is your right.

Suppose that we had a provision here that you must suspend for 30 days, but at the end of the 30th day he must grant you a hearing within 5 days.

Mr. STETLER. That we must do what?

Mr. SPRINGER. I am trying to get something here where due process begins. You are objecting to suspension. I am talking about suspension, giving an order to suspend, and that is what you think he can do under this section 502(f). Right? You think he can suspend immediately, don't you, without hearing?

Mr. STETLER. He can effectively stop us from marketing our product under this provision.

Mr. SPRINGER. Suppose we had language at that point that he could suspend for 30 days, but that he must give you a hearing within 5 days thereafter?

Mr. STETLER. No, sir; I don't think that would take care of the problem. Having once been suspended, the damage may have been done and such a procedure would not really be adequate in our opinion.

Mr. SPRINGER. Well, I am trying to get something here, and if you have a dangerous situation and he sees it, that you can keep on marketing this——

Mr. STETLER. If there is really a dangerous situation, in other words, if there is a product on the market which is really causing death or harm he has the authority at the present time to proceed against that product and to effectively take it off the market.

We are really talking about here——

Mr. SPRINGER. The labeling.

Mr. STETLER. The labeling; that is right, a much less serious situation.

Mr. SPRINGER. Can you in the next few days see if you can think of something here whereby justice can be done and yet we can protect the public interest if you feel that your rights are being infringed substantially, that we can come up with some language which preserves due process?

We have very great hesitancy in this committee about cutting off anybody from due process and you feel in this instance they are cutting off due process because immediately you are being suspended

without a hearing and nothing further is said except what the bureaucrat concludes ought to be done at this very moment.

I would suggest, if possible, you come up with some kind of language here by which he does have some authority in this labeling field, but he doesn't cut off your due process, and you are saying here he ought not to have it at all. He has to have a policy.

Think about that for a few days and see if you can come up with language or a suggestion or amendment whereby both of these shall be met?

Mr. STETLER. We will be glad to do that.

(The information requested, when supplied, will be found in the committee files.)

Mr. SPRINGER. Thank you, Mr. Chairman.

Mr. ROGERS of Florida. Mr. Mackay.

Mr. MACKAY. Thank you, Mr. Chairman.

I would like to point to page 4 of your testimony where you say:

> As indicated by earlier testimony, scientific opinion is apparently available to establish the quantity of aspirin or salicylic acid which is likely to cause death or serious injury to children of tender age. Thus we believe the limitation, as established by scientific evidence, should be written into the statute rather than left to the regulatory discretion of the Secretary of Health, Education, and Welfare.

Do you have a recommendation?

Mr. STETLER. As to the exact number?

Mr. MACKAY. Statutory language.

Mr. STETLER. No, sir; we do not. There is some difference of opinion obviously and I am sure it will be expressed before this committee the next few days in these hearings, but I think in the final analysis when you listen to that scientific evidence and opinion it will relate itself to a specific number.

We at PMA are not recommending a specific number. When we referred to previous testimony, frankly we were referring to the testimony of Dr. Palmisano when he appeared with Dr. Goddard when they talked rather specifically about numbers. I think others will be very specific on that too, but we would like to see it in the statute because if it is susceptible to determination, and finalized in the statute, we are not subjected to changes in the regulations from day to day.

Mr. MACKAY. If it can be determined I would certainly like to see it in the statute, but we need some help. You have a lot of professional competence in your association and I think it is reasonable to ask you to give us something.

Mr. STETLER. I might only say that we have not commented specifically on this because we know there is going to be substantial testimony on this point from other witnesses that will follow.

Mr. MACKAY. With reference to the safety closure on retail drug containers, we have just had some extensive hearings concerning automobile safety and methods of arriving at standards. Certainly we want to achieve the maximum measure of safety in these closures that we can get.

Can you see any procedures that might be defined by statute which would serve the purpose of achieving such safety standards and at the same time protecting your industry from what you suggested might be a frivolous application of the law by the Administrator?

Mr. STETLER. Very frankly, if we saw a development where there was a safety closure which would be effective to do what we know is intended by this section of the bill we would have no objection to that authority being given to Food and Drug Administration. However, for the last 5 to 10 years there have been some very intensive efforts by packaging institutes, packaging associations, by the PMA Production and Engineering Section, by our companies jointly and individually, and a really effective device in our opinion is not available.

We would like to see therefore some more study on this in a joint effort before authority is given to Food and Drug to have them designate something which in their opinion is an adequate safety closure but probably would not be, at least at the current stage of development.

Mr. MACKAY. Having raised two children of my own, I don't believe anybody has the ingenuity to provide a package that can't be cracked open by a determined child.

Mr. STETLER. We are willing to admit some failure on that score.

Mr. MACKAY. With reference to No. 3, drug labeling regulation, here again I would think it would be the duty of Congress to protect you from unreasonable and arbitrary requirements. On the other hand, you certainly can't write into a statute a great deal of the detail, but you can set up procedures.

I take it that you really just don't favor any legislation in this area beyond what is on the books now. Isn't that right?

Mr. STETLER. Actually, there is rather broad authority on the books right now. To our knowledge there hasn't been any problem or any identifiable inadequacy because of insufficient regulatory authority at the moment. Certainly the authority of the Food and Drug Administration is broad in this area. We don't think it needs to be broadened, and certainly not in the specifics that are referred to in section 4(b) of this bill.

Mr. MACKAY. Can you tell me whether the Food, Drug, and Cosmetic Act provides for a Council to be appointed by the Administration?

Mr. STETLER. Sorry, sir.

Mr. MACKAY. Whether the present procedure calls for an Advisory Council?

Mr. STETLER. Are there provisions in the Food and Drug Act for Advisory Council?

Mr. MACKAY. Yes.

Mr. STETLER. There is an overall Advisory Council that is provided for and has been appointed. To my knowledge that group has met three times. I don't think it has gotten down to specific issues of this type. Food and Drug in addition has called in scientific advisers where they have a specific problem with respect to a certain drug or classification of drugs, but to my knowledge there has been no Advisory Council authorized or employed in this kind of an area.

Mr. MACKAY. Wouldn't you think the appointment or addition of such Council would greatly strengthen this bill and protect your industry?

Mr. STETLER. I think frankly as far as 4(b) is concerned there are basic defects which would not be taken care of either by an Advisory Council or by a hearing procedure.

Mr. MACKAY. In the Traffic Safety Act, Mr. Rogers of Florida set up a fine Advisory Council representative of various industries that are interested, and the public similarly. The law requires the Secretary before fixing any standards to meet with this Council and really use that Council as a sounding board.

Mr. STETLER. I should say I don't want my remarks interpreted as being against advisory councils. As a matter of fact, we have approached Food and Drug on various occasions with specifics where we thought this would be quite proper. I only mention with respect to 4(b) that there are some pretty basic defects that I think would be hard to cure in that manner, but I am not opposed to the theory or the idea of an Advisory Council.

Mr. MACKAY. You have suggested one amendment to the bill there on page 4.

Mr. STETLER. Yes, sir.

Mr. MACKAY. You have suggested that if we limit by statute the quantity of aspirin that would strengthen the bill.

Mr. STETLER. With respect to that section 2 on limitations on children's aspirin, we have suggested two things, one, that the language be focused strictly on children's aspirin, that is, the flavored aspirin, and not apply to all aspirin or aspirin-containing products; secondarily, that the quantity limitations be specified in the statute.

Mr. MACKAY. Is it the assumption that if you didn't put a limitation on the large and family size a child wouldn't get very far into that because it tasted so badly?

Mr. STETLER. Actually looking at the identified problem it apparently is the children's aspirin, so there is no need to put package limitations on a lot of other products. Also, if you get to the 5-grain aspirin tablets you would soon have such a small number of tablets in each package that you would increase the cost and limit the availability of these products to the general consuming public.

Mr. MACKAY. Finally, your feeling about the safety closures and the labeling is that this is just not good legislation, isn't that right?

Mr. STETLER. Certainly not appropriate on the safety closures at this time; too broad as far as 4(b) is concerned; yes, sir.

Mr. MACKAY. Thank you very much.

No further questions, Mr. Chairman.

Mr. ROGERS of Florida. Dr. Carter?

Mr. CARTER. I have been extremely interested in this bill since I have seen many, many cases of poisoning from drugs. Certainly I favor legislation that will be fair to industry and also will protect the people.

Safety closures, as you say, have not been developed at the present time. You have none which would be effective. About how many children's aspirin do you think you would want to market in a container or would you feel you would be willing to market according to the law which may be passed?

Mr. STETLER. As I say, we are not making a specific recommendation. I gather that some of the testimony presented will indicate a figure between 25 and 35 and there is a slight variance of opinion as to what is a dangerous dosage as far as a child is concerned that consumes a whole package. I think the recommended quantity by the people who actually are producing this product will be something like 30 or 35 with the realization that it could go down to 25 and still be sensible.

Mr. CARTER. And these are tablets containing 1¼ grains, isn't that true?

Mr. STETLER. That is correct.

Mr. CARTER. Many, many times these children get drugs which have been prescribed for their parents. Do you think the present bill would require labeling of such drugs prescribed for older people or with precautions on what to do in case the child ingests such pills?

Mr. STETLER. Actually the 4(b) labeling provision would apply to all drugs, not just aspirin or children's aspirin, and it would require first aid instructions and identification of possibly foreseeable risks, a rather vague and indefinite area and one in which, as far as prescription drugs are concerned, it is very difficult to indicate on the package what should be done except to refer the patient to a doctor.

Also the other point is that with respect to prescription drugs—that is what you are talking about—this labeling would probably not be in the hands of the family because the patient would have the container that is used by the pharmacist to provide the prescription product.

Mr. CARTER. Yes, sir.

Mr. STETLER. So it would be lost in the distribution system.

Mr. CARTER. And you think that perhaps medication by the parents in many cases might cause great difficulty, for instance, if they tried to purge their child or if they tried to cause him to vomit by giving him mustard water or such things as that.

Mr. STETLER. We think this has to be decided by the doctor in each case.

Mr. CARTER. One alarming thing that I have noticed about children is that so many times they eat or drink almost anything that is available. The commonest thing in my area, which happens to be back in the rural area, in the country, is ingestion of kerosene or almost any available solvent. They are not particular about what they take. That constitutes a great problem.

We see aspirin ingested commonly, too.

Thank you very kindly.

Mr. STETLER. Thank you.

Mr. ROGERS of Florida. Mr. Stetler, would you furnish for the record, if you can, what the medically recognized first aid treatment would be for an excessive dose of aspirin taken by a child. If there are different ones depending on age or other factors you may supply that, too.

Mr. STETLER. Yes sir; we will supply such language.

(The information referred to, when supplied, will be found in the committee files.)

Mr. ROGERS of Florida. Let me ask you one last question.

Hasn't the industry pretty much decided, on a voluntary basis, the number of aspirins in a baby bottle of aspirin?

Mr. STETLER. I believe at the present time this is packaged in a box of 50, and this was based on a discussion or decision of several years ago, by doctors, industry, and Government.

Apparently the thinking on that has changed somewhat.

Mr. ROGERS of Florida. Thank you very much. The committee appreciates the benefit of your testimony.

Mr. STETLER. Thank you, sir.

Mr. ROGERS of Florida. Our next witness is Mr. Richard Fisher, Director of Public Affairs of the Glass Container Manufacturers Institute.

Mr. Fisher, the committee will be pleased to have your testimony.

STATEMENT OF RICHARD E. FISHER, DIRECTOR OF PUBLIC AFFAIRS, GLASS CONTAINER MANUFACTURERS INSTITUTE; ACCOMPANIED BY RICHARD C. PILSBURY, VICE PRESIDENT, GLASS CONTAINER DIVISION, MANAGER, MARKETING PLANNING, OWENS-ILLINOIS GLASS CO.; ALBERT S. JOHNSON, JR., SALES MANAGER, PLASTICS, GLASS CONTAINER DIVISION, OWENS-ILLINOIS GLASS CO.; AND GERALD B. RILEY, GENERAL COUNSEL, GLASS CONTAINER MANUFACTURERS INSTITUTE

Mr. FISHER. Thank you, Mr. Chairman.

I would like to introduce myself. My name is Richard E. Fisher. I am director of public affairs for the Glass Container Manufacturers Institute, Inc., of New York City, N.Y.

I would like to also, if I may, sir, introduce my associates who are with me at the table: Mr. Richard C. Pilsbury right here, vice president of the glass container division, manager of marketing planning of Owens-Illinois, Toledo, Ohio, and on my left is Mr. Albert S. Johnson, Jr., sales manager, plastics, glass container division, also of Owens-Illinois. Further, sir, I would like to introduce legal counsel who is Mr. Gerald B. Riley. He is a partner of Fuller, Seney, Henry & Hodge, general counsel for GCMI or Glass Container Manufacturers Institute, from Toledo, Ohio, also.

Mr. ROGERS of Florida. Fine. Thank you very much.

Mr. FISHER. Thank you, sir.

Mr. Chairman, as spokesman for the Glass Container Manufacturers Institute may I first express our appreciation to you and the members of your subcommittee for this opportunity to share with you our interest in and concern about that part of H.R. 13886 which will vitally affect both the consuming public and the members of our institute.

Our presence here today is prompted by the fact that collectively our members manufacture more than 90 percent of the glass containers and most of the closures which are used in packaging aspirin and other drugs covered by the bill.

Our comments will be limited to that portion of H.R. 13886 which relates to safety closures, and specifically to those amendments which would permit the Secretary to hold a drug or device adulterated if he has by regulation"required the retail container to be secured by a safety closure, unless such container is so secured in conformity with such regulation."

By passing on to this subcommittee knowledge accumulated over a period of many years relating to the manufacture of safety closures we hope to point out the importance of the contemplated legislations being written in a liberal and workable manner.

The safety of children is everybody's business, but nowhere has it been given greater priority than in our industry. One of the largest markets for our products is found in the packaging of baby foods, where the union of the closure with the container in such a manner

as to prevent contamination or deterioration of the product is a vital consideration.

Since the turn of the century we have been manufacturing containers and closures for the packaging of drugs and have been concerned with the problem of developing proper safety closures. Our efforts in this field have been accelerated since the middle 1950's.

In 1955, through the combined efforts of the Food and Drug Administration, the American Medical Association, the American Academy of Pediatrics, members of the proprietary drug industry, and others, certain guidelines were established for the protection of the American public, and especially children, against incidents of illness and death due to the consumption of overdoses of aspirin and other drugs.

From surveys conducted it was determined that the prime problem was the education of the American people as to the need for safety in the handling of the drugs. While the child's ability to remove the closure of a package would appear from the records to have contributed to only a small portion of these unfortunate incidents, we have worked diligently to perfect better safety closures.

Every new safety concept developed by or presented to our members has been thoroughly evaluated and tested. Public surveys have been carried out by individual members of our institute. We bring to this subcommittee a record of which we feel we can be justly proud.

We have attached to our statement, marked as "Exhibit A," (p. 114) a pictorial representation of some of the safety closures considered and developed since the early 1920's. From the packages shown in that picture a number have been selected which we have with us for the purpose of illustrating some of the problems which must be considered in determining whether the safety closure involved meets the many requirements of the consuming public.

A great variety of excellent safety closures have been developed. Some of these are included in the samples which we have brought with us. However, we have intentionally included a number on which extensive work was done but which were not put into commercial use because of their failure to meet, in one respect or another, the various requirements of an effective safety closure.

Our purpose in discussing these is to provide the subcommittee with concrete illustrations of the many, complex problems which are involved in developing an effective safety closure. Notwithstanding our emphasis upon these problems, we wish to assure you that adequate safety closures have been developed and are on the market today.

Each closure before you here has a built-in safety feature of sufficient merit to warrant evaluation, yet no one closure provides a complete answer for all drug products nor for all segments of the consuming public under all possible conditions.

Therefore, to meet the varying requirements of different products and of different classes of consumers, a variety of safety closures, made of a variety of materials and incorporating different safety features, has been developed.

Mr. Chairman, at this time we should be very happy to make these exhibits available to you and the members of the committee if you should so desire to look at them as I proceed to describe each of them.

Mr. ROGERS of Florida. That will be all right.

Mr. FISHER. Thank you.

Exhibit 1 is a closure with a combination lock concept. The construction of the closure and the container finish require that unique-shaped wires be affixed in a multiple manner on the internal part of the closure. The finish of a container is that portion of the container including the opening and other projections to which the closure attaches. Should these locking wires be moved or disturbed or damaged when the closure is off, the closure cannot be properly reapplied and thus the safety feature is lost.

Exhibit 2 has an intricate closure which would defy the attempt of a small child to remove it. An adult of limited intelligence and dexterity might have equal difficulty in orienting the multiple parts in the manner necessary to remove and reapply the cap. The ability of this type of closure to seal the package in such a manner as to prevent contamination and deterioration of the quality of the medication must be given careful consideration.

Exhibit 3 again involves multiple parts. In any such closure the possibility of malfunction of any component part after repeated removal and reseal must be thoughtfully appraised.

Mr. JOHNSON. Mr. Chairman, this particular closure does have a malfunction. Unfortunately, I cannot remove it to demonstrate it to the committee. I am sorry.

Mr. FISHER. Exhibit 4 has a two-piece assembly with an outer shell spinning freely over the inner threaded part until a plastic locking key is fitted into the appropriate position. Manufacturing and handling problems in the packaging must be carefully checked. The problem for the consumer lies in the possibility of his losing or not having the locking key available when the need for the medication is urgent.

Exhibit 5 would appear to be very functional and adequate. It is composed of two parts: a continuous thread or screw-on cap and a detached safety ring containing grooves into which notches on the cap must be seated. A young child would have difficulty in removing the closure, yet if an impatient parent should discard the safety ring, which can be easily done, the safety feature is lose and the closure becomes a conventional cap with no safety feature whatsoever.

Exhibit 6 represents a continuous thread safety closure utilizing the advantages available in flexible materials by incorporating a spring action between the two-piece construction so that top pressure must be applied to lock the parts together before removal or reapplication of the closure.

The closure on exhibit 7 is removed by pressing it downward and then turning it to disengage the lug on the closure from the locking bead. The cap construction and corresponding container finish lend themselves well to a plastic vial-type package.

Exhibit 8 also requires downward pressure and has a similar locking feature coupled with a screw type thread.

Exhibits 9, 10, and 11 were market tested and used in the early 1950's. All were found acceptable by the public.

Mr. PILSBURY. Exhibit 9 has a revolving rim or shell which must be pulled up to engage the upper cap and then it can be removed. Exhibit 10 has a similar outer shell which must be pushed down to engage it and then backed off. And exhibit 11 is a plastic snap cap which can be thumbed off when the thumb is pushed up between an interrupted bead just underneath the top of the container and snapped back on. It could only be removed if the thumb is in the right position.

Mr. FISHER. And a consumer preference was shown very definitely for that one, exhibit 11.

Exhibit No. 12 features a plastic continuous thread closure with a built-in lug which must be fitted into flat areas in the locking bead before removal or reseal.

Exhibits 13 and 18 are improvements of the basic concept of exhibit 11. As improved, the cap must be oriented to the flat in the glass bead before thumb pressure is applied. The top of the closure is contoured to minimize the possibility of removal by a child with his teeth.

Mr. PILSBURY. The same thing here, a small tab which must be oriented to the flat side of the container and then it can be thumbed up and off.

Mr. FISHER. Exhibit No. 14 is a one-piece continuous thread closure with a locking tab and corresponding cam action glass bead stop. To remove, the locking tab is lifted with the thumb over the glass bead stop while at the same time turning the closure counterclockwise.

Exhibits 15 and 17 are opened by placing the top of the closure down in the palm of the hand, applying pressure and turning the container simultaneously. Problems in the areas of manufacturing, packaging, and product protection must be given special attention.

Exhibit 16 has a safety dispenser which permits the removal of only one tablet at a time. Some children, intrigued by the mechanical functioning of the closure, conceivably might treat it as a toy and dispense one tablet after another.

Exhibit 19, which is the last one we have, requires the application of pressure to the center of the closure, which causes the sides to flare open and permit its removal. You heard it snap. To reapply, pressure must be exerted around the edge of the top of the closure.

Mr. Chairman, if the subcommittee members would like to examine any of these here in this hearing we would be very pleased to submit them.

Mr. ROGERS of Florida. The demonstration is sufficient.

Mr. FISHER. Thank you.

The subcommittee has probably noted that many of the closures considered have a continuous thread of screw-type feature as one of its component parts. Applied tightly, only an adult can remove it.

A reverse thread on a screwcap has been tested. It was found that a child of tender years does not realize that the normal way to remove a closure is to turn it counterclockwise, and the very closure which might provide difficulty for the adult is easily removed by the child.

We have told only a small part of the story of the development of safety closures from the 1920's to the present. The purpose of this limited discussion was to illustrate the many problems which arise and the many tests which must be applied to determine whether a closure will, in the hands of the public, achieve the desired results.

When the tests have proven the product to be adequate it has been marketed. When the closure has not met the standards it has been shelved. There are excellent safety closures available on the market today which meet the varying needs of the consumer.

Up to this point we have either completely ignored or touched with a light brush the manufacturing problems involved in the making of the closure and the container and the problems of the packer of the drugs on his filling line. These problems cannot be ignored.

A closure safe in the hands of the adult and the child must still be capable of being handled in commercially available automatic equipment. It must be adaptable to quality control testing procedures. It must lend itself to good manufacturing practices to insure proper standards of cleanliness and sterility. Its design must be compatible with packaging problems, and its specifications and tolerances must conform to the container finish to insure product protection and safety function.

In short, it must be possible for our industry to manufacture the closure and container, and for the packaging industry to use our product on its assembly and filling lines.

The conclusions drawn from this history of research, development, testing, and improvement of safety closures are these: No one safety closure has been perfected which is suitable for all products and which will be absolutely foolproof in the hands of the different segments of the consuming public.

A number of different closures are needed to meet their varying requirements. That closure which is satisfactory for the arthritic grandparent caring for the 2-year-old child might leave something to be desired for the protection of an inquisitive, energetic 5-year-old.

A closure with a two-part safety feature effective in the hands of parents with average or high intelligence might be left on the shelf by other parents, the safety lock and seal unused—a safety closure lying beside an open bottle. The benefits of the closure safe in design which does not lend itself to the requirements of manufacturing or packaging will never reach the consuming public.

During our materials and methods research and engineering development over a period of years certain guidelines have become clearly evident and must continue to be applied as tests of an effective safety closure.

We wish to share this information with you. Time and space prevent a full-blown discussion of these guidelines, and no attempt has been made to list them in the order of their importance. Those guidelines may be summarized as follows:

1. Consumer educational program: The closure construction concept must be such that all consumers can be educated to accept and know how to use and reuse the safety feature.

2. Closure construction should not require unusual strength or dexterity, either to remove or reapply the closure.

3. Closures should be easily replaceable in such a manner as to reestablish the original safety feature.

4. Product protection: Closures should seal properly to retain the strength and purity in the container. They should effectively prevent contamination and loss of potency of the medication. The requirements of the various types of medicines necessitate differing closure qualities. For example, the sealing requirements for a dry product, such as a tablet, differ from those for a liquid type medicine.

5. The safety feature should not, in and of itself, appear to be a toy that would stimulate an enthusiastic youngster's interest.

6. Consumer economic interest: The cost of medicines and drugs to the marginal income group is of great concern to this Congress and to our industry. We need a safe closure at a nonprohibitive cost.

7. The closures should not be so involved in design that consumers would be encouraged to discard the closures or their safety component at the time of the original removal.

8. The closures should be capable of being handled in commercially available automatic equipment.

9. The closures must be adaptable to quality control testing procedures.

10. The closures should be adaptable to normal cleaning and maintenance in accordance with good manufacturing practices to insure proper standards of cleanliness and sterility to avoid contamination.

11. The closures should be designed to permit the utilization of sometimes necessary packing such as cotton inserts.

12. Multiple components to the safety feature should be avoided if at all possible. Closures should be of a design simple enough to permit positive, uniform assembly for 100 percent safety function. The components required for proper function must be within commercial manufacturing tolerances. In other words, the complexity of the device must be consistent with possible packaging, manufacturing, and assembly standards to insure 100 percent function in the hands of the consumer.

13. Design of the closures and containers should be such as to avoid any possibility of fracture of either component during assembly or capping operations.

14. The closures must be made of a material that can be handled with known converting equipment.

15. The closures must be of a design which lends itself to known mold or tooling designs which will allow for release from those molds or toolings in the converting operation.

16. The safety closures must be manufactured of a material that will retain original dimensional stability after conversion.

17. Closure specifications and tolerances must be compatible with the specifications and tolerances of the container finish to insure both product protection and safety function.

18. To insure proper use by the adult the closure must have convenience appeal to the adult designed into the construction concept. It must be used as intended to be effective.

Commissioner Goddard and his counsel Mr. Goodrich, during their appearance before this subcommittee on June 24, 1966, expressed the opinion that no hearings would be required in connection with the issuance of regulations under the proposed legislation.

It was their view that the issue of whether a practical safety closure is available is simply "a practical matter that involves inspection and tests which have never really been subject to hearing procedures and which have been under the history of the Administrative Procedure Act thus exempt from hearings."

We would agree that the selection of a proper safety closure is a practical matter; we have learned from experience that it does not follow that it is a simple matter—to the contrary, it is a complex one. We believe that Commissioner Goddard, after due reflection, would join with us in our thinking.

The foregoing guidelines do not tell the complete story of all that must be considered in passing upon the acceptability of safety closures, nor do they contemplate the additional requirements which may present themselves in the future.

We believe the members of this subcommittee will well understand our objections to H.R. 13886 as presently drafted. Implied in the provisions of that bill is the right of the Secretary to define a safety closure and to determine which closure or closures will be used for a particular drug.

As interpreted by Commissioner Goddard and his counsel, Mr. Goodrich, no hearings would be required under the bill as proposed, and rules and regulations would be promulgated accepting or rejecting safety closures now on the market or developed in the future under the provisions of the Administrative Procedure Act.

Interested persons would be given a limited opportunity to object to the rules as announced. Public hearings and the right to present evidence would not be required if in the opinion of the Secretary they were not warranted. Judicial appeal from the regulations would be available only on very limited grounds.

Both the general public and the members of our institute have a great stake in the decisions which might be made relating to safety closures. We earnestly recommend that if the powers contemplated are delegated to the Commissioner, to Dr. Goddard, relevant sections of the Food, Drug, and Cosmetic Act, subsections (e), (f), and (g) of section 701, be written into the bill, thus insuring any interested or affected party the right to make timely objections, to participate in public hearings, to offer evidence, and, if deemed necessary, to test the final order by judicial process.

We trust you will not infer from the foregoing that we agree that the provisions of the proposed act pertaining to safety closures are necessary or proper in any legislation to be enacted at this time.

To the contrary, it is our deep conviction that such action is at the least premature. We recommend that that portion of the bill be deferred until this subcommittee or its agents, working in partnership with the industries involved, have had an opportunity to make a full study of the problem. We pledge our full cooperation to this subcommittee. Our knowledge and the personnel of our members are entirely at your disposal.

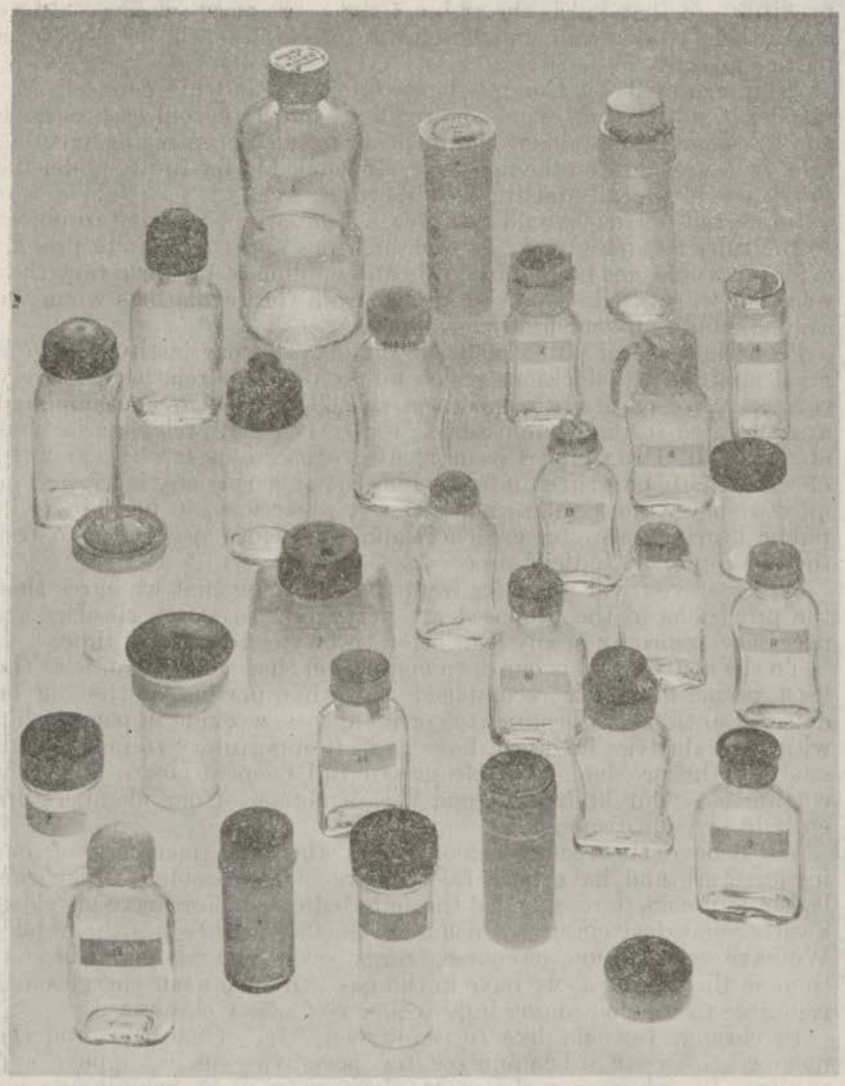
We believe the record demonstrates that the members of our institute are and have been fully aware of the problem which this legislation seeks to resolve and through dedicated effort have provided a variety of safety closures which meet the varying needs of the public. We have no intention, of course, to rest on our laurels, but will continue in the future, as we have in the past, to devote our energies and resources to the continuing improvement of safety closures.

In closing, I would like to thank you, Mr. Chairman, and the members of your subcommittee for permitting us to appear and testify. We trust that the views expressed will be helpful in your consideration of this important legislation.

(Exhibit A referred to follows:)

EXHIBIT A

PICTORIAL REPRESENTATION OF SAFETY CLOSURES CONSIDERED AND DEVELOPED



Mr. ROGERS of Florida. Thank you very much, Mr. Fisher.

We appreciate the testimony you and your associates have given us and the demonstration which has been helpful.

As I understand, under present law the Secretary does not have this authority to set the regulations for safety closure. Is that correct.

Mr. FISHER. That is what I understand; yes, sir.

Mr. ROGERS of Florida. So that if such an authority were to be conferred upon the Secretary you would want the hearing provisions as now included in the Food and Drug law included in this act?

Mr. FISHER. Yes, we would.

Mr. ROGERS of Florida. Any questions?

Mr. SATTERFIELD. No questions.

Mr. ROGERS of Florida. Dr. Carter?

Mr. CARTER. I have some questions.

How expensive would the safety closures be on the affected class of medicine?

Mr. FISHER. Your question was how expensive would they be?

Mr. CARTER. How expensive in relation. Well, of course that is relevant, but is it possible that the safety closure in many cases may cost as much as the medicine itself? Isn't that true? For instance, in the case of children.

Mr. FISHER. That may be quite true. The economics of this of course are merely something that I would simply have to guess at.

Mr. CARTER. Yes, sir.

Mr. FISHER. Because I am not familiar with the cost of any given amount of medicine unless of course we know what it is.

Mr. CARTER. You are certainly familiar with the cost of your product, I am sure.

Mr. FISHER. Of what, sir?

Mr. CARTER. Of the cost of your product.

Mr. FISHER. Oh, yes, indeed.

Mr. CARTER. What would be the price of one of those, any one of them which you have there, of your safety caps?

Mr. FISHER. I believe that this would have to be based on an estimate which would involve the gross and the closure and the container combined, and this would be very difficult to arrive at as a guesstimate right here. We could, of course, provide this information for you.

Mr. CARTER. You couldn't give the cost of any one of those containers with the safety cap that you have there?

Mr. FISHER. One of these by itself? Could we possibly work this out?

Mr. PILSBURY. We could give you a range, Doctor, if that would be helpful.

Mr. CARTER. Yes, sir. I believe one gentleman agreed that perhaps the container with the cap would, possibly, in some cases cost more than the medicine which it contained.

All right, sir.

Mr. PILSBURY. You will encounter a wide variation in closure and container costs, depending on the complexity of the closure that is involved.

Mr. ROGERS of Florida. Perhaps you could furnish for the record some figures showing the various bottles with the various enclosures.

Mr. PILSBURY. Be very happy to do that.
(The information requested follows:)

SUPPLEMENTAL STATEMENT OF RICHARD E. FISHER, DIRECTOR OF PUBLIC AFFAIRS, GLASS CONTAINER MANUFACTURERS INSTITUTE

Mr. Chairman, on August 15, 1966, I appeared before this Subcommittee as spokesman for the Glass Container Manufacturers Institute to express the views and concern of our members as to that portion of H.R. 13886 which relates to safety closures. It is not our purpose in this supplemental statement to review the complexity of the many problems involved in the development, manufacture and use of safety closures; instead, we offer additional information sought and requested by members of the Subcommittee which we trust will be helpful during their deliberation of the proposed legislation, especially that section which would delegate carte blanche power to the Secretary to define and regulate safety closures.

On August 15 we brought to the hearing room 19 safety closures and containers, explained the nature and function of each closure and demonstrated its application and removal and the problems involved in its manufacture and use.

Some of the exhibits were prototypes; others had been sold upon the market in limited quantities; some are being sold commercially today in varying quantities.

Members of this Subcommittee inquired as to the cost of producing the units exhibited and expressed a concern that the increased cost of the packaging if the more complicated and expensive closures were used might result in the doubling of the cost of the medication to the general public. We were requested to prepare a supplemental report on the actual or estimated costs of the exhibits presented physically at the hearing and shown on the picture attached to our statement as Exhibit A.

Cost studies have been made as to closures not now being commercially manufactured. We have assumed optimum conditions of manufacture and sale in order to arrive at the lowest possible price which the consuming public would be required to absorb. The cost figures arrived at and the assumptions on which those figures are predicated are set forth in Exhibit B attached hereto.

This Subcommittee's concern that the proposed legislation would result in substantially increased cost to the public is well supported in fact. If the number of children's aspirin per container is cut in half, two containers and two closures are required. Packaging and transportation costs will be increased. If there is superimposed upon these items a complicated, expensive closure which requires special handling and fundamental changes in production and packaging lines, it is well within the realm of probability that the cost of the container and closure could exceed the cost of the medication.

At the hearing on August 15 we were also requested to consider and report our views on the desirability of having a study commission or panel appointed with powers and duties similar to those of the National Motor Vehicle Safety Advisory Council.

We have carefully studied the information developed in the hearings before this Subcommittee. We are impressed by the accomplishments of the government-medical-industry panel set up in 1955 under direction of the Food and Drug Administration to study this same problem. Every recommendation developed as a result of those conferences was adopted by industry *without legislation*. We are concerned that a similar pattern was not followed in 1966 and that both this Subcommittee and the many industries involved have been precipitated into a position where we are asked to pass judgment on legislation which may or may not be necessary and proper in the form proposed and which if passed could well result in great and unnecessary damage to both industry and the public. We have noted that during the hearings members of this Subcommittee have asked pertinent questions to which answers are not presently available. For example, only a perfunctory study has been made of the circumstances and causes of incidents of illness and death from over-ingestion of aspirin. To what extent, if any, were safety closures involved?

We believe one conclusion is inescapable. Further study of the problems involved, both by agents of government and industry, working together, is mandatory before this Subcommittee should be required to sit in judgment on the provisions of H.R. 13886, especially those pertaining to safety closures.

Upon further study and reflection our conclusions are these:

1. No legislation on safety closures should be enacted until further study of the problem has been made and reported back to this Subcommittee.

2. Consideration of the appointment of an advisory subcommittee with similar powers and duties to those set forth in the National Traffic and Motor Vehicle Safety Act should be deferred until a panel or study group composed of representatives of government and industry has attempted to resolve the problems posed, following the procedures carried out so effectively in 1955.

3. This Subcommittee should take affirmative action by appointing such a panel or committee to include among its membership the following interested parties:

(a) One or more Congressmen from this Subcommittee;
(b) Two or more representatives from the Food and Drug Administration;
(c) Representation from the American Medical Association;
(d) Representation from the American Academy of Pediatrics;
(e) Representation from the membership of the Proprietary Association;
(f) Representation from the membership of the Pharmaceutical Manufacturers Association;
(g) Representation from the Glass Container Manufacturers Institute (both closure and container fields);
(h) Representation from the National Association of Retail Druggists and the American Pharmaceutical Association.

We trust that the foregoing information and recommendations requested by this Subcommittee will be helpful in its deliberation.

EXHIBIT B

ESTIMATED COSTS OF CLOSURES AND CONTAINERS PRESENTED AS EXHIBITS ON AUGUST 15, 1966

The figures given herein are estimates only and are qualified as follows:

1. The designs or shapes have not been blueprinted or engineered; calculations have been made from visual examination.
2. Assembly costs have been estimated and included in the closure prices. Any unusual special handling costs are not included in the closure prices.
3. Quantity is based upon annual requirements of a minimum of 10 million, making and shipping 500 M pieces at one time.
4. Costs are based f.o.b. plant of manufacture.
5. Cost of production molds and assembly tooling is included in the closure price on the basis of amortization over a one-year period.
6. Size of molds is based upon the optimum requirement of 10 million annually.
7. No consideration has been given to possible cost of patent rights.

With the foregoing qualifications the costs of the exhibits are estimated in approximate figures as follows:

Exhibit 1: $46.00 per M.
Exhibit 2: $38.50 per M.
Exhibit 3: $59.00 to $104. per M (cost experts are not in agreement).
Exhibit 4: $36.00 per M.
Exhibit 5: $32.00 per M.
Exhibit 6: $47.50 per M.
Exhibit 7: $32.50 to $40.00 per M.
Exhibit 8: $21.00 per M.
Exhibit 9: $23.50 per M.
Exhibit 10: $23.50 per M.
Exhibit 11: $18.00 per M.
Exhibit 12: $19.00 per M.
Exhibit 13: $18.00 per M.
Exhibit 14: $21.50 per M.
Exhibit 15: $21.50 per M.
Exhibit 16: $66.00 per M.
Exhibit 17: $15.00 per M.
Exhibit 18: $18.00 per M.
Exhibit 19: Report on closure costs not available at this time.

Mr. CARTER. That is all.

Mr. ROGERS of Florida. Mr. Mackay.

Mr. MACKAY. Thank you, Mr. Chairman.

Mr. Fisher, this presentation has been very helpful.

I understand you to say that you do not favor any legislation at this time, but if legislation is adopted that the statute provide safe-

guards that will give you notice and an opportunity to react to whatever standards are set.

Mr. FISHER. Yes, sir.

Mr. MACKAY. On page 12 you mention certain subsections, (3), (f), and (g) of section 701. Do I understand this to mean that these provisions afford you the protection that you would want?

Mr. FISHER. Yes, sir, I believe they would.

Mr. MACKAY. If on any further consideration you see the need of additional protection it would be helpful to have your suggestion on that.

As I said, we were breaking some new ground on auto safety standards and Mr. Rogers came up with an advisory council approach that seemed to make a lot of sense and would afford the interested parties a full opportunity to discuss standards before they were actually adopted, and I would be interested to have you review the sections to be sure that they contain the kind of safeguards you would want.

Mr. FISHER. We will do that, sir.

Mr. MACKAY. Is it possible to gather any accurate statistics about the effectiveness of the safety cap? It seems to me it is a hard thing to get at in an evidentiary way, about the effectiveness even of this type of safety cap, as to whether or not a child can get in the package.

Mr. FISHER. Perhaps Mr. Johnson can answer that.

Mr. JOHNSON. Consumer surveys were conducted on the exhibits 9, 10, and 11 and a consumer preference was shown for No. 11. It seems that the real answer to the safety closure is its built-in convenience to the consumer.

In other words, regardless of the construction and the safety concept, if it is too involved to use by the consumer then all the safety features are lost. This has been one of the very strong guidelines we have tried to follow.

Mr. MACKAY. Thank you, Mr. Chairman.

Mr. ROGERS of Florida. Thank you very much, gentlemen. Your testimony has been most helpful.

Mr. FISHER. Thank you, sir.

Mr. ROGERS of Florida. It is now almost 12 o'clock. The House will be in session and we had hoped to be able to cover more witnesses today. We have a number of witnesses. Unfortunately, we cannot meet this afternoon, but further meetings will be announced by the chairman.

If there are any persons present who would like to file statements for the consideration of the committee we would be pleased to receive those statements at this time, although there will be further additional time for testimony.

The committee will adjourn subject to the call of the Chair.

(Whereupon, at 12 noon, the hearing was recessed subject to the call of the Chair.)

CHILD SAFETY ACT AND PERSONNEL TRAINING

MONDAY, AUGUST 29, 1966

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to recess, in room 2218, Rayburn House Office Building, Hon. John Jarman (chairman of the subcommittee) presiding.

Mr. JARMAN. The subcommittee will come to order, please.

As is the custom, we will hear first from Members of Congress who wish to present testimony. Our first witness will be our colleague from Wisconsin, the Honorable Lynn Stalbaum. You may proceed Mr. Stalbaum.

STATEMENT OF HON. LYNN E. STALBAUM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Mr. STALBAUM. Mr. Chairman, 2 weeks ago I submitted a supporting statement during this committee's consideration of truth-in-packaging legislation. My testimony today is an appeal for approval of the Child Safety Act, which together with truth in packaging, truth in lending, and the Drug Safety Act composes the Consumer Protection Act I introduced on May 25.

In my view, this comprehensive legislation affords the most effective approach toward eliminating the practices which prey on the consumer's trust, health, and pocketbook. Admittedly, this is a large order, but it is one that must be filled.

If I were forced to single out one feature of the Consumer Protection Act for immediate action, its child safety provisions would be the obvious choice. For, as President Johnson stated in his message on consumer interests, "Children must be our first concern. They are our hope and our future."

We are powerless to guard our children against many of the hazards of 20th-century life. However, thousands of young victims of aspirin poisoning would be alive today if the quantity of aspirin in each container did not constitute a lethal dosage, or if drug containers were secured by safety closures. These are the simple and essential precautions which will spare thousands of families needless grief if the Child Safety Act is passed.

Mr. Chairman, consideration of consumer measures often provokes the "let the consumer beware" line of reasoning. It is apparent to all but the most callous that this philosophy has no validity whatsoever when applied to children.

The Child Safety Act can seal up the gaping loopholes in the Food, Drug, and Cosmetic Act which rob countless families of our most precious national resource. I urge this committee to approve it without reservation.

Mr. JARMAN. Thank you for your views, Mr. Stalbaum.

Mr. STALBAUM. Thank you for the opportunity, Mr. Chairman.

Mr. JARMAN. We will hear next from the Honorable Richard McCarthy of New York.

STATEMENT OF HON. RICHARD D. McCARTHY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. McCARTHY. My name is Richard D. McCarthy, and I am the Representative of the 39th Congressional District of New York.

The Child Safety Act of 1966, which I cosponsored, is one of several consumer protection bills referred to this committee. While several of the other bills have incurred a great deal of controversy from many sources, I believe that it is paramount that Congress act favorably on the Child Safety Act. There should be no controversy as to whether or not Congress should enact legislation to protect children from death or serious illness caused by accidentally swallowing poisons, drugs, or other harmful substances.

The Child Safety Act would amend the Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substances Labeling Act.

Even though most drug manufacturers have acted responsibly in providing appropriate warnings on labels, thousands of tragic accidents have occurred which could have been avoided by adequate labeling and packaging of dangerous substances. The Child Safety Act would fill the gaps in laws by requiring that drugs such as aspirin intended for children must be packaged in quantities established by the Secretary to be a nonlethal dose so that if accidentally swallowed could not result in serious illness or death.

Second, this bill would require that all drugs packaged in a retail container, including prescription drugs, regardless of whether or not they are intended for children must be secured by a safety closure. I believe that this is one of the most important provisions of the bill. Too often accidents occur because drugs of all types are easily opened by children. By requiring that all drugs be secured by safety closures, a child who happens to get hold of a drug container will not be able to open it.

Another section of the child safety bill stipulates that cautionary labels must be clearly and reasonably affixed to pressurized dispensers containing gaseous and other poisonous substances. Cautionary labeling would pertain to handling, storage, or use, intentional or otherwise. This is a significant provision because too often if these substances are swallowed accidentally there are not any first aid directions for immediate counteraction. This legislation adequately provides that cautionary labeling must include first aid directions as are necessary for the protection of users.

Another provision of the child safety bill is to bring all unpackaged substances under the safeguard of the Federal Hazardous Substances Labeling Act. Also included are articles bearing or containing pesticides.

This amendment requires that unpackaged hazardous substances must be labeled clearly and adequately so as to inform the consumer of dangers that might emanate from articles such as toys or other articles intended for use by children. There are many toys which are decorated by such things as jequirity beans which are used as eyes on stuffed animal toys. A child who swallows or chews one bean could die. While this is a severe case, there are many cases of inadequate labeling which causes illness attributable to allergies because toys or other articles for children are either not labeled at all or are not labeled sufficiently enough to warn consumers of the possible dangers to children. In addition, hazardous substances rightfully include other packaged substances intended for use by children or in the household which fail to bear a label.

And finally, the child safety bill bans from interstate commerce toys and other articles for children which contain hazardous substances so dangerous that cautionary labeling would be inadequate. The Secretary is authorized to determine banned hazardous substances, with the exception of chemical sets which are intended for use by children of sufficient maturity to read and heed the directions and warning in the labeling.

I do not believe, Mr. Chairman, that the child safety bill would place heavy and costly burdens on the manufacturers of drugs, toys, cosmetics, and other products as it amends the Federal Food, Drug, and Cosmetic Act and the Federal Hazardous Substances Labeling Act. The responsibility that we as legislators have to do all in our power to protect our children from senseless and needless injury, serious illness, and death caused by accidentally swallowing drugs and poisons far outweighs any argument against alleged stringent standards and criterion for adequate and cautionary labeling and packaging.

Mr. Chairman, I urge this committee to report the child safety bill without amendments as soon as possible. I believe that it is a must bill before adjournment of the 89th Congress.

Thank you, Mr. Chairman, and other members of this committee, for the opportunity to testify before you in behalf of what I consider necessary and vital legislation for the protection of our children.

Mr. JARMAN. Thank you, Mr. McCarthy.

Our next witness this morning as we continue hearings on these bills is Mr. Edward J. Breck, president of the Toilet Goods Association. Our colleague, Congressman Boland, of Massachusetts is here with us and will introduce Mr. Breck.

STATEMENT OF HON. EDWARD P. BOLAND, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS

Mr. BOLAND. Mr. Chairman, I am grateful for the opportunity of being permitted to introduce Mr. Breck. He is one of our most distinguished citizens in Springfield. I appreciate that you are putting him on first. I understand what the problems are with all these gentlemen here. But he does come from a considerable distance, and I have arranged for other appointments with agencies this afternoon, and because of that, would like for him to appear first.

I am grateful to you for extending this courtesy. As I have indicated, he is a distinguished citizen of our community, he is one of the leading citizens in this particular association, he is president of the

Toilet Goods Association of the United States, and at one time, was the president of the Breck Toilet Goods Co., which is one of the greatest and most famed of the world, so it is a pleasure for me to introduce Mr. Edward J. Breck, president of the Toilet Goods Association of America.

Mr. JARMAN. Thank you.

STATEMENT OF EDWARD J. BRECK, PRESIDENT, TOILET GOODS ASSOCIATION; ACCOMPANIED BY FULLER HOLLOWAY, COUNSEL

Mr. BRECK. Thank you, Mr. Chairman. I am accompanied by Mr. Fuller Holloway who is counsel of the Toilet Goods Association.

Mr. JARMAN. All right, we will be glad to hear him.

Mr. BRECK. The Toilet Goods Association, Inc., is a trade association composed of manufacturers of perfumes, cosmetics, and other toilet preparations which in aggregate manufacture more than 90 percent by volume of all such products sold in the United States.

I also wish to call to your attention that the National Beauty & Barber Manufacturers Association, representing manufacturers and distributors in the beauty salon and barbershop field, has authorized me to advise your committee that it fully supports the views I will express in this statement.

We wish to comment only on subsection 4(c)(1) of H.R. 13886, which subsection amends section 602 of the Food, Drug, and Cosmetic Act, the misbranding section, to include a new paragraph (f) providing for cautionary labeling as follows:

> (f) If because of its nature, composition, or packaging it involves a substantial risk of causing injury to health during or as the result of any foreseeable handling, storage, or use by any individuals, whether intentional or otherwise, unless in either case it bears (in addition to any other prescribed labeling) (1) such cautionary labeling as is necessary for the protection of such individuals and (2), where necessary or appropriate, instructions for first aid treatment. Whenever the secretary finds any cosmetic or class of cosmetics is subject to the provisions of this paragraph and in his judgment a declaration to that effect will promote the objectives of this paragraph by avoiding or resolving uncertainty as to its application, he may by regulation declare any such cosmetic or class of cosmetics to be, and it shall during the effectiveness of such regulation be deemed to be, subject to such provisions. Nothing in this paragraph shall be construed to exempt any article otherwise subject to the requirements of this paragraph from such requirements by reason of the absence of such a regulation.

Cosmetics are created and produced for application to the human body and are not injurious to health under normal circumstances. The Food, Drug, and Cosmetic Act bans a cosmetic from sale if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual (sec. 601(a) of the Food, Drug and Cosmetic Act). There is no hazard to the user in the normal use of cosmetics.

Normal use of cosmetics does not, of course, include ingestion by children, who may, because of lack of experience, expect every substance is for tasting. It is for this unintended use, we understand, that the proposed legislation is intended to guard against.

A survey has been made within the past 2 weeks of a substantial number of cosmetic producers in order to determine the magnitude of incidents of injury to children because of accidental exposure to cosmetic products. Complaint files of these cosmetic companies revealed that reported incidents of injury are extremely rare.

It may be that such reported incidents are sparse simply because any external injury to those children who have experimented with cosmetics is highly unlikely and any injury from ingestion is not likely to be of a serious nature.

The Department of Health, Education, and Welfare, in a recent bulletin, indicated (table 2, p. 125) that there were 3,271 reported accidental ingestions, of cosmetics, in 1965 among children under 5 years of age, 620 of them received some treatment, and 20 of them were hospitalized for a short duration (table 5, p. 125). The bulletin (p. 3) explains with respect to all types of substances:

TABLE 5. Table 5 provides some rough indications as to the seriousness of the accidents. Approximately 20 percent of the reported cases are hospitalized. However, a great many of these may have been admitted to a hospital simply for observation; on the other hand, petroleum products do have a greater hospitalization rate and for a significantly greater time. Cosmetics conversely have less hospitalization and for shorter lengths of time relative to other types of ingestions.

Sound judgment must be exercised in order to avoid overlabeling with respect to relatively innocuous substances and thus tending to defeat the purposes of cautionary labeling—the prevention of or alleviation of injury because of exposure to toxic substances.

As stated above, cosmetics are deliberately and carefully made for application to the human body. Cosmetics are not made for ingestion (although many cosmetic ingredients are also food additives). There is also some incidental ingestion by adults of cosmetics; for example, lipstick. Such cosmetics are carefully compounded of materials which are safe for the indicated use, considering incidental ingestion.

Because of the nature of the product and the relatively remote potential of injury inherent there is grave doubt that there is any need for coverage of cosmetics under any cautionary labeling requirements. In any event, to be most effective, any cautionary statement should be directed precisely at the potential for harm; that is, accidental child exposure.

Some cosmetics are sold in pressurized containers, and hence, such containers should bear a warning with respect to the hazard involved. Such warnings are already customarily placed on such containers.

We propose that section 4(c)(1) of the Child Safety Act amend section 602 of the Food, Drug, and Cosmetic Act to read as follows:

[SEC. 602. A cosmetic shall be deemed to be misbranded—]

(f)(1) If because of its nature, composition or packaging it involves a substantial risk of causing substantial injury to health during or as a proximate result of any reasonably foreseeable handling or ingestion by children unless its labeling bears in addition to any other prescribed labeling, either in conjunction with directions for use, if any, or on other labeling, the cautionary statement: "Keep out of reach of children."

The balance of the clause will be exactly the same.

Whenever the Secretary finds that any cosmetic or class of cosmetics is subject to the provisions of this paragraph and in his judgment a declaration to that effect will promote the objectives of this paragraph by avoiding or resolving uncertainty as to its application, he may by regulation declare, with appropriate exemption provisions for packages of small quantities, any such cosmetic or class of cosmetics to be, and it shall during the effectiveness of such regulations be deemed to be, subject to such provisions. Nothing in this paragraph shall be construed to exempt any article otherwise subject to the requirements of

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this paragraph from such regulations by reason of the absence of such a regulation;

(2) If it is contained in a dispenser pressurized by a gaseous propellant unless it bears such cautionary labeling with respect to handling, storage, and use of such container as is necessary to prevent, if complied with, the causing of injury to the health of any user or other individual during, or as the result of, reasonably foreseeable handling, storage, or use thereof.

Under such provisions the maximum protection is available and directed at the potential injuries—handling or ingestion by children and the hazards of a pressurized container. At the same time, a cautionary statement should not be required on products which can cause only an inconsequential injury or illness, such as regurgitation of the product after swallowing.

It would defeat the purpose of the act to require overlabeling with respect to products which could cause only insignificant or negligible illness or injury.

In summary, because of the nature of cosmetic products and their deliberate compounding for use on the human body, their remote potential for any substantial injury, and because overlabeling should be avoided, it does not really appear necessary to require cautionary labeling on cosmetic products.

The one potential, though remote in terms of any substantial injury, is the possibility of unintended use by way of ingestion by children.

Even here, the undesirable effect of overlabeling must be weighed against the potential for relatively inconsequential injury. Pressurization of containers is a container problem, not a cosmetic problem, and appropriate cautionary warning should appear on all such containers. Weighing all factors, any cautionary labeling requirements should be directed as above suggested.

In addition, it seems to us that any amendments which you pass ought to be uniformly applicable in all of the States. If you do decide to enact any part of the proposed legislation, we urge that you also provide for preemption in that particular area.

Variations in requirements between the Federal law and the various States can only create chaotic conditions.

Thank you, Mr. Chairman.

(The tables referred to follow:)

TABLE 2.—*Accidental ingestions among children under 5 years of age, type of substance by year of report, reported by poison control centers,*[1] *1962–65*

Type of substance	1965		1964		1963		1962	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	34,483	54.4	28,780	51.3	24,335	51.8	20,563	50.4
Internal	30,870	48.7	25,446	45.4	21,588	46.0	17,964	44.1
Aspirin	16,328	25.8	12,917	23.0	10,808	23.0	8,799	21.6
Other	14,542	22.9	12,529	22.3	10,780	23.0	9,165	22.5
External	3,613	5.7	3,334	5.9	2,747	5.9	2,599	6.4
Cleaning and polishing agents	9,343	14.7	8,918	15.9	7,520	16.0	7,085	17.4
Petroleum products	3,073	4.9	3,014	5.4	2,601	5.5	2,098	5.1
Cosmetics	3,271	5.2	3,058	5.5	2,459	5.2	2,179	5.3
Pesticides	3,856	6.1	3,882	6.9	3,370	7.2	3,030	7.4
Gases and vapors	87	.1	84	.1	64	.1	78	.2
Plants	2,028	3.2	1,700	3.0	1,350	2.9	1,135	2.8
Turpentine, paints, etc	3,095	4.9	2,878	5.1	2,373	5.1	2,017	4.9
Miscellaneous	3,766	5.9	3,484	6.2	2,541	5.4	2,246	5.5
Not specified	350	.6	299	.5	341	.7	344	.9
Total	63,352	100.0	56,097	100.0	46,954	100.0	40,775	100.0

[1] Includes 97 cooperating hospitals in 1965; 99 in 1964; 102 in 1963; 73 in 1962.

Source: Individual reports submitted to the National Clearinghouse for Poison Control Centers (U.S. Department of Health, Education, and Welfare, Public Health Service, Division of Accident Prevention, May 1966).

TABLE 5.—*Accidental ingestions among children under 5 years of age, treated cases, by type of substance and days of hospitalization, reported by 341 poison control centers,*[1] *1965*

Type of substance	Days of hospitalization [2]											
	Total		No days		1 day [3]		2 to 3		4 or more		Unknown	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Medicines	19,300	100	16,667	86.4	849	4.4	527	2.7	136	0.7	1,121	5.8
Internal	18,180	100	15,744	86.6	780	4.3	490	2.7	127	.7	1,039	5.7
Aspirin	11,308	100	9,889	87.4	473	4.2	293	2.6	52	.5	601	5.3
Other	6,872	100	5,855	85.2	307	4.5	197	2.9	75	1.0	438	6.4
External	1,120	100	923	82.4	69	6.2	37	3.3	9	.8	82	7.3
Cleaning and polishing agents	3,677	100	2,967	80.7	118	3.2	156	4.2	146	4.0	290	7.9
Petroleum products	1,857	100	1,212	65.3	108	5.8	166	8.9	128	6.9	243	13.1
Cosmetics	620	100	579	93.4	10	1.6	8	1.3	2	.3	21	3.4
Pesticides	2,021	100	1,661	82.2	104	5.1	64	3.2	39	1.9	153	7.6
Gases and vapors	42	100	26	61.9	6	14.3	2	4.7	1	2.4	7	16.7
Plants	640	100	582	90.9	20	3.1	9	1.4	5	.8	24	3.8
Turpentine, paints, etc	1,258	100	1,024	81.4	50	4.0	52	4.1	36	2.9	96	7.6
Miscellaneous	689	100	595	86.3	31	4.5	19	2.8	13	1.9	31	4.5
Not specified	182	100	142	78.0	8	4.4	11	6.0	4	2.2	17	9.3
Total	30,286	100	25,455	84.0	1,304	4.3	1,014	3.3	510	1.7	2,003	6.6

[1] Includes 97 cooperating hospitals.
[2] Excludes 3,753 cases unknown as to hospitalization.
[3] Includes some patients who are hospitalized for 1 day for purpose of observation only.

Source: Individual case reports submitted to the National Clearinghouse for Poison Control Centers (U.S. Department of Health, Education, and Welfare, Public Health Service, Division of Accident Prevention).

Mr. JARMAN. Thank you, Mr. Breck, for your contribution to this hearing. Mr. Satterfield?

Mr. SATTERFIELD. No questions, Mr. Chairman.

Mr. JARMAN. Mr. Nelsen?

Mr. NELSEN. Isn't it true that as far as ingestion is concerned, that even in the instance of salt, or any other food item, if it is taken in sufficient quantities, would create some problem? I presume that in the instance of cosmetics you feel that this product is so nearly safe in all instances that the effects of its ingestion would be no different than would, say, salt or some other product, which in gross amounts would be harmful to some degree.

Mr. BRECK. That is right, yes.

Mr. NELSEN. Thank you.

Mr. JARMAN. Mr. Breck, one thing certainly is helpful in your testimony, in our consideration of these bills, and that is, where you do object, or oppose part or parts it is certainly helpful to have the recommended language that you feel would cover in the particular field of your own knowledge, and we appreciate that.

Mr. BRECK. Yes, sir, thank you.

Mr. JARMAN. Mr. Mackay.

Mr. MACKAY. No questions.

Mr. JARMAN. Thank you very much.

Mr. HOLLOWAY. Mr. Chairman, may I?

Mr. JARMAN. Yes, Mr. Holloway.

Mr. HOLLOWAY. I have reviewed the testimony of Dr. Goddard, while he was up here, and I have the highest respect for Dr. Goddard. I think he is one of the finest officials in the Government, and I am quite certain that he would like for me to, or someone to, perhaps correct the record, in one part of his testimony.

And Dr. Goddard is a very busy man, and I don't know who wrote his statement, but he had stated in referring to the Poison Control Center clearance bulletin, which was published this spring, that there were 3,058 reported cases of accidental poisoning of children under 5 by cosmetics. I think if we look on table 2 of that——

Mr. JARMAN. That was for 1964?

Mr. HOLLOWAY. 1964. If we look at table 2, attached to Mr. Breck's statement, we find the figure under "1964," and opposite "Cosmetics," of 3,058, which is the same figure Dr. Goddard's statement uses, but that table says it is accidental ingestion, among children under 5 years of age, by types of substances. It does not say anything about those children being poisoned by the cosmetic. And if we look over to table 5, you will find that under "Cosmetics," opposite the cosmetic line, there were 620 cases of treatments after accidental ingestion, and that of those 620 there were 579 of them had no days in hospital, or no hospitalization whatsoever, and I understand from some slight research that the usual treatment would have been the prescribing of a glass of milk, or something of that sort, just to dilute whatever might have gotten into the child's stomach, and consequently, we did want Dr. Goddard's statement to be checked against the record.

In the statement he also suggests that there had been a problem with respect to nail hardeners, which has caused numberous injuries.

Mr. MACKAY. Mr. Chairman, excuse me. If I could interrupt the witness there, I would like to really get clear in my own mind about the definition of the word "poison." What do you think Dr. Goddard

meant when he said they had been poisoned? Does the word poison carry with it mortality?

Mr. HOLLOWAY. Well, Mr. Mackay, I think, insofar as Dr. Goddard's statement was concerned, that whoever wrote it simply made an error in the use of that term here.

Mr. MACKAY. But is the word "poison" a scientific term? Does it really mean something?

Mr. HOLLOWAY. As I understand the term as used by pharmacologists—they don't like the use of the word "poison," they like the use of the word "toxic," because there are variations, and a thing may be toxic at one level and create some problems, and at another level, no injury whatsoever.

Mr. MACKAY. For example, I think we need to know what this table really means here, when it says accidental ingestions. I could see where there could be many accidental ingestions that would have so bad effect on the person.

Mr. HOLLOWAY. I think that is apparent. That with over 3,000 ingestions, and only 620 the doctor or who ever attended the matter prescribed anything.

Mr. MACKAY. But the fact that this appears here means that it came to the attention of the Clearinghouse, the Poison Control Center, because someone was concerned enough about it to take the child to a physician.

Mr. HOLLOWAY. Yes; that is right.

Mr. MACKAY. They really did not know what had happened, and they thought they had better get some medical advice.

Mr. HOLLOWAY. There was an abundance of caution, which is the right thing to do.

Mr. MACKAY. Do these tables tell you to what extent, well, for instance, whether there was any permanent injury, death or permanent injury?

Mr. HOLLOWAY. Congressman Mackay, they don't really but I went over to the Poison Control Clearinghouse Center of the Department of Health, Education, and Welfare, which is located over in Arlington, to check on the raw data they have, the control sheets that come into that Center, and what I am about to say, of course, is completely hearsay, but looking over that record, I found in the case of cosmetics for the year 1965 that we were checking on that there was no indicated injury to any child, other than one in the whole year.

Now the Center apparently did not have the record of what it was, but I suspect it was some kind of a hair preparation, and in that, had some chemical which burned the child's mouth.

Otherwise, there was nothing there that would indicate that there was any indicated injury of any sort to children. Now there may have been, had not the Control Center or the doctor come in and taken care of it, and I would respectfully urge the committee to some way get the Poison Control Center people to come over here, and tell you what the situation is, because they have better information than anyone else, I would think.

Mr. MACKAY. Mr. Chairman, that was really the next point that I wanted to make. I hope we can get the compiler of this information over before the committee to see if there is some hard data here. You know, the popular charges that this bill is just good politics, to have a child safety bill, and, of course, I don't think the Congress functions that way.

I don't think we want to legislate unless there is some hard data to support the legislation. Mr. Chairman, I do hope before we conclude these hearings, that we can hear from the leaders of the poison control centers, to interpret these charts to us, so that we can know whether we are dealing with a really large problem or one that looks large on this particular arrangement of the figures.

Thank you. Excuse me for interrupting.

Mr. JARMAN. We will make every effort to get that information.

Mr. HOLLOWAY. Thank you, Mr. Chairman. I did want to straighten the record.

Mr. JARMAN. Yes.

Mr. Rogers.

Mr. ROGERS of Florida. I am sorry I was late, and did not hear your statement. I will read it. Is the point you are making that aspirin or poisoning is not of a sufficient problem to legislate against?

Mr. BRECK. Only in cosmetics.

Mr. ROGERS of Florida. Just in cosmetics. You feel there is no problem there?

Mr. BRECK. Some 3,000 ingestions by children under 5 in 1965, and when you realize that the retail dollar volume of the industry, in 1965 was practically $3 billion, and the number of units are certainly in that category in the contents of a package brings that up, it is really a very fine record.

Mr. ROGERS of Florida. Fine. Thank you.

Mr. JARMAN. Thank you, Mr. Holloway.

Mr. BRECK. Thank you.

Mr. JARMAN. Our next witness this morning is Mr. John L. Harvey, Washington counsel, Drug & Allied Products Guild.

Mr. Harvey, until his recent retirement, served as Deputy Commissioner of Food and Drugs. We are pleased to have you with us this morning.

STATEMENT OF JOHN L. HARVEY, COUNSEL, DRUG & ALLIED PRODUCTS GUILD

Mr. HARVEY. Mr. Chairman and members of the committee, my name is John L. Harvey. The guild is an association of 130 smaller manufacturers of pharmaceutical products, antibiotics, and allied products. Nearly every State in the Union is represented in the membership.

We are stanch believers in and supporters of the laws regulating drug manufacture and distribution. We admire and respect the Food and Drug Administration and its officers. We support and endorse the purpose of H.R. 13886 to provide greater safety to children and adults alike in the use of hazardous substances.

We do, however, wish to voice a strong objection to the procedural provisions of the bill, or some of them.

Section 2, in amending section 501(a) of the existing law, will require the Secretary of Health, Education, and Welfare or in fact any member of the department that he may designate to set a limit on the quantity of aspirin or other salicylic drug, intended for children, which may be packed in a single container for retail sale.

The limit fixed will have the full force and effect of law but no provision is made for notice so adversely affected parties for the taking of

evidence or for any opportunity to be heard or for the development of any record or opportunity for judicial review.

The maximum amount of aspirin or similar drug that a child can safely ingest must be derived primarily from the accumulated experience of many physicians throughout the world who have dealt with accidental poisonings. Establishment of such limits inevitably will cause serious economic loss in change of machinery, package design, and equipment.

The questions involved are grave ones and there is no apparent reason why we should shortcut the making of a rule which is intended to have the force of law by authorizing executive fiat.

Again in amending the same section the Secretary is required to make a law without notice, hearing, record, or review. This provides that all drugs which the Secretary thinks may be hazardous to children must, when packed in retail containers, be secured by a safety closure.

This allows the Secretary to decide what drugs should be so classified and what kinds and types of closures are safety closures. The public, drug manufacturers and sellers, physicians and scientists have an important concern over the decisions to be made to implement this section.

It is important that an opportunity for hearing and making a record be provided. The determination of the kinds and types of safety closures regarded as acceptable by the Department has the effect of granting license to some and denying it to others.

In section 4, provision is made whereby the Secretary must make determinations classifying drugs and prescribing labeling for such drugs, indicating matters to be included in or omitted from such labeling and with respect to manner and form of such statements.

Again no provision is made for notice, for hearing, for record, or for judicial review. Yet the decisions of the Secretary can have the most profound influence upon the public welfare as well as upon those who manufacture and distribute drugs.

Attention is called to the fact that in section 4(2) of the bill provision is made for due process including notice, hearing and review when the Secretary undertakes to classify cosmetics. Again in section 202(2) when the Secretary makes rules regarding hazardous substances, the provisions of section 701 (e), (f), (g) apply and provide for notice, hearing record, and review.

It is difficult to see why full opportunity for hearing and review is afforded on some types of hazardous substances and on cosmetics but denied on drugs.

There appears to be no relief in the application of the administrative procedure act since in the absence of a provision in specific statute, the administrative procedure act does not compel provisions for hearing and review.

We submit that the bill should clearly and unequivocably deal with the rulemaking power granted to the Secretary in a manner consistent with giving force of law to the rules he makes.

We suggest the amendment in the bill of section 4(2) on page 5 of the bill at line 20, by striking all the matter in line 20 and inserting "501(a), 502(d), 502(f), or 502(h) or the second sentence of section 602(f)."

With such changes we recommend that the bill be passed.

Mr. JARMAN. Thank you, Mr. Harvey.

Do I understand that the basic position, then, that your organization takes is that if hearing and judicial review is provided for, that you would be in favor of passing 13886?

Mr. HARVEY. That is correct, with proper implementation of the provisions.

Mr. JARMAN. Mr. Rogers.

Mr. ROGERS of Florida. Thank you, Mr. Chairman. It is good to see you, Mr. Harvey.

Mr. HARVEY. Thank you, Mr. Rogers.

Mr. ROGERS of Florida. What products, other than drugs, does your group produce?

Mr. HARVEY. A few household chemicals.

Mr. ROGERS of Florida. I see. Would they, any of those, be subject to labeling as "hazardous substances"?

Mr. HARVEY. Some of them are; yes.

Mr. ROGERS of Florida. Now, what use is the present law in regard to these situations? Does the law generally provide for hearings?

Mr. HARVEY. Yes. Yes, this procedure of giving notice by publication in the Federal Register, and inviting comment from adversely affected parties, considering the comment and determining whether the objections to the proposals warrant a hearing, the holding of a hearing of record, if necessary, and the publication of a final order, with an opportunity for adversely affected parties to take the matter to the court of appeals, for determination of whether the rule that has been made is supported by substantial evidence in the whole record.

This is the regular administrative procedure, for extension of the congressional lawmaking power, so that it is surrounded by the safeguards of a review, and we don't have this problem of collateral attack, or attempted collateral attack, and the question of trying to determine whether there was caprice, or unreasonableness, when you have no record to base it on.

Mr. JARMAN. Would the gentleman yield?

Mr. ROGERS of Florida. Yes.

Mr. JARMAN. Would this have to be on a case-by-case basis?

Mr. HARVEY. No, I think it would be on a section-by-section basis in the act. The Secretary is authorized to determine the amount of aspirin that can go in a package for children. This is is one thing. This would be determined once and for all, unless new evidence justified a change.

Mr. JARMAN. But on the subject of closures, again.

Mr. HARVEY. No.

Mr. JARMAN. It would have to be on a case-by-case basis?

Mr. HARVEY. No, I think he would afford interested parties an opportunity to supply him all the information that he could get on the devices for closures, and he would have to determine, subject to review, what he thinks a safety closure is, what types of thing would come in that category, and, second, he would have to determine what products it applied to.

You see, the closure rule doesn't apply just to aspirin for children. It applies to any drug that the Secretary thinks, intended either for children or adults, may be a hazard to children, unless it is stoppered in such a way that child can't get into it.

Mr. ROGERS of Florida. How do we presently handle hazardous substances? Is a hearing afforded?

Mr. HARVEY. Rulemaking on hazardous substances borrows from the Food, Drug, and Comestic Act itself, by applying the regulations of 701 (e), (f), and (g); that is, notice, hearing, and review.

Mr. ROGERS of Florida. So far as you can see, there is no reason why it should not apply here?

Mr. HARVEY. Not in this very bill, Mr. Rogers, when we extend the Hazardous Substances Labeling Act, to Hazardous Substances Regulation Act because we got hooked a little bit by confining it to labeling, we continue the provisions for hazardous substances that we adopted before, after due consideration of hearing review, and so forth, we do that in here. We do that for the cosmetic classification, but we do not do it for the drugs.

I see no reason why we should shortcut. These things are very important—not only important to manufacturers, important to the public. This question of investigating the maximum quantity of aspirin that a child can safely ingest, I am glad the new management has to decide that, not me. I would want not only all the advice, but I would want all the reviewing consideration I could get on a problem of that kind.

Mr. ROGERS of Florida. Thank you.

Thank you, Mr. Chairman.

Mr. JARMAN. Mr. Nelsen?

Mr. NELSEN. I notice on page 2, the second paragraph, the last sentence:

> The questions involved are grave ones, and there is no apparent reason why we should shortcut the making of a rule which is intended to have the force of law by authorizing executive fiat.

Mr. HARVEY. That is right.

Mr. NELSEN. Now, do I understand that under the provisions of this bill, the normal procedure of establishing a rule, where there are hearings, will be shortcut so that the Secretary by his own decision will determine whether or not the proper procedures are followed?

Mr. HARVEY. That is my view, and the view of most other lawyers I have talked to, as to what it means.

Mr. NELSEN. Yes, sir.

Now you mentioned children's aspirin. Am I to understand that we will have a bottle that is marked for children, and one that will be marked for adults?

Mr. HARVEY. Yes.

Mr. NELSEN. What prevents the child from going to the medicine cabinet, and taking momma's bottle, and taking its contents? They are not going to read whether it says child's aspirin bottle or adult, are they?

Mr. HARVEY. No, I think the Congressman's position is well taken, but I understood that it was the intent here to confine it to the product that is intended for children. These are smaller tablets, and they are flavored, and so forth, that would particularly appeal to a child, and the child becomes familiar with it, doubtless, from his mother giving it to him, so the hazard would be greater, I think.

Mr. NELSEN. Now in the event that a manufacturer would proceed, and if in the judgment of the Secretary of Health, Education, and Welfare, or of the Food and Drug Administration, they are in violation, would he then be guilty until he proves he is innocent?

Mr. HARVEY. If the Secretary has made a rule, and it is not complied with, they stand in violation of the law, yes.

Mr. NELSEN. I would like to point out that in our proposed legislation on truth in packaging, by virtue of authority in that bill, cease-and-desist orders may be issued in the case of a food product which is not hazardous to health, and then you are permitted to come into court to prove that you are innocent, but you are guilty until you prove you are innocent. It seems to me almost all of the bills that we get to indicate a very dangerous direction in which we are moving. Certainly, none of us here want to put any product on the market that will be harmful to the health of a child, but at the same time, I think there is some danger in moving too far in the direction of giving an individual authority to make all the decisions without hearings.

Thank you, Mr. Chairman.

Mr. HARVEY. Thank you.

Mr. JARMAN. Mr. Satterfield?

Mr. SATTERFIELD. No questions.

Mr. JARMAN. Thank you very much, Mr. Harvey, for contributing to our hearings.

Mr. HARVEY. Thank you, gentlemen.

Mr. JARMAN. We are pleased so have with us this morning our colleague from Tennessee, Congressman Grider, who will introduce our next witness.

STATEMENT OF HON. GEORGE W. GRIDER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mr. GRIDER. Thank you.

Mr. Chairman, I would like to introduce Mr. Harry Solmson, and Mr. Charles Sullivan, of Plough, Inc., they are the largest manufacturers of aspirin for children in the industry, St. Joseph's aspirin.

I have followed this industry very closely for a number of years. Their testimony will show that there has never been a substantiated case of poisoning. The number of tablets that they put in the bottle is at the suggestion of the Food and Drug people, and their closures are just as ingenious as the mind of man can devise.

I am very proud to introduce these gentlemen to this committee.

Mr. JARMAN. Thank you very much.

Mr. GRIDER. And I thank the committee for hearing them.

Mr. SOLMSON. Thank you, Congressman. Thank you very much, Congressman. Thank you, Mr. Chairman.

Mr. JARMAN. Mr. Solmson.

STATEMENT OF HARRY B. SOLMSON, EXECUTIVE VICE PRESIDENT, PLOUGH, INC., MEMPHIS, TENN.; ACCOMPANIED BY CHARLES SULLIVAN, PLOUGH, INC.

Mr. SOLMSON. My name is Harry B. Solmson, and I appear on behalf of Plough, Inc., of Memphis, Tenn. It has been in business over 58 years, and has manufactured and distributed over these years a number of proprietary drug items.

Our net sales in 1965 were $64 million, which puts us in the classification of being in our industry a medium-sized company.

We have approximately 12,000 shareholders scattered over the United States, and approximately 1,800 employees

The records of the Food and Drug Administration, the Federal Trade Commission, Securities and Exchange Commission, Internal Revenue Service, and other branches of the Federal Government will reflect that never in the history of this company have we been accused of any misdeeds or violations of the law, nor has our history been one of being a controversial noncooperative company with any branch of Federal, State, or city governments with whom we have come in contact during our over 50-year business life.

We therefore respectfully submit that our record is not only respectable and responsible, but also reflects affirmative cooperation with the various branches of Government. Certainly we are not in the business of seeking to profit from the production and sale of a dangerous product.

In 1947, Plough, Inc., introduced the first flavored aspirin tablet in a specialized dosage form for children. The product was introduced as St. Joseph Aspirin for Children and is today, so far as we know, the largest selling pediatric aspirin for children on the American market.

In the belief that it will be of interest, we shall relate why St. Joseph Aspirin for Children tablets contain 1¼ grains of aspirin and why each package contains 50 tablets. Prior to our introduction of a specialized aspirin tablet for children, we consulted with a number of widely respected practicing pediatricians concerning proper dosage per tablet and number of tablets per bottle.

Based upon the advice received, we packaged, beginning in 1947, fifty 1¼-grain tablets per bottle. Our judgment in this regard was confirmed in a meeting called in Washington, D.C., by FDA on February 14, 1955. This was termed "Meeting of Medical Advisory Panel on the Accidental Ingestion and Misuse of Salicylate Preparations by Children" and was sponsored by the Division of Medicine, U.S. Food and Drug Administration.

I attended the meeting as a representative of Plough, Inc. The meeting was presided over at the request of FDA by Dr. Charles McKhann, who was at that time professor of pediatrics, Jefferson Medical College, Philadelphia.

Official representatives of the American Academy of Pediatrics, the American Medical Association, the American Public Health Association, the Division of Medicine of the Food and Drug Administration, and the drug industry were present.

The American Academy of Pediatrics was represented by Dr. Jay M. Arena, professor of pediatrics of Duke University School of Medicine and Dr. George M. Wheatley, who was chairman of the Accident Prevention Committee; the American Medical Association was Represented by Dr. Torald Sollmann, Western Reserve University; The American Public Health Association was represented by Dr. Edward Press, and the Food and Drug Administration was represented by its Commissioner, Mr. George Larrick; its medical director, Dr. Albert H. Holland, Jr.; Dr. McKhann and approximately 10 other officials from its technical and administrative staff.

The deliberations of this meeting resulted in a FDA recommendation that all pediatric aspirin tablets be 1¼ grains in dosage; that not more than 50 tablets be packaged in 1 retail container; that a caution to

keep out of the reach of children be printed in a prominent position upon each package; and that all manufacturers do all possible to develop the most effective and practical safety closure.

This is why a package of St. Joseph Aspirin for Children contains 50 tablets of 1¼ grains (one-fourth the strength of an adult aspirin tablet); has repeated warnings "Keep out of children's reach"; and has the best presently available safety cap, which our company was the first to develop and use.

When this question of proper total dosage per package was recently again raised by FDA, we stated to the Commissioner our opposition to H.R. 13886 as written, but indicated our willingness to be cooperative with FDA and the Congress in legislation to achieve the purpose of the bill.

We, however, received no notice of the hearing held before your subcommittee on June 24, 1966, having first learned of the hearing about 1 hour after it was over.

We respectfully submit, in spite of our desire and willingness to be cooperative, that the bill as drawn goes far beyond simply being a bill to enable FDA to properly regulate aspirin for children for child safety.

As written, we respectfully submit that this bill is a highly controversial bill containing broad new regulatory powers (without the requirement of even a hearing), is not clear, and can easily be the subject of unnecessary misunderstanding.

Its aspirin provision alone goes far beyond a mere limitation upon the number of tablets in a bottle of flavored aspirin for children. It covers all aspirin and acetylsalicylic acid containing products. Packages of these products all include—as they are required to do—dosage units for children.

For example, directions for regular adult aspirin must include the breaking of tablets for children, and the bill applies to such dosage form.

Further, by way of putting this matter in proper perspective, so far as aspirin for children is concerned, we would estimate that today approximately 50 million packages of aspirin for children are sold in the United States every year.

We have literally thousands of written communications from pediatricians, general practitioners, and mothers expressing approval and complimenting us for first making available to the doctors and mothers of America a form of medication that is convenient to use; that enables an exact dosage to be given; and one that is palatable so that a sick and fretful child does not have to be unpleasantly forced to take it.

We respectfully contrast the position of the administering physician or mother today to their position prior to the introduction of a specialized aspirin for children, when perhaps in the middle of the night they had to take a razor blade and cut a 5-grain tablet into four parts, or in half, in order to obtain an approximately correct dosage, and then were faced with forcing a fretful child to swallow an unpalatable medicine.

These are the reasons for the success of the product; for its wide recommendation for use by most pediatricians and general practitioners in the United States, and we have been able to successfully market this product at a price under 1 cent per tablet at the retail purchase level.

We apologize for the length of this statement, but in the belief that the subcommittee desires the facts we shall, as briefly as possible, further comment upon the bill itself. Although we do not feel the present dosage per package to be lethal, which as explained above was confirmed by FDA, this aspect should properly be presented to you by recognized medical experts, and it is my understanding that it will be.

We, however, emphasize that available official statistics involve "aspirin and other salicylates."

Many drugs contain aspirin which are not called aspirin. Many forms of salicylate-containing products are not aspirin. Yet, all deaths from salicylate-containing products (adult 5-grain aspirin, aspirin compounds, methyl salicylate (oil of wintergreen), many other salicylate-containing drugs, and aspirin for children) are reported under one category "aspirin and other salicylates."

Accidental deaths in children from many household chemicals (such as petroleum products, lead and its compounds, alcohol, and so forth) are specifically reported in the official records, but we know of no official figures reflecting deaths of children from accidental ingestion of aspirin for children alone.

Now at this point, Mr. Chairman, with your permission I would like to just briefly digress from my prepared statement to cover one point, sir.

Mr. JARMAN. Very good.

Mr. SOLMSON. Testimony has been given this committee, and I quote, "every 3 days, a child dies from an overdose of children's aspirin."

That is a very positive statement, one that concerns us very much, and an inquiry has been made of FDA to determine the basis for this statement.

We are advised that the statement emanates from figures accumulated by the National Clearinghouse for Poison Control Centers, and issued by the U.S. Department of Health, Education, and Welfare.

These figures reflect the number of deaths due to accidental poisoning in children under 5 years of age for each of the years 1960 through 1964. The figures reflect 19 different general types of substances, and the latest year, 1964, does reflect a total of 125 children as having died from poisoning due to "aspirin and salicylates."

We know that three times 125 approximately equals the number of days in the year, but we feel it to be a grave injustice to the manufacturers of aspirin for children for this entire figure of 125 deaths to be equated solely with children's aspirin as a basis for saying that a child dies every third day from children's aspirin. As I have previously indicated, there are many drugs that contain aspirin that are not called aspirin, and there are many salicylates that are lethal in nature that are not aspirin.

These take the form of prescription as well as nonprescription drugs. For example, salicylates of different types are routinely prescribed in rheumatic and arthritic situations. The category aspirin and salicylates, is therefore a broad one that contains many, many products, and of the whole scope of products in this category, although I am not a medical man, it is my understanding that the 1¼-grain aspirin tablet for children is the least toxic, and the least dangerous.

We have diligently sought to obtain a breakdown of deaths due to poisoning in children by specific product rather than by general

categories of products. The only figures of an official governmental nature that we have been able to find were recently published by the Illinois Department of Public Health.

This report was prepared by Dr. Norman Rose, chief of the Bureau of Hazardous Substances and Poison Control of the State of Illinois, is a matter of public record, and reflects a total of 45 deaths, in the State of Illinois, in 1965, in children 12 years of age and under, as having been caused by poisoning from various substances. The record reflects that of the total 45 deaths, 12 were caused by different types of salicylates, but only 1 of these was caused by children's aspirin.

There are over 10 million people in the State of Illinois, over 5 percent of our population, and if this a fair sample, it would follow that it is unfair to say that 125 deaths from aspirin and salicylates resulted solely from aspirin for children.

It is interesting to note that there were more deaths of children in Illinois in 1965 from the overingestion of furniture polish, than from aspirin for children. There were more deaths from roach poisoning. Many other common household chemicals and drugs were culprits.

Of the total 45 deaths, 19 resulted from drinking paint. Although one death from whatever accidental cause is a tragedy, and we will probably never achieve perfection, we respectfully submit that a grave injustice is being done by the statement that has been made before this committee and the resulting publicity.

Before coming here to testify, I checked our files. We have been manufacturing and distributing over 20 million bottles of St. Joseph Aspirin for Children each year for many years, and have yet to receive a single communication from a physician or a parent or from any other source attributing the death of a child to St. Joseph Aspirin for Children.

In the last 7 years, we have received a total of 38 letters concerning accidental ingestions of St. Joseph Aspirin for Children, but during the same period, we have received many letters from druggists and mothers complaining that where a house has three or four sick children, barely a day's supply exists in the present bottle, and urging a package containing more tablets.

We, of course, are not here to argue in favor of more tablets. As a matter of fact, if in the considered judgment of this committee fewer tablets than 50 should be included, we will respectfully accept that judgment.

We feel it is proper to point out, however, that although St. Joseph Aspirin for Children and one other brand have approximately 85 percent of the total aspirin for children market, there are other brands of aspirin for children sold, and some of these are today packaged 100 1¼-grain tablets to a bottle.

We have an affirmative attitude toward cooperating with FDA but we respectfully point out that this bill would make it the prerogative of the individual who happens to then be the Commissioner to set the number of tablets to be contained in one package.

If, in the opinion of Congress legislation must be adopted, unless a definitive total grainage or number of tablets is spelled out in the bill, industry and the mother will be put in a difficult position since in order to retail these tablets at a nominal price, they must be packaged on high speed, close tolerance, fully automatic equipment.

A packaging line consists of a machine to put the bottle on the line; a bottle cleaner; a filling machine which fills approximately 15,000 tablets per minute; a machine to stuff the cotton in the bottle to keep the tablets from breaking in shipment; a capper; a labeler; a machine to put the bottle in the carton; a cellophane wrapper; a bundler; and a shipping case sealer. This series of machines bought from different manufacturers is synchronized in a packaging line to feed each other at approximately 300 bottles per minute.

I might interpose here, gentlemen, to say that in 1947, our price for St. Joseph Aspirin for Children was 39 cents, and it has remained the same since then, which we have been able to do in spite of rising costs of all types, of which you are aware, by virtue of increased volume and this automatic equipment that we obtained a few years ago.

One does not have to be an engineer to understand the ramifications of frequent or even infrequent changes in package size and the resulting effect upon the manufacturers and the purchase price to be paid by the mothers of America.

Further the doctor and mother prefer a standardized package, so that when the mother has one, two or more children ill and she is told by her doctor to use aspirin for children (or if she is not told by her doctor) she can know by past experience the number of tablets she is getting in a package.

Where one Commissioner may honestly conclude that x tablets is the correct number, his successor may think y tablets would be correct and his successor might think z tablets is the correct number.

It would appear that with this simple product (and aspirin is the most widely used medication in America) having been on the market for many years and so widely used, competent medical advice could presently determine the proper number of tablets per package and this could be written into the bill itself rather than left to the FDA.

Based upon our experience and constant study, covering a period of many years, we have thought that the packaging of children's flavored aspirin in containers of fifty 1¼-grain tablets did not present undue hazards.

This was the conclusion of FDA in 1955. However, we are agreeable to further limiting the number of tablets provided the limitation is practical in the light of realities in production processes and convenience aspects to the mother and physician and provided the limitation is written into the law itself rather than prescribed from time to time by regulation.

We must assume that your subcommittee is interested in the factor of convenience to the mother who often has several sick children and the problem of having adequate dosage handy in the middle of the night or at any other time.

Further, from an economic standpoint, only minute cost reductions can result from a smaller bottle with fewer tablets since it will require the same number of people on the packaging line; the same number of people in the quality control laboratory, the same shipping, freight, recordkeeping, and the other expenses of doing business.

We respectfully and strongly urge that less than 24 to 25 tablets per package would be extremely difficult in mass-production processes and would constitute a constant source of frustration and nuisance to the mother with several sick children.

The labeling requirements of H.R. 13886, so far as section 502(f) of the Federal Food, Drug, and Cosmetic Act is concerned, duplicates the wording in H.R. 13885, are intricate, serious and highly controversial and we respectfully urge that this section as it applies to section 502(f) be deleted.

As regards the safety-cap provision of the bill, we could write a book on safety closures as we have spent many thousands of dollars and countless hours of many people investigating many, many safety closures both from technical and practical usage standpoints.

We are continuing to do this and are presently market testing a new bottle and cap that is proving to be a considerably improved safety closure, but it must be remembered that the perfect safety closure is one that nobody can open. I understand expert testimony is to be presented on this section of the bill.

Well, in this—this was written before the gentlemen from the Glass Institute presented theirs. I might say at this point, as a matter of interest to you gentlemen, this is the present package of St. Joseph aspirin for children. And this closure is removed from the bottle, not by turning, but by pressing up at a break in the neck ring on the bottle.

We are presently testing incidentally, in the State of Florida, Mr. Rogers, what we feel to be an improvement on this, in that you can't get that cap off at the break in the neck ring, and you first turn, in order to get that little obtrusion there in the right spot, and then you can push it off.

Of course these safety closures present a lot of problems. Now here is one that we happen to have a patent on, and we have agreed to make it available to anybody in the event it becomes practical, but in order to get any aspirin tablets out of this particular bottle, you have to turn it upside down, and take the cap off upside down, and then the tablet is lying in the closure.

That is the only way the tablet can be gotten out, but our problem is twofold. No. 1, we have got to figure some way to get cotton in the bottle, because it we don't, the aspirin tablets will break in shipment and the other one is the big question of whether we can educate the public, when they remove a closure, to keep it upside down, but this is just a typical example of what we have been going through.

Incidentally, on our present closure, I would like to call attention to an article in the Journal of the American Medical Association of March 14, 1959, on this particular safety closure, that we are now using. This article in the Journal of the American Medical Association was written by Dr. J. Arena, of Duke University, and in it, he reflects some figures that we obtained through an independent survey in 1,600 homes, where there were children 5 years of age and under, that reflect that in 93 percent of the cases, the children 5 years of age and under could hardly open this at all, but if they could open it, as against 7 percent that could open that closure, 44 percent could open an ordinary screw cap.

I think one of the gentlemen asked a question about that at the last hearing, is the reason I bring it up.

In closing, we must comment on the time allowed to comply with any act that pertains to aspirin for children. We normally keep a 3-month inventory of packaging materials and supplies and a 3-

month inventory of finished goods in order to properly service the many outlets for aspirin for children.

Substantial stocks are also normally retained at wholesale and retail levels. This is particularly true with a product of this kind since an outbreak of any children's disease that is accompanied by fever or an outbreak of any form of influenza in a particular area of the country brings about an immediate, heavy demand for a product of this kind; hence it is normal for people in the industry—manufacturers, wholesalers, and retailers—to maintain a relatively heavy inventory of aspirins for children.

Further any change in package size requires a new bottle mold, cap mold, and production time for our suppliers. In addition, we would require again new equipment and/or substantial change parts for existing packaging equipment.

Under present conditions it takes from 6 to 10 months to obtain delivery of equipment plus the time of getting the bugs out of a new production line. We respectfully ask for 15 months after any legislation before the manufacture of any new package size may be required.

In conclusion if in the opinion of the Congress, it becomes necessary to enact legislation to meet the purposes of H.R. 13886, we respectfully request that such legislation be limited to aspirin for children; that not less than 24 or 25 1¼-grain tablets be specified as the maximum number per package, unless in the opinion of the FDA it becomes safe due to future improved packaging concepts to permit more than said specified tablet maximum; that the labeling provisions of H.R. 13886 be considered at the time of the scheduled hearing on H.R. 13885; that a realistic viewpoint be taken concerning the practical aspects of the safety closure problem with administrative hearings provided for; and that industry be given at least 15 months after the enactment of any legislation as a minimum time within which to change over to the manufacture of a new package size should this be required.

Thank you.

Mr. JARMAN. Thank you, Mr. Solmson.

Now, am I correct, Mr. Solmson in understanding that children's aspirin is also packaged in liquid form?

Mr. SOLMSON. It is not aspirin per se Congressman. It is a somewhat different salicylate from aspirin. This is called salicylamide. It is a salicylate, but it is not acetyl salicylic acid or aspirin.

Mr. JARMAN. Does your company manufacture that?

Mr. SOLMSON. No, sir.

Mr. JARMAN. Mr. Rogers.

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

As I recall the testimony of Dr. Goddard, he stated that the facts pertaining to children's aspirin were such that out of 12,000, I believe, cases of poisoning, 10,000 were directly attributable to children's aspirin.

Now he used the term children's aspirin.

Mr. SOLMSON. Well that gets back to the question, Congressman, that I believe Mr. Mackay asked of one of the previous witnesses this morning, on this word poisoning, and I would respectfully like to call to your attention, and there has been filed, as I understand it, a statement with this committee by Dr. Sunshine of Cleveland. (See p. 305.)

Dr. Sunshine is the technical director of the Academy of Medicine of the Cleveland Poison Information Center, and is president of the

American Association of Poison Control Centers, and in his statement on this question of poison, he says in part this:

> Accidental ingestions of foreign substances is potentially harmful, or poisoning, but this is not always so for many different reasons. Too frequently, those who quote the national clearinghouse data equate accidental ingestions with poisoning. Table 5 of the 1965 Clearinghouse Report illustrates that not all ingestions have harmful effects, that is, are poisonings. It gives the data on the days of hospitalization required for therapy following accidental ingestions. About half of the cases reported to the clearinghouse were treated, and of these, ten percent, 2,828, required one or more days of hospitalization.
>
> This last group represents those that were poisoned. The others were exposed to a hazard but were not poisoned, for one reason or another. Our experience showed that approximately ninety percent of those who ingested salicylates had no symptoms and no ill effects.

In other words, according to this gentleman, about 10 percent of the accidental ingestions of salicylates as a group might properly be called a poisoning, or might be termed somewhat serious.

Mr. ROGERS of Florida. Where they had to have hospitalization?

Mr. SOLMSON. Yes, sir, of course, what happens I think Congressman, as a matter of practice, a mother finds that her child has ingested accidentally a number of tablets, and she of course, naturally is upset and calls the local poison control center, and they list that as one of the ingestion cases, when actually, it probably amounts to nothing, and apparently, from Dr. Sunshine, in 90 percent of the cases.

Mr. ROGERS of Florida. Yes. What is the first aid treatment?

Mr. SOLMSON. Well there will be a doctor to follow me on that that can doubtless comment on it better, but as I understand it, it is to cause the child to vomit.

Mr. ROGERS of Florida. How do they do that? Do you know the normal procedure?

Mr. SOLMSON. As I understand it, they do it readily through the use of ipecac, or some other way that might be available to the mother.

Mr. ROGERS of Florida. What about the provision in the bill that would require you to put a first-aid treatment on your label?

Mr. SOLMSON. Well, I respectfully would like to say that I would prefer one of the doctors, who will testify later, to comment on that. The problem from our standpoint has legal connotations, which you can appreciate, as well as medical connotations. And I understand that both of those aspects of the label will be treated by a later witness.

Mr. ROGERS of Florida. All right. Now there has been proposed to the committee that we should abolish in interstate commerce any candy-flavored aspirin for children, on the theory that if it is not attractive to children, then they would not be as likely to take an overdose of aspirin. In other words, if you made a child's aspirin, but not put the flavoring in it. What would be your reaction to that?

Mr. SOLMSON. Twofold, sir. In the first place we are told that until a child gets somewhere between 2 and 3 years of age, it does not have any sense of taste anyway, which would seem to be brought out by the official figures of the number of children that drink paint and insecticide, and kerosene, as Congressman Carter commented on a couple of weeks ago.

So I don't know that the flavoring has too much to do with it, but the reason that the flavored aspirin was an instantaneous success with the pediatrician and the general practitioner as well as the mother was that where you have a sick and fretful child, they seem to find it

easier to administer, because the child was used to taking orange juice, and this is flavored with a pure extract of orange, and I think that is the reason for the success of the product, and the reason that about 50 million bottles a year are sold.

Mr. ROGERS of Florida. I believe that is about all the questions I have. I think it might be well to note that it is a good idea that whenever there is legislation before the Congress, that is, in which your company is interested, it is a wise idea to leave a letter to be notified with the clerk, because normally, the clerk would not know which companies in America are involved.

Mr. SOLMSON. Yes, sir; thank you, sir. This is a new experience for us.

Mr. ROGERS of Florida. Thank you. Thank you, Mr. Chairman.

Mr. JARMAN. I understand that St. Joseph packages only in the fifty 1¼-grain bottles?

Mr. SOLMSON. Yes, sir.

Mr. JARMAN. Does any other company in the country package in smaller quantities?

Mr. SOLMSON. Not to my knowledge. The other leading seller in the country is Bayer aspirin for children and they have the same sized tablets and the same number of tablets to the bottle.

As I remarked, we are aware of some companies that do package a hundred, one and a quarter grains to a bottle.

Mr. JARMAN. If we followed your recommendations and whether it be by legislation or by regulation, do you think that the limitation should be in terms of the number of tablets or should be in terms of the grains?

Mr. SOLMSON. Congressman, I don't think it makes any difference. The reason I say that is that for medical reasons all of the pediatricians that we have conferred with or talked to or heard from, all want one and a quarter grains per tablet.

They seem to tie it in, that particular grainage seems to tie into a formula that they utilize as regards the weight and age of the child, in saying how many tablets should be used. So I don't know of any aspirin for children on the market today that is other than one and a quarter grains.

Now when this matter came up in the FDA meeting in 1955, 62 and one-half grains was discussed along with the fifty-one and a quarter grain tablets. It just happened to figure out that way.

I would say from our standpoint it would not make any difference. Of course, from the standpoint of the costs of production, the more tablets there are in the bottle, the less we would have to charge per tablet, in which, of course, you are getting down to fractions of a penny, but from the standpoint of economy to the consumer, we could do better by them if we had 36 than if we had 24 or 25, because you have certain fixed costs that just don't change.

Mr. JARMAN. Thank you.

Mr. Nelsen.

Mr. NELSEN. Thank you, Mr. Chairman.

You referred in earlier testimony to the term "poisoning." Would the term "ingestions" be more accurate than "poisoning" as far as the report is concerned?

Mr. SOLMSON. Yes, sir. Very much so.

Mr. NELSEN. Now, on the 50-tablet container, do I understand that this is a standard that has been adopted after hearings by the Food and Drug Administration? Do all manufacturers of children's aspirin follow the 50-tablet standard?

Mr. SOLMSON. When this matter came up in 1955, Congressman, Mr. Larrick, who was then the Chairman of the Food and Drug Administration, and Dr. Jerry Holland, who was the Chief of the Medical Staff, took the viewpoint that at that time—and whether they are right or not, I don't know—but they took the viewpoint that FDA did not have the authority to say, "You can only put 50 1¼-grain tablets in a bottle." But as I indicated in my statement, the result of the meeting was an affirmative recommendation to that effect, which was based on AMA and Pediatric Academy advice.

So there is no law or regulation limiting the bottle to 50 tablets.

I would say that of all the aspirin for children sold in the United States, that approximately 90 to 95 percent of it is in a bottle containing fifty 1¼-grain tablets. There are some few manufacturers, as I indicated, that still put 100 1¼-grain tablets in a bottle, but it is a decided minority.

Mr. NELSEN. Now, in the event, we will say, that the Food and Drug Administration is given the authority to set the number of tablets in a bottle, or, shall we say, if the law is amended so they could make that a standard, as I understand it, you feel that you should have the opportunity of hearing and discussion before such an order were put into effect.

Is that correct?

Mr. SOLMSON. Well, yes, sir; if they are given that authority, we certainly feel we should have that opportunity because, in all honesty, I think we can give them some factual information they would want.

At the same time, if this committee feels that 50 tablets is too many, we would hope that they would specify the number in the bill, and the reason for that, as I indicated in my statement, is twofold.

First, it is not an easy thing, when you are operating a production line, running 15,000 tablets a minute, to change that thing around, even infrequently, to adjust from 25 to 36, or 36 to 25, or whatnot.

That is one reason, and the second is that this is a very widely used product, as you gentlemen probably know. I would imagine that most mothers in America use this product for simple aches and pains, for if a child has got the measles, and he has got fever, it is an antipyretic. It is a simple drug, it rapidly brings down fever, and it is routinely prescribed, or routinely told by doctors and pediatricians to mothers to give aspirin for children.

Today, a mother knows that if she goes into a drugstore and asks for a bottle of St. Joseph aspirin for children, or Bayer's aspirin for children, or whatever it might be, she is going to get 50 tablets.

The pediatrician knows that if he tells the mother to get a bottle of aspirin for children, and the mother might have two or three sick children, he knows how many tablets she is going to get, because it is a standardized package, and I think from that aspect, it would be a source of inconvenience to the doctor and the mother, a source of nuisance, perhaps, to have the quantity changed from time to time.

Mr. NELSEN. Well, of course you realize that if we were to sit here and decide how many tablets are to be in a bottle, and likewise with very many commodities that are on the market, we would be here forever. We would like to get home sometime in October.

Mr. SOLMSON. Excuse me. There will be medical testimony on that subject.

Mr. NELSEN. Yes. I think the thing that we are concerned about primarily is to be very sure that any rulemaking authority that we grant to any agency of Government provides for proper hearing.

We like to pass a bill that is practical, and one we can live with.

Thank you, Mr. Chairman.

Mr. JARMAN. Mr. Satterfield?

Mr. SATTERFIELD. Thank you, Mr. Chairman.

Listening to your testimony, I feel very much like the gentleman who just questioned you, as to how we are going to make a determination of the number of pills you ought to put in a bottle.

Do you think it is possible that some limitation insofar as the total grains of aspirin are contained in one package might be a proper way to approach it?

Mr. SOLMSON. Yes, sir; that would be equally proper. Right now, of course, there are 62½ grains of aspirin in St. Joseph aspirin, and in most other aspirin for children.

The number of grains would be proper. I think it would automatically follow that all manufacturers would use 1¼ grains, so if you do establish grainage, we would certainly want it to have some multiple based on 1¼.

Mr. SATTERFIELD. Well, that may be or may not be, but the point that bothers me is, what evidence we would have and what qualifications we have to make this type of determination.

It seems to me more properly left to people with medical experience.

Mr. SOLMSON. Well, there will be medical witnesses to testify, sir. Of course, we went through this with the American Medical Association, and the American Academy of Pediatrics and the FDA before in 1955.

Mr. SATTERFIELD. Of course, they have gotten some experience since then on this type of aspirin, though, haven't they?

Mr. SOLMSON. Well, it had been on the market 6 years prior to that meeting.

Mr. SATTERFIELD. Well, it is a fact——

Mr. SOLMSON. Eight years.

Mr. SATTERFIELD. It is a fact, nevertheless, that the ratio of the grains of aspirin that might be ingested by a child and whether or not it is toxic, depends upon his physical condition, and predominantly his weight. Isn't that correct?

Mr. SOLMSON. That is my understanding, although I am not a medical expert.

Mr. SATTERFIELD. We have had testimony in these hearings previously, from the FDA, stating that in their considered opinion, any dose that exceeded 1 grain per pound of body weight was toxic, and would probably require hospitalization.

Do you disagree with this?

Mr. SOLMSON. I would really respectfully not comment on it, sir, because there will be doctors that can give intelligent testimony, and I don't think I really could.

Mr. SATTERFIELD. Well, let's assume, for example, that this might be true, and that the average weight of a child around 2 years of age might be 30 pounds.

It would seem to me that if there were reasonable limitation placed upon the number of grains in a package, that rather than put these

things out at 1¼ grains per pill, your industry might decide to do it at three-quarter grains and not have to change your packaging setup at all.

Mr. SOLMSON. Well, I think there will be a pediatrician to testify, but our experience with the pediatricians is that they want 1¼ grains.

It seems that, and I certainly emphasize that I am not a medical expert, but it seems that that has proven to be a desired and convenient form or dosage form for the tablet, and based upon the age and weight of the child, as you commented, it is my understanding that based upon that, the pediatrician will say to the mother, give the child two or three, or whatever it might be, aspirin for children.

Mr. SATTERFIELD. Well, it seems to me that this is a critical area. You mentioned and referred to a table of aspirin and salicylics combined insofar as the total number of deaths in 1960 to 1964 was concerned.

Are you familiar with another table that accompanies the report of the National Clearinghouse for Poison Control Centers dated May and June of 1966, that shows a hospitalization incidence of children under 5 years of age who have ingested medicines of all kinds internally?

Mr. SOLMSON. Yes, sir.

Mr. SATTERFIELD. I notice that it shows that the internal ingestion of children under age 5 is 18, 180; immediately below that, they show that 11,308 ingested aspirin, and that as a result of this, 9,889 days in the hospital were spent, as a result of this ingestion.

Did you disagree with these figures?

Mr. SULLIVAN. Which table is that, sir?

Mr. SATTERFIELD. Table 5.

As I read that table, if you want me to repeat. It shows that the internal ingestion of medicines by children under 5 that were reported by the poison control centers showed a total ingestion or internal ingestion of 18,180. And 11,308 of these were from aspirin.

Mr. SULLIVAN. That is right.

Mr. SATTERFIELD. And that of that 11,308, that required——

Mr. SULLIVAN. That says "no" days, that means that 9,889 required no days of hospitalization; 87.4 percent.

Mr. SATTERFIELD. It is not number of days.

Mr. SULLIVAN. No, sir, that is "no" days. The next one is one, two, three, and four or more.

Mr. SOLMSON. This conforms to Dr. Sunshine's statement that his experience as head of the poison control center in Cleveland is that only 10 percent of the accidental ingestions situations required hospitalization, or what he would call a poisoning.

That is "no" days. Not number of days.

Mr. SATTERFIELD. You had about 800, then, that required one or more days in the hospital?

Mr. SOLMSON. There is one other factor of this that honestly I don't know, Congressman, and that is this: They say, "Medicines, internal. Aspirin, other." So far as we know, that category also contains other salicylates. Now the reason that I think it does is that we have been unable to find, to obtain from the source of this material a breakdown between aspirin and other salicylates. And as I mentioned before, there are a number of other salicylate containing drugs that are quite serious drugs.

Such as methyl salicylate, and sodium salicylate, and there are 16 to 20 different salicylate drugs other than aspirin, and although this does say "aspirin" so far as we have been able to determine, the same category of "aspirin and salicylates" is the basis for the figure.

Mr. SATTERFIELD. But this nevertheless includes only those that took the trouble to report to the poison control centers.

Mr. SOLMSON. Yes.

Mr. SATTERFIELD. And the point I am getting at is this: If you agree that a certain amount or a certain number of grains in a bottle is toxic, it would seem to me that it follows that it would be awfully wise to put this product in a package that in the greater number of cases could not be toxic.

And the question is, Who is going to make the decision as to what this standard should be? It is the one that I understand you object to in the bill. You think we should make it?

Mr. SOLMSON. Well, I would hope that you would, and after hearing the medical testimony.

Mr. SATTERFIELD. But you are not opposed to conforming to whatever standard is arrived at?

Mr. SOLMSON. No, we will conform, of course. The only point I am trying to make, however, sir, is that when you get below 24 or 25 tablets, you are getting into a, well, so far as we know, we can't get a bottle we can run on an automatic packaging line, that is the bottle will be so small that it is presently impractical to run it on a line, and it is impracticable to put adequate instructions for use on the label if you get below 25 tablets.

Now I might say that we have tried. We test marketed in Birmingham, Ala., a few years ago, a strip packaging of aspirin for children. This package here, which is in cellophane strips. Each tablet is in an individual compartment. And we sent a crew of men into Birmingham and built displays in drugstores in Birmingham of this package, alongside our regular package, on the counter, and each package sold for the same price, and we had little signs made, over the display, indicating that the purchaser would get the same number of tablets, and it was the same tablet, at the same price.

And we advertised it in the newspaper. The only trouble was, nobody would buy it. It seems that the mother wants something that is a little bit more convenient, and easy to get at. We thought maybe this might work, but it was really a flop.

Mr. SATTERFIELD. Thank you, sir. I have no other questions.

Mr. MACKAY. Thank you, Mr. Chairman.

I just remembered that either you or your competitors sent giant-sized bottles of aspirin to all of the freshmen Congressmen right after we got elected. [Laughter.] That was a brilliant stroke.

Mr. SOLMSON. I must say that we were not that smart.

Mr. ROGERS of Florida. Would the gentleman yield?

Mr. MACKAY. Yes, sir.

Mr. ROGERS of Florida. I understand they are asking that you send them back to them now? [Laughter.]

Mr. MACKAY. I wanted to thank you for your testimony, which I think has been very helpful. This legislation bothers me, because it seems to me we are moving in the wrong direction, of further legisla-

tion, when evidently there has been inadequate administration of existing law.

I have not been able to get into the extent to which the Congress has required the executive branch to gather useful data, but the most shocking thing we have found in the traffic safety hearings is that there is not enough data on which you can make hard judgments.

Now I have reviewed my constituent, Dr. Goddard's testimony, and on page 2, he said:

> The tragic part of the picture is that in 1965, 16,328 children under 5 were reported poisoned from the accidental ingestion of aspirin and other salicylates. Many of these children died.

Well this just leaps out at you as a monstrous situation, if you accept it at face value.

Mr. SOLMSON. That is true. But the only problem with it, as we——

Mr. MACKAY. Well, I say, when you look inside the package, when you examine what is in the bottle, you come up with a much more bland situation. For example, do you know how many children died in 1965 that we know were poisoned as a result of taking aspirin?

Mr. SOLMSON. No, sir; we don't.

Mr. MACKAY. I mean do we even have an estimate?

Mr. SOLMSON. No, sir.

Mr. MACKAY. Well, does it not seem reasonable, or appropriate, for the Public Health Service to be able to give us that figure, rather explicitly?

Mr. SOLMSON. I think we would all be in a better position if we knew where we stood a little better because when you throw all salicylates in with aspirin, you are mixing watermelons and peas. When you think of a lot of salicylates that are fairly lethal, and a one and a quarter grain aspirin tablet, of the whole group of salicylates, I think—I am sure that any doctor would doubtless say that this is the least toxic of the whole group, and yet, they are all in that group of 125, and that is the figure that bothers us.

Mr. MACKAY. Now the second thing is, it seems, as I understood your testimony, the reason you went to the 50-pill bottle was because of conferences held in 1955, so you have been working cooperatively with the Government.

Is that right?

Mr. SOLMSON. Well, we actually, Congressman, went to 50 when we started, and that was in 1947, and we did that on the best pediatric advice we could get, and then when the FDA called this conference in 1955, we were, of course, pleased that our judgment was confirmed, at that meeting.

And that has been the package we have had since 1947.

Mr. MACKAY. And I think Dr. Goddard testified further that 50 aspirin is a lethal dose, if I am not mistaken.

Mr. SOLMSON. I don't recall whether he did nor not, but I would appreciate it if you would ask that question of a doctor when he gets before this committee.

Mr. MACKAY. Well, here on page 3 of Dr. Goddard's testimony, it says, it is our belief that a limitation on the quantity of children's aspirin in a retail package is needed to do the job.

We do not think it is necessary to forbid the sale of flavored children's aspirin, but since there are many cases where young children

have eaten as many as 50 baby aspirin at one time, and since that is a lethal dose for some children, we feel that the hazard can best be controlled by limiting the bottle contents to less than an amount that might kill.

The two leading producers of children's aspirin packaged 50-tablet bottles. This is well above the toxic dose for a 3-year-old, and you said there were other companies that packaged more than 50 tablets, didn't you?

Mr. SOLMSON. Yes, sir; they represent, I would guess, about 4 or 5 percent of the total aspirin for children sold.

Mr. MACKAY. Well, if you arrive at a scientific judgment that the figure maybe is 40 or 45, or something like that, and it is stated as a matter of the law, then the whole aspirin industry would know exactly where it stands, and you don't have to worry about hearings or anything.

Isn't that correct?

Mr. SOLMSON. That is right, sir, and that is what we would hope.

Mr. MACKAY. What is the total consumption of aspirin a year; have you any idea?

Mr. SOLMSON. I think it could be expressed in tons, sir, but I am not in a position to say.

(The following letter was subsequently submitted by Mr. Solmson:)

PLOUGH, INC.,
Memphis, Tenn., August 30, 1966.

Hon. JOHN JARMAN,
Rayburn House Office Building,
Washington, D.C.

DEAR CONGRESSMAN JARMAN: I am writing to express to you my sincere appreciation and thanks to you and your subcommittee for the courtesies and time extended to me in behalf of our company in the hearing yesterday morning.

It was my first time to participate in or witness a hearing of this kind, and I was most impressed with the sincerity of purpose evidenced by each member of the subcommittee.

As you recall, I was asked as to the amount of aspirin consumed by the people of the U.S. in one year, and I was unable to be exact in my reply, but merely stated that it would be measured in tons. Aspirin, as you are doubtless aware, is by far the most widely used drug in the country.

In order to obtain an answer to your question, we telephoned the Dow Chemical Company of Midland, Michigan today to get their best estimate on the amount of aspirin used in this country in all types of drugs which would also include APC tablets, aspirin compounds of every kind, etc. Dow, who are one of the few basic manufacturers of the drug, gave us their best estimate of 40,000,000 lbs. as being the annual aspirin consumption in this country.

If in your considerations, there should develop any further questions upon which we can possibly furnish factual information, we will certainly be pleased to seek to do so.

Again, thank you and your subcommittee.

We are respectfully yours.

Sincerely,

H. B. SOLMSON,
Executive Vice President.

Mr. MACKAY. Well, you could justify a legislative rule here, when you might not be able to on a product that was consumed in much smaller quantity, couldn't you?

Mr. SOLMSON. That would be our hope, sir, that medical testimony that will be presented here would enable you gentlemen to be able to answer the questions, the question that is obviously in your mind as to what would be a proper total grainage.

Mr. MACKAY. And is this overdosage of aspirin by children associated almost exclusively with the flavored aspirin? Does bad taste repel a child from taking regular aspirin?

Mr. SOLMSON. I really don't know, sir. I have never seen a breakdown on it.

Mr. MACKAY. Well, that is a kind of statistic that would be very helpful to us in arriving at our objective, wouldn't it?

Mr. SOLMSON. Yes, sir, I am sure it would.

Mr. MACKAY. And it could be gotten at, too, couldn't it?

Mr. SOLMSON. Yes, sir, we know that there is a certain amount of what is called therapeutic overingestion of aspirin, that is a situation where a parent stupidly—if you will pardon the word—gives the child just too much aspirin.

We had a situation in Memphis, not too long ago, where a parent over in Arkansas in the country gave a 2- or 3-month-old baby two 5-grain aspirin tablets every 3 hours, all day, and then they took the baby to a hospital in this little town, and the nurse injected aspirin by rectum, because the child had high fever, and when they brought the child into the Methodist hospital, in Memphis—and the reason I happen to know of it is that a close friend of mine, who is one of our leading pediatricians, happened to be in the hospital, and was called into the case, the child had salicylate poisoning, and couldn't be helped.

Now I don't say that is a common thing, but it is not an uncommon thing, either, and we do everything conceivably possible to do, in our labels and our circulars, and on our cartons, to guard against that.

It is just those things that happen, like the 19 children that died from drinking paint in Illinois in 1965. Every one is a tragic situation.

Mr. MACKAY. Do you see where you can improve the safety closure by giving an administrator power to regulate over the present situation?

Mr. SOLMSOM. Well, I might comment on it this way: If we could improve that closure, and we have worked and worked for many years to improve it, and as I remarked a little while ago, I think we have one now that is better, we certainly would do it, because it would give us a competitive advantage that we would love to have.

Mr. MACKAY. Could you say that any of your competitors are cutting corners by not using as good safety closures as are available, and thereby, exposing children to hazard?

Mr. SOLMSON. Those that I am aware of are using the present safety closure that we use. Now there may be some that aren't, but those that I am aware of do use this closure. And this new closure that I showed you gentlemen, that is somewhat similar to the closure we use, but requires one more move in order to open it, that we are testing in Florida, Mr. Rogers, was developed by our engineers, together with the engineers of Owens-Illinois Glass Co., and if it proves to be successful, I would guess it would be used throughout the industry.

We developed the present closure that we use, and it immediately was adopted throughout the industry.

Mr. MACKAY. Finally, you could be of help to us, if you feel the executive branch could and should get better data than has been furnished the Congress. I would appreciate any specific recommendations that you might have as to how this data could be improved.

Mr. SOLMSON. We certainly have the same objective in view, sir. We would very much like to know more than we know.

As I mentioned, the only specific data that we know where there is a breakdown of this category, "aspirin and other salicylates," is the one that was made by this doctor in Illinois. That is really the only one of an official nature, of which we know.

Now we have talked to a number of heads of Poison Control Centers, and there is testimony in the record from a doctor that is the head of the one in Cleveland I mentioned, on what he has found. But we know of no—I don't think you could get today—any national figures, because of the one problem, and that is, it has been customary, if a child dies from any form of salicylate poisoning, that the coroner puts down on the record "salicylate poisoning."

Now, our people have gone to various cities and have looked at the coroners' records in an effort to get this information. And frankly, we haven't been able to get it. The only specific thing we can find is that of the 12 salicylate deaths in Illinois, in 1965, one was from aspirin for children.

Mr. MACKAY. Thank you, Mr. Chairman.

Mr. SOLMSON. Now if you equate that to the 125, it becomes about 10 or 12 over the Nation. I don't say it is correct or not. It may be a fair sample.

Mr. MACKAY. Thank you, Mr. Chairman. No further questions.

Mr. JARMAN. Dr. Carter?

Mr. CARTER. What do you consider a lethal dose of aspirin?

Mr. SOLMSON. Dr. Carter, I would not seek to answer that. There will be medical witnesses to follow me, however, that may be more helpful to the committee on that point than I have been.

Mr. CARTER. You represent a big firm, and you sell more children's aspirin than any other, and you package them in bottles of 50.

Do you think 50 of those baby aspirin would be lethal?

Mr. SOLMSON. We don't; no, sir. And the reason that we don't is that this subject was the subject of considerable thought, discussion, and consideration upon the part of official representatives of the American Medical Association, American Academy of Pediatrics, and the Food and Drug Administration, and it was their conclusion that 50 1¼-grain tablets was not a lethal dose, and would be proper, as a standard package.

Mr. CARTER. Now you speak of aspirin and salicylates together. Isn't it true that we have a drug labeled aspirin, if it contains methyl salicylate or salicylate, as you will, that that medical salicylate should be labeled on the bottle also?

Mr. SOLMSON. I think under the law, it must be, sir.

Mr. CARTER. You just don't put acetalsalicylic acid, plain.

Mr. SOLMSON. No, sir.

Mr. CARTER. You have got "methyl," also.

Mr. SOLMSON. I think under the law that that would be required, sir. We don't package anything like that.

Mr. CARTER. I have a great respect for the American Medical Association, of which I am a member, and also of the Pharmaceutical Association, but I greatly fear that 50 aspirin is too much. I am sure in my own mind that that contains more than a lethal dose for a 2-year-old child.

I think that we will have to certainly cut that, the number of aspirin.

Mr. SOLMSON. Well, as we have stated, sir, we are not here to——

Mr. CARTER. Yes, sir.

Mr. SOLMSON. We are only here to try and give the facts that we have, and from the medical testimony that will follow, we would hope that if in the judgment of this committee, less than 50 tablets would be proper, you would establish a number of tablets.

Mr. CARTER. Certainly, that would be hard on the industry, but at the same time, we have got to be factual, I should think, and for anyone who has studied medicine and has seen children who have ingested too many aspirin, you know that 50 is absolutely beyond the range of the dose which a child should ingest safely.

I think it will have to be cut more than half, I am afraid, to be entirely safe.

That is all, Mr. Chairman.

Mr. JARMAN. Mr. Gilligan?

Mr. GILLIGAN. Thank you, Mr. Chairman, no questions.

Mr. JARMAN. Thank you, Mr. Solmson.

Thank you very much, Mr. Solmson.

Mr. SOLMSON. I appreciate the time, sir.

Mr. JARMAN. I appreciate your contribution to this hearing.

Mr. SOLMSON. Thank you.

Mr. JARMAN. Our next witness is Mrs. Fritz R. Kahn, temporary chairman, Legislative Committee, National Congress of Parents and Teachers.

STATEMENT OF MRS. FRITZ R. KAHN, TEMPORARY CHAIRMAN, LEGISLATIVE ACTION COMMITTEE, NATIONAL CONGRESS OF PARENTS & TEACHERS, ON BEHALF OF MRS. EDWARD RYAN, CHAIRMAN

Mr. JARMAN. Mrs. Kahn, we are very glad to have you.

Mrs. KAHN. Thank you.

Mr. Chairman and members of the committee, we appreciate very much this opportunity to express the concern of the National PTA for the safety of small children, and our support of this Child Safety Act of 1966.

This statement is on behalf of Mrs. Edward Ryan, of Manchester, Mass., who is the chairman for legislation of the National Congress of Parents & Teachers. She, unfortunately, has been called out of the country, and I am presenting this statement on her behalf.

I am Mrs. Fritz Kahn, of Fairfax, Va.

Long before the National PTA reached its present membership of more than 11 million, its thousands of PTA's around the country were guiding parents to the importance of making homes safe for young children, and of teaching children habits of safety.

Nevertheless, accidents remain the first cause of death among children. Substances that may be harmful or even fatal to children have proliferated in household articles that are in everyday use and easily available in millions of homes.

The common use of medicines has greatly increased the number of children who find them unguarded. Every year more than half a million children are reported to have swallowed poisons accidentally.

In another area addressed by this bill, it is hard for parents and relatives to know that even some attractive toys are dangerous gifts because of hidden poisons or harmful chemicals.

We, therefore, welcome and are glad to support the provisions of the Child Safety Act of 1966. We believe that packaging of children's aspirin in limited quantities, safety closures on drug containers, more careful labeling, and the ban on articles imminently hazardous to health, will be a great assistance to parents in rearing children safely despite the multitude of pressures and distractions of present-day living. It will undoubtedly mean life itself to many children.

We do ask for your favorable consideration of this bill and thank you for this privilege.

Mr. JARMAN. Thank you very much, Mrs. Kahn.

Mr. Rogers?

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

Mrs. Kahn, we appreciate your statement. Thank you for being here.

Thank you.

Mr. JARMAN. Mr. Nelsen?

Mr. NELSEN. Thank you, Mr. Chairman.

I noted in your statement that you support the provisions of the Child Safety Act of 1966, and I think that we might say that all of us support the objectives of any legislation that would contribute to greater child safety.

However, I would assume from the language you use that you do not necessarily take the position that every detail of the bill and the administration of it and the factfinding of it is necessarily correct in every detail. However, it is the objectives that you speak to.

Mrs. KAHN. That is true, Mr. Nelsen, and in listening to the hearings, we certainly feel that many of the people who have presented testimony have presented ideas which will be incorporated into the final bill, and we would have no objection to these changes.

Mr. NELSEN. I am sure you would not disagree with the observation that some of us have made that proper procedures should be followed so that in every case, all the details are brought to public attention, and nothing is overlooked by some arbitrary rulemaking that could possibly develop. I might, however, say that it is our experience that Food and Drug Administration has been doing a very fine job and have performed very well. At the same time, we could assume that at some time in the distant future, you might have someone who might be inclined to be arbitrary. We feel that we should guard against this eventuality. It is the objectives, as you point out, that we seek to find. I thank the lady for her very fine statement.

Mrs. KAHN. No, we certainly would have no objection to any of the procedural safeguards that have been suggested.

Mr. NELSEN. Thank you.

Mr. JARMAN. Mr. Satterfield?

Mr. SATTERFIELD. No questions, Mr. Chairman.

Mr. JARMAN. Dr. Carter?

Mr. CARTER. I just want to thank the lady for her statement, and say that we are glad to see the interest of the parent-teachers' associations in areas of this kind. Not only does ingestion of drugs cause trouble for children, in our section of Kentucky, but ingestion of kerosene, and things of that nature, often take place.

It seems that an educational program by the PTA would be extremely helpful to educate the parents as well as the children, if that is possible. It would be extremely helpful.

I congratulate you on your appearance.

Mrs. KAHN. Well, this is something that we give constant attention to, and we certainly agree that the parents have a great job in this, too, and a great stake.

Dr. CARTER. Thank you.

Mr. JARMAN. Mr. Mackay?

Mr. MACKAY. Mr. Chairman, I have just become an ex-PTA member, but I would nevertheless like to associate myself with the viewpoint of the association.

Thank you. No questions.

Mr. JARMAN. Mr. Gilligan?

Mr. GILLIGAN. No questions. Thank you, Mrs. Kahn.

Mr. JARMAN. Mrs. Kahn, thank you very much.

Our next witness this morning is Mr. James H. Merritt, executive vice president of the National Association of Chain Drug Stores, Inc.

STATEMENT OF JAMES H. MERRITT, EXECUTIVE VICE PRESIDENT, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC.

Mr. MERRITT. Mr. Chairman, members of the committee, my name is James H. Merritt. I am executive vice president of the National Association of Chain Drug Stores, Inc.

I appear today only with respect to title I of H.R. 13886 as it pertains to drugs. Since there is no reason to repeat arguments made by others this morning I supplement very briefly the statement provided the committee at the time of your last hearing 2 weeks ago today.

Many of our members operate retail pharmacies in more than one State and therefore must comply with State as well as Federal laws.

Uniformity of State statutes with the Federal requirements is most important to the owners and operators of chain drugstores just as it is to manufacturers selling in interstate commerce.

In 1967, 47 State legislatures convene in regular session to consider proposals on all subjects. Experience shows that many bills introduced at the State level are patterned after Federal proposals.

There is a strong argument for uniformity when Congress has acted in a particular area of interest. When Congress has not acted, public-spirited State legislators introduce their own versions of legislation considered at the Federal level, usually with provisions differing from those introduced in Congress. We hope uniformity can be achieved.

(The full statement referred to follows:)

STATEMENT OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, PRESENTED BY JAMES H. MERRITT, EXECUTIVE VICE PRESIDENT

The National Association of Chain Drug Stores, Inc. is an association of 134 drug chains which operate more than 4,000 drug stores in most of the states in the U.S. The Association was organized in 1933 and is headquartered at 1625 Eye Street, N.W. Washington, D.C., 20006.

This statement is intended to fulfill a dual purpose by (1) supporting the principle of safety closures on containers of some products intended primarily for ingestion by children and (2) raising some questions concerning the intent and possible results of HR 13886.

First, the National Association of Chain Drug Stores' members throughout the United States support, generally, the principle that products intended primarily for ingestion by children be packaged in a container with a closure of such a nature that it will deter accidental (which might be intentional in the case of a child) ingestion of a product which by its nature and active ingredients could cause health problems for the child.

After that general statement of support and to keep your record short and expedite your hearings, we will avoid several specific questions which might be raised concerning the effect of HR 13886 and mention only a few points.

We support the recommendation that in Sec. 2, line 11 after the word "intended" insert "primarily" and delete the word "use" and substitute in lieu thereof the word "ingestion" so that the text would read "* * * preparation in a dosage form intended primarily for ingestion by children * * *"

The pharmaceutical industry has made marvelous strides in the past few years in both product and packaging. At the present time there are, for example, on the market pediatric suppositories which contain acetylsalicylic acid (some are packaged in foil packs) which do not lend themselves to the safety closure requirement.

In this same Section the National Association of Chain Drug Stores supports a specific aggregate quantity limitation in the statute to cut confusion as to what "the most recent regulation says."

Sec. 3 raises two questions for our members.

The language "or (6) if it is a drug packaged in a retail container (including a container in which such drug is dispensed on prescription) and the secretary has, in the interest of protecting the health and safety of children, by regulation applicable to such drug (whether or not such drug is intended for children) * * *" indicates to us the granting of broad authority to the secretary to require safety closures for any or all pharmaceutical products; particularly, those which are limited to dispensing on prescription. There are prescription products, too, which because of their nature and long-term, continuous administration have compelled manufacturers to design special dispensing packages. Contraceptive tablets is an example—and the need to use a container with a safety closure would be an unnecessary expense to the public.

Sec. 3 requires also that the "retail container * * be secured by a safety closure." Our question relates to the standards for a "safety closure." Queries to suppliers get response indicating that while the question of safety closures has been the subject of much research for many years the solution is not so simple. There are many ideas, some patents, but no standards.

The authority granted by HR 13886 is extremely broad and should be amended to require that any determinations to carry out the intent of this legislation be made only after due notice and hearing in accordance with Sec. 701 (E) of the Federal Food Drug and Cosmetic Act.

It is the goal of the members of the National Association of Chain Drug Stores to get needed medication into the hands of the patient as professionally, ethically, quickly and economically as possible. We would hope, therefore, the burden of complying with the proposed statutory authority would be economical insofar as pharmacist labor and cost of container closure are concerned and uniform to make compliance easy saving the pharmacist's time, particularly in view of the increased demands on professional service arising as a result of the passage of the Social Security Act amendments of 1965.

Mr. MERRITT. Thank you very much.

Mr. JARMAN. Thank you very much.

Are there any questions?

Mr. ROGERS of Florida. No questions, Mr. Chairman.

Mr. NELSEN. No questions.

Mr. SATTERFIELD. No questions.

Mr. MACKAY. No questions.

Mr. JARMAN. Thank you very much for your contribution. We are nearing 12 o'clock, and the convening of the House. It is possible to go on for a few more minutes, perhaps, until a quorum call, but time is now becoming a factor in our hearing this morning.

The next two witnesses are Mr. Melvin Block and Dr. Maurice L. Tainter.

I mention the time element before welcoming you here this morning, and if either of you is in a position to make a short presentation to the committee, summarizing your position on the bills, it might be preferable to call on you, rather than have one of you start on longer testimony with no possibility, perhaps, of completing.

STATEMENT OF MELVIN BLOCK, ATTORNEY, BROOKLYN, N.Y.

Mr. BLOCK. Mr. Chairman, I am Melvin Block. I will make a short statement. A more detailed documented statement with statistics, reports, and documents is also being given to the reporter for the record.

(The additional material submitted will be found in the committee's files.)

Mr. JARMAN. We are not trying to shut off any testimony before the committee. There will be another session of the committee on these bills, but we will be very glad to hear from you, Mr. Block.

Mr. BLOCK. With your permission, Mr. Chairman, my name is Melvin Block. I am appearing as an interested private citizen not associated with any organization or any group. I am a private attorney, engaged in a private practice of law and formerly a police judge and prosecuting attorney in the village of Massapequa Park in New York.

Now I am here due to a moral urgency and conscience, so to speak. Those of you who are attorneys know that after a certain case, sometimes there remains the need to do something about material discovered in the processing of the case and which gave rise to the case, and the end of the case is not really the true end, especially where a request is made that the record be impounded.

I am here to support the bill in general, but ask this committee in their deliberations and in their ultimate decision, to include adequate labeling and design of dynamite blasting caps by the individual manufacturers of dynamite blasting caps, under the provisions of the Child Safety Act.

I am happy to say that since contacting this committee, and since the preparation of my statement, I am informed that Commissioner Goddard is now of the opinion that a dynamite blasting cap is a hazardous substance. Hence, I will address myself to the aspect of the act which deals with the banning of hazardous substances, where adequate labeling in and of itself is insufficient to protect the public.

We have been talking about drugs and pharmaceuticals this morning; however, a blasting cap is different from these items: a blasting cap nearly always results in blinding, maiming, or killing of the innocent victim, who finds a shiny object, and does not know what it is, and as a result thereof, tampers with it, experiments with it, and plays with it, and ultimately, is rendered without hands to play with anything else.

I am happy to say that the National Society for the Prevention of Blindness, pursuant to a suggestion I made, contacted Senator Magnuson, when they had hearings this past Friday on this bill, and they are in favor of legislation covering the dynamite blasting cap situation, and a copy of that letter is included in my statement submitted herewith.

(The letter referred to follows:)

NATIONAL SOCIETY FOR THE
PREVENTION OF BLINDNESS, INC.,
New York, N.Y., August 22, 1966.

Hon. WARREN G. MAGNUSON,
Chairman, Senate Commerce Committee,
Washington, D.C.

DEAR SENATOR MAGNUSON: The National Society for the Prevention of Blindness is deeply concerned about eye injuries caused by dynamite blasting caps. These tragic accidents are *preventable* causes of blindness.

Proper labeling of dynamite caps emphasizing the dangers involved would offer some protection.

I respectfully urge that your committee consider an amendment to the present Federal Hazardous Substances Labeling Act, P.L. 86-613, Sec. 17 to cover proper labelling of blasting caps.

Cordially yours,

JOHN W. FERREE, M.D.,
Executive Director.

Mr. BLOCK. I only have to present a few tragic situations, Congressman Jarman, to illustrate the point and the danger involved. In an Iowa classroom, an 11-year-old boy traded a notebook for a small object one of his friends had found in a neighboring field.

The object was a shiny metal cylinder, and the boy was anxious to find out what it contained. About the time school was to be dismissed, he took out his pocket knife, and began to investigate.

Suddenly, there was an explosion that rocked the classroom. The boy was killed. He had traded his notebook and his life for a dynamite cap.

In Oklahoma, Congressman Jarman, three cousins were blinded in both eyes—six eyes—with a total loss of vision—after the explosion of a dynamite blasting cap.

In one of our Southern States, a boy found a blasting cap, bit into it, and was killed.

In Coram, Long Island, three farm boys found blasting caps which had been stored on a farm for many years. One of the boys hit one with a hammer. The 10-year-old boy was killed, the 8-year-old boy was blinded in both eyes, and the 3-year-old boy was rendered blind in one eye.

After contacting your committee, I read an AP dispatch in the New York Times of August 1 of this year which states:

> Two boys were killed and three injured yesterday when a box of detonator caps exploded in a group of boys playing near a refuse dump.

We all know that recently a radium capsule was lost, and there is a nationwide search on for it. That is only one capsule. I venture to say that there are hundreds of caps strewn around the country, a virtual minefield.

I notice that you gentlemen are perusing a placard sent in by the trade organization of the manufacturers, the Institute of Makers of Explosives. The unfortunate part is, kids don't find the placards. They find the caps, and the individual manufacturers should have the responsibility to design and label and distribute their caps safely. What it stated as legend on the placard should be legend on the caps, and the caps should be designed to that it contains an adequate warning that "this can kill"; "this can blind"; "this can maim"; "call police"; "do not touch."

Furthermore the cap should be designed that only an expert can detonate it, one with a certain expertise in the field, and not a child who can heat it, scratch it with a nail, drop it.

There are even reported cases of workmen who negligently put it in the pockets of their shirts, and the body heat sets it off and they are killed.

I have in my submitted prepared statement statistics running from 1947 to the present time, and here are some of the explosives industries own reported figures they run from figures of 99 up to 139, 128, and these are not ingestions of pharmaceuticals that are subsequently pumped out. How many unreported tragedies are there? How many near misses? How many over 17 years of age? These statistics only go to 17.

They are permanent eyes that are lost, they are hands that are blown off, and they are children who are killed. It is a fait accompli.

The lost, the blown off hands, and the dead child, is final and irreversible. Now I have in my hand newspaper statistics, and clippings of individual children killed, blinded, and maimed, and it only covers a 3-year period, and they were obtained through discovery proceedings in Federal court, and it is a harrowing story. They are being presented for the record.

This item which is inherently dangerous, had no warning whatsoever up until 1955. The reason that a warning which says, "dangerous, explosive," was required to be put on in 1955, and I submit that that warning is still insufficient, because the words "dangerous explosive" may mean nothing more to a child than a type of explosive he uses in a cap pistol, or a firecracker, but the reason that came about in 1955 is that in 1953, in the State of Ohio, a child found a little shiny object.

He took it home. He showed it to his father. His father did not know what it was. He showed it to his uncle. His uncle did not know what it was. He dropped it. Boom, two eyes gone.

The Lions International, which is interested in sight conservation, obtained for this boy a braille typewriter, and became interested in this case. They went to the Ohio Legislature and spoke to a very fine, dedicated, conscientious lawmaker, who had previously been instrumental in passing antifireworks legislation. Then Ohio passed a law making it mandatory that every cap sold in that State have the words "dangerous, explosive" and prescribed a penalty for failure to do so.

As to time delay in effective dates of legislation, which certain industry groups have requested today, this may be of interest to you gentlemen: That though this accident happened in 1953 in Ohio, in March of 1953, the manufacturers asked the Ohio Legislature to make it effective January of 1955, in order to exhaust inventory. In the interim, approximately a hundred kids were maimed, blinded, or killed.

The individual manufacturers know, from their own placards, from their own literature, which they send out sporadically, that this is a dangerous situation, and these placards state:

> Don't touch, these are blasting caps, high explosives. They are not playthings. Leave alone. It may be the last thing you touch. You may have nothing to touch with, after this.

Well, kids don't find placards, they find blasting caps, which are high explosives.

My children have never seen this. I venture to say that many of you gentlemen may not have known, prior to looking at this placard, what a blasting cap was.

I venture to say many of your children and grandchildren do not know what it is, and yet it is a lethal weapon.

The trade association even has a spot filmed by Mickey Mantle or Willie Mays which is on television once in awhile, which says that a blasting cap exploded at home plate will have enough power to propel fragments into center field. But what have the individual manufacturers done? Where is the competition for safety between them?

As to another aspect of the design of this item: One of the children whom I represented still has metal fragments in his eye, which cannot be removed because they are not magnetic. There is no reason for this. Why, knowing that children will find it, foreseeing that blasters will lose them, foreseeing that they will cache them away instead of putting them in a magazine, knowing that these are practically talismanic that kids will ultimately come up with them, why don't they design it so that when a child does get injured, he will be able to have proper medical care, and give the doctors an even chance to render his full services to the child?

The trade association also puts out a film which has this as its brief story. A boy, Chuck, 12, and his pal, Tag, 11, find a blasting cap, while playing in a field.

They plan to toss it into an outdoor grill during a birthday celebration, and scare Katy, 8, a neighbor's child. The boys know the cap will make "a big noise," but not that it could cause serious injury to all of them.

The story has a considerable drama and suspense, but the ending is happy and positive.

Unfortunately, there are many parents and children today who not in filmdom but in actuality are living the more unhappy ending, with sightless eyes, missing hands, and a memory of a child at a certain age.

This has come about, and here, I think, is the essential vice in the situation, because, by agreement, the safety of this item is left to the manufacturer's Institute of Makers of Explosives, their trade association, which basically is their legislative and public relations arm and which shares an office with the Sporting Arms Manufacturers Association in New York, as witness this statement by an institute and company high official—

> Well, we find it impractical to imprint on the cap itself anything that would stay and we have never found a suitable way to do it, so we have felt we are doing a better job in this area by putting our money into advising people that children and others in the field of the proper use of these instruments, than trying to mark something that might not stay on the cap.

The public suffers because safety design by the manufacturers is abdicated to the trade association and there is no competition in safety for the public's benefit.

The same source stated that in 1959, approximately $40,000 was spent by the Institute of Makers of Explosives for its blasting cap safety campaign. The individual companies should have redesigned and retooled instead.

Now, this sum is spent by an industry consisting of some of the largest chemical and explosive companies in the world, and they continued to manufacture and design their caps without any warning and allocating a portion of its trade association budget for safety, until the tragedy in Ohio in 1963, about which I spoke a bit earlier, forced legislation.

The Ohio law says now—

> No person shall normally sell or distribute any blasting cap or electric blasting cap after January 1, 1965, unless the words dangerous explosive are legibly printed thereon.

Though the effective date of this legislation was October 10, 1963, in March of 1963 the industry requested that the cutoff date be January 1, 1965, in order to exhaust their inventory. No problem in retooling, marking, or redesigning was mentioned as previously stated so I say here that I don't think there would be any problem in redesigning if this bill is passed.

Though the State of Ohio has taken the first step, the wording it requires is inadequate to describe the true dangerous nature of the product, or the product itself, labeling of both the cap and the tag with wording, "This will kill"; "This will blind, this will maim, do not touch, call police, dynamite." There should be a graphic illustration of a child being injured as appears on one of the placards by the trade association.

There is a tag on many of these caps, and it is used as a mode of communications by the manufacturers themselves, because the tag has on it a numeral which denotes to the blaster the amount of milliseconds in which the cap will detonate, after the catalyst, after the electricity is applied, so the manufacturers themselves are using a tag, as a means of conveying information, and hence, in their own minds, feel that it will ultimately reach an ultimate person, who must rely on that information.

As I said——

Mr. NELSEN. Mr. Chairman, at this point, you say, a tag. Is this a piece of paper that is used?

Mr. BLOCK. Well, different manufacturers have different tags, and they are generally on the electric blasting cap, Congressman. Some are metallic, almost tinlike tags. Others have—are sort of laminated cardboard, but I say that is insufficient, too, and only supplementary.

I say that something should be embossed, engraved on the cap itself; and in this concept of embossing, I hope to have the opinion of the former supervisory blasting inspector of the city of New York, who says that that can be done, and that should be done to prevent these horrible tragedies.

The caps should be made longer—you have the placards there—so that sufficient information should be contained on it. No reason why the cap can't be redesigned.

I am holding the trade association's most recent placard, after the Ohio law. Prior to the Ohio law, you have no legend, "Dangerous explosive," on it at all. The electric caps, naturally, are the ones with the wire, the two top ones. The bottom caps are what are called fuse caps. A child finding that bottom one, I venture to say, thinks he is finding a firecracker.

Mr. NELSEN. Will this print withstand weathering?

Mr. BLOCK. Well, that, I frankly do not know but I venture to say that the manufacturers in this field, with slogans such as "better things for better living through chemistry," certainly can find adequate chemical processes to have adequate design and adequate labeling for that.

Mr. NELSEN. Don't most of the accidents involve old caps that have been carelessly left somewhere, and picked up.

I am wondering about deterioration of any marking on a cap that might have been lying around. I can remember that when I was a little youngster, I found a dynamite cap on the shelf in the granary of of our farm. It had been there a long time.

Mr. BLOCK. Yes, sir.

Mr. NELSEN. Fortunately, nothing happened, but it could have happened.

Mr. BLOCK. Yes, sir.

Mr. NELSEN. I presume there are others like it. I wonder about the mark on such a cap. Would it endure, lying there for so long? How could we be sure of it? That is the thing.

Mr. BLOCK. I personally do not possess the scientific knowledge, but I have spoken to others who have, and they say it can be done, both by embossing, tags, and redesign. All I can say is that these manufacturers certainly have the scientific experts, if anyone. They advertise permanent paints, they come up with new products by the score. The institute lists among its members Du Pont, Hercules, American Cyanamid, Commercial Solvents, Atlas, and others. Also, the cap should be designed and encased so that only an expert can use it.

Mr. CARTER. Would you yield?

Mr. NELSEN. Yes.

Mr. CARTER. I have seen quite a few of these accidents, and I know it is quite a problem.

I have seen children maimed and their eyes blown out. However, I doubt if labeling the cap is going to do much good. I feel perhaps that a stricter accounting by the companies which sell them, and to the people who use them, would probably be more effective. If you see a little cap there, such as this, it is hard for a child to read on them anything.

The chances are they won't read these things. Like the gentleman from Minnesota, what is labeled on there might wear off. And children might get hold of them who can't read or write.

In fact, many of them do. You see 3- and 4-year-old children get hold of these things. I feel that even perhaps that we might be working at the wrong end and perhaps a stricter accounting of the caps, stricter control of them, might be more effective.

Thank you, Mr. Chairman.

Mr. BLOCK. In response to that, if I may, Mr. Chairman, I have statistics here also obtained from the manufacturer in my case, broken down into age group, into sex for every year, running from 1957 to the present, and these charts, these statistics show that the majority of the children who are injured are in the age group from 9 to 16, and hence they can read the elementary words which are what I gave in my presentation.

Of course, better licensing control of blasters which would have a better control of the distribution of explosives, and better magazine

laws and control is helpful, and needed. I mean it transcends this immediate problem, also. It goes into the other problems, such as various groups obtaining explosives and using them to dynamite for their own purposes. But the trade association states in its own literature that despite the best of care, caps are lost and misplaced.

I am saying at this point that the manufacturers have it within their control to adequately label and design these items. I don't gainsay the idea of having better controls over blasting and better blasters contributions, and magazine control. They are not mutually exclusive. Everything helps.

Mr. NELSEN. Mr. Chairman, I might point out that a number of years ago, I blasted a rock on the farm, and the hardware merchant asked me how long a fuse I wanted.

I told him I wanted one long enough so I could run at least a half mile. The explosion was very successful, however.

Mr. BLOCK. You see, Congressman, at least you knew what you were handling. The child does not. He is literally playing with dynamite.

Mr. NELSEN. Very true. Very dangerous.

Mr. BLOCK. And that, I am saying, may be the rationale for Commissioner Goddard's statement that it is a hazardous substance, because it is used on farms for stump blasting, rock blasting, posting, and drainage, and all of the other myriad needs.

Mr. JARMAN. Mr. Block, the House is now in session, and we are going to have to terminate shortly.

Mr. BLOCK. All right, I appreciate the time, Congressman Jarman, and all I say is at this point, to quote the great Irish playwright, Sean O'Casey, if you consider as he does that it is against the law of nature for parents to bury their children, but rather children should bury their parents, I beseech you to pay heed to my recommendations.

(Mr. Block's full statement follows:)

STATEMENT OF MELVIN BLOCK, ATTORNEY, BROOKLYN, N.Y.

Re Adequate labeling and design of dynamite blasting caps under the child safety bill.

Mr. Chairman, Members of the Committee:

My name is Melvin Block. I am an attorney engaged in the private practice of law and formerly was acting Police Judge and Prosecuting Attorney of Massapequa Park, New York.

I here represent no one but a love of children, a duty to my profession and my own conscience.

Once in a while in the hurly-burly of an active practice, after a case is completed, there still remains a moral urgency so compelling to do something to remedy a wrong which gave rise to the case, that something should be done and in response to that moral directive I am here.

I ask that your Committee amend the present Federal Hazardous Substances Labelling Act, P.L. 86-613, so that dynamite blasting caps are included.

During the course of representing two children against one of the major manufacturers in a case that has been concluded and in the course of processing another matter against another manufacturer now pending, material and statistics obtained disclose that over the years children are rendered blind, maimed, deaf, killed and otherwise injured because of lack of proper labelling and warning on dynamite blasting caps.

Some examples are as follows:

In an Iowa classroom, an eleven year old boy traded a notebook for a small object one of his friends had found in a neighboring field. The object was a shiny metal cylinder and the boy was anxious to find out what it contained. About the time school was to be dismissed, he took out his pocket knife and began to investigate. Suddenly there was an explosion that rocked the classroom. The boy was killed. He had traded his notebook—and his life—for a dynamite cap.

In Oklahoma, three cousins were blinded in both eyes after exploding a dynamite blasting cap.

In one of our Southern states a boy found a blasting cap, bit into it and was killed.

In Coram, Long Island, N.Y., three farm boys found blasting caps which had been stored on the farm for many years. One of the boys hit one with a hammer. The 10-year old boy was killed, the 8-year old boy was blinded in both eyes, and a 3-year old boy was rendered blind in one eye.

After contacting your Committee I read an A.P. dispatch in the New York Times of August 1, 1966 which states: "Two boys were killed and three injured yesterday when a box of detonator caps exploded in a group of boys playing near a refuse dump."

There is no need to go on with the chronicling of this toll of tragedy. The statistics and newspaper clippings which I offer as a part of the record are eloquent testimony of the havoc worked upon the young and their families.

A prior study of the statistics of the National Association for the Prevention of Blindness reveals that 11% of traumatic blindness suffered by schoolchildren is caused by dynamite blasting caps and dynamite.

Your Honorable Committee is here today discussing, among other things, the regulation of aspirin and other items. I respectfully submit to you that there is no more dangerous product in a child's hands than when a child is literally—and we don't need quotes for this—playing with dynamite. The lost eye, the blown-off hand and the dead child is a fait accompli, final, irreversible.

The annexed statistics and clippings reveal that no section and no child is immune from this hazard. They occur in urban, suburban and rural areas.

All these accidents have a tragic common denominator: The children do not know what these shiny, innocent looking objects really are and their lethal consequences. I venture to say that many members of this Committee, and perhaps the majority, cannot identify a dynamite blasting cap. Ask your children and your grandchildren and see what response you obtain. I venture to say that they do not know what it looks like.

The amount of mayhem is set forth in the following accident statistics (exhibits A–C) tabulated by the Institute of Makers of Explosives who obtain their statistics from a press clipping service and its member companies:

EXHIBIT A

Report of blasting cap accidents [1] by age group and sex, 1957–65

Age	1957		1958		1959		1960		1961		1962		1963		1964		1965	
	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls	Boys	Girls
1 to 4	5	2	6	0	0	2	2	1	0	0	3	0	0	1	0	0	1	1
5 to 9	42	6	42	6	37	2	29	5	12	0	19	6	20	2	10	1	9	0
10 to 14	58	4	69	2	64	5	49	5	40	6	22	0	31	0	26	0	30	0
15 to 16	19	1	14	0	18	0	8	0	6	0	3	0	5	0	8	0	15	0
Total	124	13	131	8	119	9	88	11	58	6	47	6	56	3	44	1	55	1
Yearly total	137		139		128		99		64		53		59		45		56	

[1] The above data is based upon clippings provided by a professional news reading service which contracts to scan carefully every daily and weekly newspaper published in the United States. This service forwards reports on every explosion and blast appearing in print. Among doctors and hospitals it is the practice to advise police of treatment of wounds that result from explosions, without regard for the blast source or seriousness of the injury. Police records are reviewed daily by news reporters and almost invariably find their way into print.

Thus, within reasonable limits of time, expense, and practicable survey methods, this statement is presented as the most complete report that can be rendered on numbers of accidents involving youth under age 17 suffering injury from a blasting cap explosion.

EXHIBIT B

Blasting cap accidents, 1958–62—Children injured—By States in order of frequency

State	1958	1959	1960	1961	1962	5-year total
Pennsylvania	26	8	6	4	9	53
California	9	3	8	6	9	35
New York	3	6	9	8	1	27
Texas	4	18	4	0	1	27
Ohio	6	6	7	3	1	23
Michigan	9	6	2	3	1	21
Florida	4	2	9	1	2	18
Tennessee	5	4	2	5	1	17
West Virginia	2	8	1	3	2	16
Virginia	5	7	2	0	1	15
Wisconsin	5	5	1	2	2	15
New Jersey	5	1	3	4	0	13
Washington	6	2	2	0	3	13
Connecticut	2	1	6	3	0	12
Indiana	4	3	3	2	0	12
Minnesota	8	1	2	1	0	12
North Carolina	2	3	4	3	0	12
Arizona	3	3	3	2	0	11
Georgia	0	5	2	4	0	11
Oregon	1	3	5	1	0	10
Arkansas	0	6	0	0	3	9
Idaho	4	1	1	0	3	9
Colorado	0	6	2	0	0	8
Illinois	4	1	2	1	0	8
Kentucky	2	0	2	1	3	8
Massachusetts	2	4	0	2	0	8
Iowa	4	2	1	0	0	7
South Carolina	1	0	0	1	5	7
Kansas	3	1	2	0	0	6
Oklahoma	1	0	0	1	3	5
Rhode Island	1	3	1	0	0	5
Missouri	0	1	2	0	1	4
New Mexico	2	0	2	0	0	4
Alabama	2	1	0	0	0	3
Maine	0	2	1	0	0	3
Nevada	0	3	0	0	0	3
Hawaii	0	0	1	1	0	2
Louisiana	0	1	0	1	0	2
New Hampshire	1	0	1	0	0	2
Wyoming	2	0	0	0	0	2
Delaware	0	0	0	0	1	1
Mississippi	0	0	0	1	0	1
Montana	1	0	0	0	0	1
Utah	0	1	0	0	0	1
Vermont	0	0	0	0	1	1
Total	139	128	99	64	53	483

EXHIBIT C

Blasting cap accidents, 1963–65—Children injured—By States, in order of frequency

State	1963	1964	1965	State	1963	1964	1965
Pennsylvania	11	12	6	Texas	0	0	4
California	5	4	8	Connecticut	0	0	1
New York	8	5	4	Arkansas	0	0	0
Ohio	5	6	7	Colorado	1	0	2
Tennessee	1	3	2	Maryland	1	0	2
West Virginia	2	3	0	Missouri	1	0	1
Georgia	4	0	0	Alaska	0	0	2
Massachusetts	2	3	1	Hawaii	0	0	1
Washington	2	1	2	Indiana	0	0	0
Idaho	0	0	3	Mississippi	0	1	0
Michigan	0	1	1	Vermont	1	0	0
South Carolina	0	0	0	Delaware	0	0	0
Virginia	3	2	0	Kansas	0	0	1
Wisconsin	1	0	1	Louisiana	0	0	0
Florida	2	0	0	Maine	0	0	1
Arizona	2	0	1	Rhode Island	0	0	1
Illinois	2	1	1	Oregon	0	0	0
Kentucky	1	0	0	Utah	0	0	1
Minnesota	4	0	0	Wyoming	0	0	1
New Jersey	0	1	0				
North Carolina	0	2	0	Total (3-year total: 160)	59	45	56
Oklahoma	0	0	1				

You will note that the statistics pertain to children up to the age of seventeen. We do not know how many more involve children over the age of 17 and adults. It is fair to assume that every accident does not make the newspapers. What about the many near misses where devastation has been averted in the nick of time? The majority of reported cases involve children who are able to read. The average age is 11.

The manufacturers have been derelict and to blame because since the inception of the industry they know that blasters would lose, displace, cache away blasting caps and children would find them with the inevitable end result. They also know that sometimes children would pilfer these items with the same woeful ending. Foreseeing all this, they did nothing to label their caps and their tags with an adequate warning identifying it and stating the harm and injury it could cause. Adequte and all-encompassing warnings should be on the caps, but instead it is on placards—children find caps, not placards.

Here are industry's own words on its literature: "Dont touch. These are blasting caps. They are dangerous. High explosives. They can hurt—blind—even kill. Blasting caps are used to explode dynamite. *They're not playthings.* If you find one, tell a policeman, fireman, sheriff, military unit. Remember—leave blasting caps alone—don't touch."

"Hi, kids. This is Mickey Mantle. Here you see me hitting out a few in batting practice." Some sports writers refer to this as blasting.

There's another kind of blasting that's necessary for America's progress. It's the kind you see here.

Dynamite for that big explosion was set off by little blasting caps like these.

Sometimes caps are lost around construction jobs, around mines, on farms . . . other places.

If you see one, don't touch it. Call a sheriff or a policeman or a fireman and tell him where it is. Again, don't touch it—it's dangerous.

It's so powerful that if one were exploded at home base, it could hurt someone standing as far away as center field.

Don't ever play with a blasting cap. Save your hands and eyes—you need them.

"More than 100 million blasting caps are used every year in the United States for construction and building, for mining and quarrying. Without them, heavy industry would be impossible. In industry, blasting caps are used only by explosive experts—men highly trained to handle these sensitive explosives safely. Men who see to it that they're stored, handled and transported with the greatest security and safety possible. But despite their efforts, a few of the 100 million blasting caps do manage to become lost, strayed or stolen. And when they get into the wrong hands, the results can be tragic.

When handled improperly, blasting caps can cause serious injury, or even death. The one and only way for you to avoid this danger is not to handle them.

This poster shows what blasting caps look like, full-size. If you see one, don't touch it. Call a policeman, fireman or sheriff. He'll contact someone who can safely and properly dispose of it.

Remember, in untrained hands, blasting caps can be very dangerous. So if you find one, don't touch. You may end up with nothing to touch with."

"All blasting caps are dangerous when held by uninformed, untrained, or careless hands.

Each blasting cap contains a highly sensitive and powerful explosive. This is required since these little caps must pack a big enough wallop to set off dynamite and blasting agents which are necessary in various types of mining and construction work.

Heat from friction (rubbing), a flame (matches, candles, or stove) can cause a blasting cap to explode.

A jolt (from dropping on a hard surface) or a blow (from a hammer or shoe heel), even a light rap, can cause a cap to blow up.

Picking at the cap's contents (with an ice pick or screw driver or a stick) will cause it to detonate.

Electric current from a flashlight battery or household lighting system or any source will make a cap explode.

These are the most common things children do to make blasting caps "go off", intentionally or accidentally, almost always with tragic results. Boys and girls must be taught that blasting caps are not playthings, no matter how shiny and attractive they may appear to a child's searching eyes and inquisitive fingers.

What to do when you spot a blasing cap:

Note carefully where it lies—Don't Touch It! If accompanied by a friend, send him to report "the find" to a policeman, fireman, sheriff, or other adult. You stand guard to prevent anyone from disturbing the blasting cap.

If alone when you find a blasting cap, don't touch it! Mark the spot by dropping your handkerchief, and carefully note features of the nearby area such as trees, paths, rocks, or bushes that will guide you back to where the cap lies. Then immediately report it to a law enforcement officer or an adult.

Blasting caps should only be removed by a competent, informed adult. Don't try to move or pick up the cap yourself. Leave it to an expert.

Why "Don't touch it!"?

An exploding blasting cap can maim—blind—deafen—even kill. Yes, the shattering explosion of this little metal tube, a blasting cap, can do all these things. When it detonates, a blasting cap may throw hundreds of small fragments in all directions for a distance of several hundred feet with sufficient force to cause painful puncture wounds. Held in the hand, an exploding blasting cap can tear off fingers. Injuries caused by a blasting cap can be tragic beyond one's imagination. And all such accidents are needless and preventable.

Be smart! Be safe! Don't touch blasting caps!

"But even the best safety practices cannot eliminate all accident hazards. That's because of the 'human factor.' A thoughtless workman may leave a cap unaccounted for. Mischievous boys may break into storage magazines and steal them. More often caps are lost, misplaced, or hidden away presumably out-of-reach.

"Yet children do find these caps and play with them. The result can be serious injuries. Some children lose fingers, hands, or toes. Others are blinded. Some have been killed."

The Institute of Makers of Explosives have a film entitled, "Blasting Cap—Danger!". The following is its description of the safety message mentioned in the film:

"The safety information is constructively presented in this episode: Chuck, 12, and his pal, Tag, 11, find a blasting cap while playing in a field. They plan to toss it into an outdoor grill during a birthday celebration and scare Kathy, 8, a neighbor's child. The boys know the cap will make a 'big noise', but not that it could seriously injure all of them. The story has considerable drama and suspense, but the ending is happy and positive."

Unfortunately, there are many parents and children today who, not in filmdom but in actuality, are living a more unhappy ending, one with sightless eyes, missing hands, and a memory of a child at a certain age.

This has come about because the individual companies, by agreement, have abdicated their safety responsibility in the design and labelling of their own individual products and shifted the manufacturer's safety responsibility to the Institute of Makers of Explosives, its legislative and public relations arm, as witness this statement by an Institute and company official:

"Well, we find it impractical to imprint on the cap itself anything that would stay and we have never found a suitable way to do it, so we have felt we're doing a better job in this area by putting our money into advising people, the children and others in the field, of the proper use of these instruments, than trying to mark something that might not stay on the cap."

The same source stated that in 1959 approximately $40,000, was spent by the Institute of Makers of Explosives for its blasting cap safety campaign.

The industry consisting of the largest chemical and explosives companies in the world, continued to manufacture and design their caps without any warning and allocating a portion of its trade association budget for safety until some time in 1964.

A tragedy occurred in the State of Ohio in 1963, when a boy found a shiny object and asked his father what it was and his father did not know. It was subsequently set off by some means by the boy resulting in almost total loss of vision of both eyes. The Lions Clubs of Ohio, an organization interested in sight conservation vigorously pursued the enactment of a dynamite blasting cap labelling law which reads as follows: Ohio Code Supp. Section 3442.091. "No person shall normally sell or distribute any blasting cap or electric blasting cap after January 1, 1965 unless the words 'Dangerous Explosive' are legibly printed thereon."

Though the effective date of this legislation was October 10, 1963, in March of 1963 the industry requested that the cut-off date be Jan. 1, 1965 in order to exhaust their inventory. No problem in design or retooling was mentioned.

Though the State of Ohio has taken a first step, the wording it requires is inadequate to describe the true dangerous nature of the product or the product itself. Labelling of both the cap and a tag with wording which states: "This will kill"—"This will blind"—"This will maim"—"Do not touch"—"Call police"—"Dynamite" and a graphic display of injured children being blasted is in order and should be required. An appropriate symbol should be included. The present wording required by the State of Ohio in and of itself to a child may mean nothing more in terms of potency than the type of cap children use in a cap pistol.

Many of the blasting caps used in the industry today do have tags with the manufacturer's name and a numeral on it to indicate to the blaster the amount of time involved between the ignition and the explosion. Hence, the industry itself is using the tag for a means of communication. It should be used to communicate to the children the true nature of the instrumentality. The entire cap should be redesigned so as to make it impossible for one not having expert knowledge of the product to detonate it. Further, one of the chilren whom I represented was rendered blind in one eye and still has fragments of the cap in his eye. The fragments cannot be removed because they are non-magnetic. The cap should be designed so as to prevent this medical problem.

The need for federal regulation in the area (1) to provide a uniform pattern; (2) to deal with Interstate Commerce; (3) to provide leadership for the States in this endeavor; is demonstrated by the following letters:

E. I. du Pont de Nemours & Co., Inc.,
Explosives Department, Sales Development,
Wilmington, Del., September 12, 1963.

Mr. Melvin Block, Esq.,
Brooklyn, N.Y.

Dear Mr. Block: Your letter to the Du Pont Company requesting information on labeling blasting caps has been referred to me, and I find that there has been no successful efforts in the past to label individual blasting caps with a warning or description of their dangerous nature, mainly due to the lack of space on the cap and no reliable material for making a legend readable. Of course, the boxes in which caps are sold contain appropriate warnings.

There is also room for doubt that any wording adopted would deter either children or adults from carelessly handling caps or endeavoring to detonate them, since experience has shown that accidents involving caps are usually the result of intentional efforts to explode them.

Yours very truly,

N. G. Johnson,
Industry Manager,
Sales Development Section.

COMMONWEALTH OF PENNSYLVANIA,
DEPARTMENT OF LABOR AND INDUSTRY,
Harrisburg, September 12, 1963.

Mr. MELVIN BLOCK,
Attorney at Law,
Brooklyn, N.Y.

DEAR SIR: This will acknowledge receipt of your letter of August 30, 1963, addressed to the State of Pennsylvania, Bureau of Mines, and forwarded to this office for disposition.

The Regulations governing manufacturing, sales and the disposition of electric blasting caps clearly indicate that each explosives package must be labeled before it can be shipped or transported interstate or intra-state. However, the Division of Mines, Quarries and Explosives would not be in favor of each individual cap being identified by either imprinting or by other means that it is an explosive article.

Rules and Regulations of the Commonwealth of Pennsylvania fully cover this situation by clearly stating and making it mandatory that all explosives used within the Commonwealth of Pennsylvania must be kept or maintained within a State approved, licensed and locked magazine.

Very truly yours,

WILLIAM P. YOUNG,
Secretary of Labor and Industry.

DEPARTMENT OF THE INTERIOR,
BUREAU OF MINES,
Washington, D.C., October 2, 1963.

Mr. MELVIN BLOCK,
Brooklyn, N.Y.

DEAR MR. BLOCK: Your letter of August 30, 1963 to the Federal Coal Mine Safety Board of Review has been referred to this Agency by Mr. Back, Secretary of the Board.

I am pleased to report that the manufacturers of blasting caps in this country are now preparing to alter their manufacturing process to include marking the shell of every cap. The words "Explosives, Dangerous" will be placed on each cap in letters as large as possible. They estimate that it will be six months to a year before their plants will be completely prepared for the new marking procedure.

We appreciate your interest in this problem and hope that the new warning will assist in preventing these deplorable accidents.

Sincerely yours,

GLENN H. DAMON,
Staff Research Coordinator—Explosive,
Office of the Director—Coal Research.

A bill was introduced in the House in 1955 (84th Congress, 1st Session, H.R. 3721) requiring the labelling of blasting caps. It never got out of Committee. The statistics submitted are a result in part of the demise of that bill. Who knows what other bills there were.

Mr. Chairman, members of the committee, if you believe as I do in the sentiment expressed by the Irish playwright Sean O'Casey that it is against the law of nature for parents to bury their children; children should bury their parents, then I beseech you for our own sake to amend the Federal Hazardous Substances Labelling Act so as to include the proper design and labelling of blasting caps as set forth in my statement as a minimum standard.

The item itself may very well be deemed a household item in that it is stored and used on farms for blasting of stumps and rocks, soil and sub-soil blasting, tree planting, drainage, foundation and excavation chores, water holes, digging post and pole holes and splitting logs. The statistics and newspaper clippings submitted herewith show the frequency of accidents to young farm boys.

In any event, an amendment is needed.

For the children's and God's sake, do **something!**

Mr. JARMAN. Thank you.

Are there any questions?

Mr. MACKAY. Mr. Chairman, as a lawyer, I would just like to commend Mr. Block for coming out of the courtroom into the legislative hall. I am interested as a former State legislator who participated in banning fireworks in Georgia, that the District of Columbia permits the sale of fireworks.

Mr. BLOCK. I was surprised to see that when I got off the plane, too. I think it is shocking.

Mr. GILLIGAN. If the gentleman will yield. I bought $10 worth of the fireworks in the District of Columbia last year, and did not get a loud fizzle out of the whole bag. [Laughter.]

Mr. JARMAN. Any other questions?

Mr. SATTERFIELD. No questions.

Mr. JARMAN. Mr. Block, we appreciate your being with us to comment on this very serious problem.

Mr. NELSEN. A very fine statement.

Mr. JARMAN. The House is in session, and the subcommittee will stand adjourned, subject to the call of the Chair.

(Whereupon, at 12:17 p.m., the subcommittee adjourned, subject to call of the Chair.)

CHILD SAFETY ACT AND PERSONNEL TRAINING

MONDAY, SEPTEMBER 12, 1966

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to notice, in room 2218, Rayburn House Office Building, Hon. John Jarman (chairman of the subcommittee) presiding.

Mr. JARMAN. The committee will come to order.

We will continue our hearings today and our first witness this morning is Dr. Maurice L. Tainter, Sterling Drug, Inc., of New York.

Dr. Tainter, you may proceed.

STATEMENT OF DR. MAURICE L. TAINTER, VICE PRESIDENT, STERLING DRUG, INC., AND VICE CHAIRMAN, STERLING RESEARCH BOARD; ACCOMPANIED BY JAMES L. LUTHER, VICE PRESIDENT, LEGAL AFFAIRS, STERLING DRUG, INC.

Dr. TAINTER. Mr. Chairman, may I introduce my associate, Mr. James Luther, who is an attorney for Sterling Drug.

Also, I have a written statement prepared here, but I will deviate from that at a number of places because I have charts to show, and I would like to request with your permission, to have my statement spread on the record so that we can get complete coverage.

Mr. JARMAN. Without objection, it may be done.

(The prepared statement of Dr. Tainter, with accompanying curriculum vitae, follows:)

STATEMENT OF DR. MAURICE L. TAINTER, VICE PRESIDENT OF STERLING DRUG INC., AND VICE CHAIRMAN OF THE STERLING RESEARCH BOARD

This statement of Dr. Maurice L. Tainter for Sterling Drug Inc. is submitted to aid the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce in its consideration of Section 2 of H.R. 13886. The curriculum vitae of Dr. Tainter is attached hereto for the information of the subcommittee.

Section 2 would impose a quantity limitation on aspirin and salicylate-containing products intended for use by children. Literally, it would also apply to adult aspirin and all products containing aspirin or any other salicylate if their labeling contained directions for use by children. We understand that such a broad coverage of products was not intended by the bill's proponents. Rather, we are advised that this section is intended to cover only the children's aspirin in 1¼ grain tablets and other salicylate-containing products primarily intended for use by children. The testimony in support of the bill presented on June 24 makes it quite clear and specific that the alleged problem sought to be solved by this quantity limit involves only the children's products, and not the adult ones. We assume, therefore, that a clarifying amendment will be adopted at the appropriate time. The balance of this statement is based on that assumption.

Under this Section FDA would be authorized to issue regulations limiting the total quantity of children's aspirin or other forms of salicylic acid contained in a retail package to an amount to be determined arbitrarily by FDA which will not be "likely to cause deaths or serious injury if ingested by a child of tender age at one time". Failure to comply with such a regulation would render the product legally adulterated and, therefore, subject to multiple seizures.

Sterling Drug Inc. does not oppose appropriate limitations on the quantity of aspirin in packages of children's products. We nevertheless question the need to handle this matter by legislation. As was done in 1955, so today, problems of this type can best be handled through voluntary cooperation among the FDA, the medical profession and industry. This method is more flexible and will permit taking prompt advantage of new packaging techniques and encourage the development of new knowledge about the phenomenon of children's accidental ingestions of foreign substances. Up to 28% of children involved in accidental ingestions are "repeaters", i.e. they have been "poisoned" one or more times previously. See: Wehrle, P. F. et al.: *The Repeater Problem in Accidental Poisoning*, Pediat. *27*:614, Apr. 1961; Sobel, R. et al.: *Repetitive Poisoning in Children: A Psychosocial Study*, Pediat. *35*:641, Apr. 1965. This certainly suggests that the problem is much more complex than simply the availability of a potentially harmful substance. Research is currently going on designed to obtain greater scientific understanding of the entire phenomenon and all its aspects. Notwithstanding, Sterling Drug Inc. does not oppose legislation in this area if such is deemed necessary. We do earnestly urge, however, that such legislation be based upon complete information and firmly established facts and that due consideration be given to the amounts of children's aspirin that doctors and mothers need to treat childhood diseases.

For many years Sterling Drug Inc. has manufactured Bayer Aspirin for Children—one of this country's leading children's aspirin products. In fact, and in order to put a dimension on this subject, Sterling Drug Inc. itself has distributed eight billion six hundred and thirty-nine million (8,639,000,000) tablets of Bayer Aspirin for Children in the ten year period 1955–1965. You will recall that Mr. Solmson estimated a yearly use of 50,000,000 bottles or 2,500,000,000 tablets.

Our marketing policies and practices (including the limitation to 50 1¼ grain tablets per package) have conformed strictly to the 1955 recommendations of the FDA sponsored FDA-profession-industry conference on children's aspirin. We regret that the FDA has not reconvened this conference instead of asking for the present farreaching legislation. We stand ready to follow the recommendations of such a conference today.

In testimony before this Subcommittee on June 24th it was stated that the purpose of this Bill was to save the lives and health of infants and young children who ingest an overdosage of children's aspirin—the 1¼ grain tablets. It is doubtful that further limiting the amount of children's aspirin in a single bottle will accomplish this worthy end, for reasons which are set forth below. What is certain is that such a limitation will seriously interfere with the proper medical use of children's aspirin. What is also certain is that such a limitation will not lessen, but will probably increase, the number of cases of accidental ingestion of children's aspirin. Until the real cause of this problem—adult negligence and carelessness—is attacked head-on no significant increase in "Child Safety" should be anticipated from legislation of this type.

A. CHILDREN'S ASPIRIN—THERAPEUTIC REQUIREMENTS

Why is children's aspirin packaged in bottles of 50 1¼ grain tablets? The answer is simple. This was agreed to by all interested experts, including the FDA, to be the right size of bottle, as I will explain in more detail below. Large amounts of children's aspirin are needed by mothers and prescribed by doctors in treating childhood diseases. For example, according to Nelson's Textbook of Pediatrics (8th Ed. W. B. Saunders Co., Phil., London, 1964) (see fig. 1) the children's aspirin dosage that doctors initially prescribe for acute rheumatic fever is from 19 1¼ grain tablets per day for a two year old to 28 tablets per day for a five year old. Within the same age spread, the prescribed dosage of children's aspirin for rheumatoid arthritis ranges from 16 to 23 tablets per day; for pyrexia (fever) the range for the two to five year old is from 10 to 24 tablets per day. For children over five years of age, the prescribed dosage is correspondingly higher. Even the safe home medication dosage of children's aspirin given on the label ranges between 5 tablets per day for a three year old to 15 such tablets per day for a seven year old. It might also be pointed out that in families where more than one youngster is ill, as when a winter cold goes through the family, the

daily children's aspirin requirement is multiplied several times. It is apparent that a bottle containing only 25 tablets would last only one day under many circumstances. A mother would therefore be compelled in an ordinary illness either to buy a new bottle every day or to purchase a number of them at one time.

Since doctors, especially pediatricians, prescribe children's aspirin in reliance on its being in the home in adequate quantities, one thing is certain: Mother will find a way to follow the doctor's orders where her children's health is concerned.

B. STATISTICS OF ACCIDENTAL INGESTIONS ARE UNRELIABLE AND MISLEADING

The statistics of child mortality due to accidental ingestion of aspirin are confusing and misleading, even to the experts, because national figures quoted in these hearings do not differentiate among baby aspirin, adult aspirin, combination products containing aspirin, other forms of salicylic acid, or even the highly toxic oil of wintergreen (methylsalicylate). In other words, they are all lumped together into one statistic under the International Classification System of Diseases heading of "Aspirin & Salicylates". (See fig. 2.) The best data available shows that about one-half of all the deaths ascribed to salicylates are due to oil of wintergreen and not due to aspirin at all. (See fig. 3.)

A great information gap apparently exists concerning these statistics. On June 24, the following statement was made to this Subcommittee in support of Section 2:

> "The statistics (the latest report of the Division of Vital Statistics, Public Health Service) lead us to one inescapable conclusion—every three days a child dies from an oversdose of children's aspirin". (Report of Proceedings, p. 6.)

Since this conclusion was stated to be based on reports from the Public Health Service, a search was made of the appropriate publications of the Division of Vital Statistics, Public Health Service, U.S. Department of Health, Education, and Welfare. Our search confirmed our statement above that no official published report, including the latest one of the Division of Vital Statistics, broke down the reports of salicylate deaths into the specific salicylates or dosage forms allegedly involved. Then written inquiry was made of this Division to determine if this information were available although unpublished. The response dated July 19 was "no" and the explanation follows:

> "With respect to the questions contained in your letter of July 13, the mortality tables contained in the chart (the basis for the June 24 Statement) were taken from data tabulated by the Division of Vital Statistics. *They obtain their information from death certificates supplied to them on a confidential basis.* They tabulate in terms of chemicals or products causing fatality, not in terms of size of dosage. A death due to phenobarbital would be tabulated as a barbiturate death whether it was a 30 mg. or 60 mg. tablet. Also, "in some cases, the strength of the tablet may not be shown. *Therefore, we cannot supply data on the number of deaths that were caused by children's aspirin or adult aspirin . . .*" (Emphasis supplied.)

Following are several typical examples of other aspects of this "information gap." Here is an experience that actually occurred in the home of one of Sterling Drug Inc.'s executives. A maid who brought her young child to her employer's home one day suddenly noticed the youngster playing with an empty bottle that had contained 100 medicinal tablets. The maid, frightened, shouted to the housewife that the child had swallowed the tablets. Since the child showed no symptoms, after medical consultation no immediate action was taken except to keep the child under strict observation. A week later the maid found all of the tablets behind one of the cushions on the sofa on which her child had played.

If this incident had been reported to a Poison Control Center or a hospital, it would have been recorded and forever inscribed in the statistics of "accidental poisonings". How many other such incidents are reflected in the statistics of "accidental poisonings"? No one knows, because these reports, including reports of fatalities, are rarely investigated.

Another example is the Mayo Clinic's experience with patients allegedly suffering from salicylate intoxications during the 10 year period of 1953 through 1962. Their observations were reported in the August 16, 1965 (page 85) Journal of the American Medical Association. The authors stated that during this 10-year period 308 children under seven years of age were seen at the Mayo Clinic because of "salicylate ingestion." The records of the Clinic show that not one of these children actually showed any symptoms of salicylate intoxication. In that entire period the Mayo Clinic had only one record of a fatality from salicylate

intoxication and that was of an 18 month old child who had swallowed an undeterminated amount of oil of wintergreen, which is methylsalicylate.

The problem of obtaining accurate information on this problem is complicated by the fact that inaccurate terminology is frequently (though unintentionally, of course) used by those who compile or refer to this information. For instance, as exemplified by the testimony already given in support of this bill on June 24, the phase "accidental poisonings" is regularly used to refer to what are really "accidental ingestions" and/or therapeutic overdosages. As an example, on line 14, p. 5 of the June 24 *Report of Proceedings*, the following appears ". . . in 1965, 16,328 children under five were reported *poisoned* from the accidental ingestion of aspirin and other salicylates." This number apparently came from Table 2 of the May–June 1966 Bulletin of the National Clearing House for Poison Control Centers which is entitled "Accidental *Ingestions* Among Children Under 5 Years of Age." Thus the very emotional label of "poisoning" is applied to all reports of actual or suspected accidental ingestions of aspirin even though the child involved has no symptoms or, in fact, has actually swallowed only a therapeutic dose or even less. About 90% of the reported accidental ingestions cause no symptoms so that poisoning is definitely not present in them.

Another reason why the reliability of statistics on this subject must be questioned arises from a very human and understandable frailty. Most of these reports are necessarily based upon a mother's hasty information given at a time of high emotion and perhaps colored by her own remorse for having been negligent in administering or safeguarding the medicine involved. Experienced people know well the unreliability of information obtained under such circumstances from even the best-intentioned persons.

C. RECORDS OF DOCUMENTED FATILITIES

Our company, Sterling Drug Inc., one of the leading manufacturers of children's aspirin, does not have a single documented record in its files of a child fatality from its product. Additionally, in a recent study at one of the leading Poison Control Centers in which all available information on salicylate fatalities in several cities of the United States during periods of up to thirteen years was reviewed, only four reported cases of death following overdosage of children's aspirin were found. Furthermore, the circumstances associated with these fatalities, and the dosages, are not known. You will also recall that in the detailed data cited by Mr. Solmson for Illinois in 1965 there were 45 children's deaths from poisoning of which 12 were ascribed to salicylates, but only one of these was children's aspirin.

D. SAFETY OF CHILDREN'S ASPIRIN

The medical literature contains reports of children three years and younger who are supposed to have taken the equivalent of as many as 278 tablets of children's size aspirin without injury. In fact, there is an even more fantastic report that a three year old and a one year old between them consumed the equivalent of 667 1¼ grain tablets without injury to either one.[1] Some do not believe that these children consumed the amounts reported but the report does exist and, if nothing else, it exemplifies the unreliability of much published data on this problem.

To give another example, the National Clearing House for Poison Control Centers reports that in 1965 there were 16,328 cases of ingestion of aspirin-containing tablets by children under five years of age. Records regarding hospitalization were available for 11,308 of the children. Of these, 9,889—or 87.4%—were not hospitalized for even one day.[2] This is consistent with other reports to the effect that about 90% of reported cases of supposed aspirin poisoning had no symptoms from ingestion of the tablets.

On June 24, Dr. Palmisano, Acting Deputy Director of the FDA's Bureau of Medicine, advised this Subcommittee that the toxic dose (not the lethal dose) for an average two year old—from two to four years are the ages in which almost all accidental ingestions occur—was "about 22" 1¼ grain flavored aspirin tablets and that, therefore, "Somewhere in the neighborhood of 29 to 25 tablets of 1¼ grain aspirin "flavored would seem to be the place where you have to cut it off * * *" (*Report of Proceedings*, p. 38). Dr. Palmisano arrived at this estimate (20 to 25 tablets) by applying the age-weight method of dosage calculation. This method is undoubtedly safe and very conservative but it is not universally ac-

[1] Winters, R. W., White, J. S., Hughes, M. C. and Ordway, N. K.: Pediat. *23*:260, Feb. 1959.
[2] Table 5, May–June 1966 Bulletin, National Clearing House for Poison Control Centers, U.S. Dept. of HEW, Public Health Service.

cepted. For instance, Dr. Harry C. Shirkey, Director of the Children's Hospital in Birmingham, Alabama and a recognized authority in this field has stated in 1965:

> "From careful clinical observation it has been repeatedly noted that *dosage based on weight* is not a reliable method of dosage determination. This is especially true in the infant. If an infant is dosed proportionately using the adult dosage as standard, the infant is underdosed (based on weight)."
>
> * * * * * * *

He also says:

> "*Dosage based on age* shows great limitations when one considers the variability of weight in even the normal children of a given age."
>
> * * * * * * *

Finally:

> "The surface area of the body has become a valuable basis for determining drug dosage and fluid requirements not only for children but for the entire post-infantile periods of life (adults as well)." (*Italic* is author's). Shirkey, H. C.: *Dosage-Posology Handbook*, American Pharmaceutical Assn., pp. 6, 7 (1965).

By application of the Surface Area method the toxic dose of aspirin for an average two year old would be 47 grains for 38 1¼ grain tablets, which emphasizes that the 20–25 tablets limit suggested by Dr. Palmisano is probably lower than necessary or desirable.[3]

Rather than relying on the somewhat indefinite opinions of those who may not have had much personal experience with the toxicology of aspirin, we have gone to the published literature to survey and summarize for this Hearing the actual facts as they are established by the weight of the published scientific articles on this subject. We have brought together here the data on all published individual cases between 2 and 5 years of age in which the dosage and age were definitely given. We reviewed over 200 medical articles for this purpose covering the years 1947, when this product was first used, to the present. In these articles 123 cases of aspirin ingestion in 2 to 5 year old children were described.

The amount of aspirin swallowed is marked on this chart (see fig. 4) for each case according to the age. The deaths are marked by crosses and the survivals by circles. Also marked on the chart are the amounts of aspirin that would be contained in 25 and 35 tablet bottles as well as the present 50—1¼ grain size. You can see that there is only 1 fatality which comes within even the 50 tablet line.

In the 2½ year old child there was a very serious blood disease present so that the child was in critical condition before the aspirin was taken. The other fatal cases received aspirin doses greater than that of even a full bottle of 50 of the present tablets.

The table also shows how large the doses are that children this age can take and yet recover. It might also be pointed out that aspirin is different from many other drugs or hazardous substances in that it does not damage the vital organs in such a way as to leave any significant permanent injury after overdosage. Recovery from overdosage is therefore usually prompt and complete.

Based on these data, and the total weight of the medical evidence, it is clear that the lethal dose of aspirin for a 2 year old child is above 78 grains or 62 1¼ grain tablets (400 mg. per kg. body weight), and the toxic dose for such a child is well above the 47 grains or 38 tablets suggested by the surface area dosage formula.

We believe therefore that the present bottle of 50 tablets is very safe, particularly when you take into account the 50,000,000 bottles a year being used with a mortality rate, I estimate, of only ten to twelve per year from both accidental ingestions and therapeutic overdosage of these children's aspirin tablets. If it is felt that legislation on this matter is needed, then a 35 tablet size would widen the margin of safety by about one-third. A 25 tablet bottle referred to earlier in these hearings would go still further. However, as I have already indicated, as you decrease the size of the bottle below the amounts required for ordinary use, you create the need for multiple bottles to be kept on hand and thus increase the opportunity for accidental ingestion and reduce the safety.

---

[3] The formula for using surface area is as follows for a 2 year old:

$$\frac{\text{Surface area of child's body}}{\text{Surface area of adult's body}} \times \text{adult dose (toxic)} = \text{child's dose (toxic)}$$

or

$$\frac{.57}{1.7} \times 140 \text{ gr.} = 47 \text{ grains or } 38 \text{ 1¼ tablets}$$

E. CAUSE OF THE ACCIDENTS—ADULT NEGLIGENCE

There is no set pattern in how a child comes to get an excessive number of aspirin tablets. However, published studies show that in about two-thirds of cases it is because the bottle was not in the medicine chest—in other words, through adult carelessness. (See fig. 5.) Very astonishing is the published data that about 25% of the cases are in children with previous history of accidental ingestion. (See fig. 6.) They have possibly a psychological drive to attract attention or to frustrate their parents.

Also, published reports show that from 14% to 74% of so-called aspirin poisoning cases are due to the administration of an over-dosage by the mother, either on her own or on the recommendation (mistaken or otherwise) of a physician.[4] (See fig. 7.)

These cases obviously are not "accidental" in the accepted sense, yet they are included in the statistics as "accidents". It is not necessary to mention here that limiting the number of tablets in the bottle would not reduce this substantial proportion of the total aspirin incidents at all.

F. THE SOLUTION TO THIS PROBLEM IS EDUCATION

Responsible heads of drug manufacturing companies are greatly concerned about the proper use of their products, especially with respect to their efficacy and safety. There can be no question that adult carelessness with potentially toxic materials is the real culprit in childhood poisoning. *But carelessness cannot be abolished by legislation.*

Realizing this, members of the drug industry recently formed the Council on Family Health. This non-profit group was created to attack this whole problem in the most effective way—through mass education. The principal target is Mother, keeper of the family health; and through all media the Council is distributing materials that alert Mother, and others, to the problems of home safety—and how to overcome them.

G. INDUSTRY'S RECORD OF COOPERATION AND CARE

The drug industry is in the business of helping and healing people and not of hurting them. Because the industry recognizes its responsibility in this area it has developed many safeguards over the years to help eliminate the misuse of medicinal preparations.

The government, the professions and industry have been cooperating for years in the matter of Children's Aspirin. For example, an article in the Drug Trade News of February 28, 1955 reported the agreement reached at a conference called by the FDA on the accidental misuse of children's aspirin and attended by the representatives of the American Academy of Pediatrics, the American Medical Association, various groups interested in accident prevention, the FDA and industry. The recommendations of that conference have been followed exactly by Sterling Drug Inc. and all the other leading manufacturers. Today practically 100% of the children's aspirin tablets marketed comply with the following recommendations of that conference:

(1) Children's aspirin bottles to be limited to a maximum of 50 tablets.
(2) The tablets to be standardized to 1¼ grains each.
(3) On the specific choice of the medical profession children's aspirin tablets continue to be flavored.
(4) The industry has urged through labeling that parents keep all medicines out of the reach of children.
(5) The industry has provided detailed dosage recommendations for specific indications and for specific ages to assure a safe and proper dosage. And finally,
(6) The best presently available safety closure is universally used.

If we make the bottle cap too difficult to remove we defeat our purpose for the mother will simply fail to put it back on the bottle. Even so, pharmaceutical manufacturers have never stopped their efforts to develop improved safety closures. Sterling Drug Inc. is planning to market Bayer Aspirin for Children with a still

[4] See the following reports:
1. 74%—Segar, W. E. and Holliday, M. A.: *Physiological abnormalities of salicylate intoxication*, New Eng. J. Med. *259*:1191, Dec. 1958
2. 69%—Riley, H. D., Jr. and Worley, L.: *Salicylate intoxication*, Pediat. *18*:578, Oct. 1956
3. 28%—Winters, R. W., White, J. S., Hughes, M. D. and Ordway, N. K.: Disturbances of acid-base equilibrium, Pediat. *23*:260, Feb. 1959
4. 50%—Rose, N. J. (State of Illinois Department of Public Health) to Poison Control Centers Sep. 24, 1965

further improved closure very shortly. Incidentally, during these years consumer and market tests have been conducted by us to determine the acceptability of children's aspirin sold in strip packs in which each tablet is separately wrapped. Consumers did not like this type of packaging and preferred the conventional type of bottle.

Mr. Rogers asked Mr. Solmson if it would be possible to leave out the flavor of the children's aspirin (page 183). This question was debated at the 1955 conference. The physicians there believed that the flavor did not add appreciably to the hazard, and greatly improved the acceptability of aspirin to the sick child. They therefore preferred that the tablet be flavored. The American Medical Association, the FDA and the manufacturers agreed to this decision, so such tablets are now usually flavored.

H. THE LEGISLATED MINIMUM

If Congress feels the necessity to reduce by legislation the quantity of children's aspirin per bottle this should be 35 1¼ grain tablets. Due recognition must be given to the fact that a bottle of tablets after the sealed carton has been opened for the first use, thereafter always contains less than the original number. The fact, as discussed in Section D, that 90% of the children involved in accidental ingestions of salicylates show no symptoms at all suggests that in most instances the children do not consume the entire contents of a bottle—either out of choice or because it is not full. Although adequate statistics are not presently available on this point, what there are suggest that more than two-thirds of the reported cases of accidental ingestion of children's aspirin involve taking substantially less than 50 tablets, and over one-half involve ingestions of 25 tablets or less.

The first portion of this statement set forth the relatively large numbers of children's aspirin tablets required to treat childhood diseases. If the quantity permitted by law in one bottle is too low, mother through necessity to meet the dosage needs of her children will purchase several bottles at one time—thus multiplying the availability of the tablets in the home. The greater number of bottles available in the home, the greater the opportunity for children to experiment. Dr. Palmisano admitted this fallacy in the demand for an excessively small bottle when he admitted that he expected the mothers would buy a lot of the small bottles (page 40).

Another practical and important aspect of reducing the container to even 25 tablets is the effect such a reduction will have on the effectiveness of the smaller label as a medium of communication. The important dosage and warning information, which by law and by good medicine we place on the labels of our children's aspirin, would become so small in type size as to virtually be illegible. It would be a distinct disservice to the public if this information were to become unreadable or if it were removed entirely from the label—yet if the bottle size is materially reduced, what alternative is there? And will the consumer who needs this information benefit?

Mr. Rogers raised the question (page 85) with Dr. Stetler of the desirability of first aid instructions on the bottle. It would not seem wise to put directions on the bottle of how to treat suspected aspirin overdosage for several reasons. In the first place, about 9 out of every 10 reported cases of accidental ingestion never have any symptoms of overdosage, and the child may have swallowed none or only insignificant amounts of the tablets. Secondly, in the remaining 10% of the children the first treatment is to evacuate the stomach. Vomiting is not easy to induce, particularly by an excited mother in the home. There is no good emetic commonly available in homes which can be relied on to invariably produce prompt and copious vomiting. Syrup of ipecac has been recommended for this use, but it is found in very few homes and may take as long as 30 minutes to take effect. If the mother has to go to the drug store for it, she might as well take the child to the doctor's office or hospital. The aspirin remains in the stomach long enough without causing damage that a reasonable time can be taken to getting it out.

There is no specific antidote for aspirin, which would neutralize it in the stomach like bicarbonate of soda would neutralize an acid. In authentic poisoning cases the stomach needs to be washed out by passing a stomach tube, which can only be done by experienced personnel. The most useful first aid directions would be to put on the label the warning statement "In case of accidental overdosage call your physician or hospital at once."

Mr. Rogers also asked Dr. Stetler (page 86) why first aid directions are suitable for packages of hazardous substances but not for drugs. The materials covered

by the Hazardous Substances Act are in general corrosives, irritants, caustics, etc., which do damage immediately on contact with the body. Speed of neutralization or removal is therefore an important factor in preventing injury. It is much less important with aspirin since symptoms of overdosage may take as long as 12 hours to appear.

For these and other reasons we believe the proposed legislation limiting the quantity of children's aspirin per bottle will not have the desired effect of eliminating or decreasing alleged fatalities and alleged injury due to accidental ingestion. As a matter of fact, such legislation could actually increase *misuse* of the product by creating greater availability in the home. Calls to the nation's Poison Information Centers would probably increase, thereby further inflating these already unreliable statistics.

As a matter of high public interest, if the maximum quantity of children's aspirin per bottle is to be limited through legislation rather than the present voluntary agreement, Congress should specify the limit and not delegate this responsibility to an administrative agency which would set the limit by arbitrary regulation. Delegation of such authority by the Congress is entirely unnecessary. No scientific question exists. Nothing can be gained through regulatory fiat in this situation. Based on FDA's own statements here, Congress can set a limit of 25 1¼ grain tablets and be excessively safe, or based on this present statement and other authorities in this Hearing, Congress can select a limit of 35 1¼ grain tablets and also be more than safe. The 35 tablet limit is especially preferable because it goes farther towards providing enough children's aspirin per bottle to cover several days of therapeutic use in treating one child's illness. Moreover, whether the maximum limit limit be 25 or 35 tablets, the fact of the matter is that, on an overall average, after the bottle is first opened it will probably contain only a fraction of the maximum number specified.

Whether or not the Congress specifies the maximum number, if legislation is decided upon, FDA should be empowered by Congress to increase the number of tablets when better closures become available, and if the product is made available in strips of tablets or in any single tablet dispensing forms. The regulatory process would be appropriate here because these are possible, not actual, situations and these criteria are measurable objectively. Thank you for your attention.

Curriculum Vitae—Maurice Lane Tainter, M.D.

Dr. M. L. Tainter was born in Carroll, Iowa, on May 10, 1899.

Stanford Univerity: A.B., 1921; A.M., 1924; M.D., 1925. D.Sc., Hon., 1951, Rensselaer Polytechnic Institute.

Brief Chronology of Career

1926–27: Fellow, National Research Council, Johns Hopkins Medical School.

1930: Volunteer Worker, Pharmacological Institute of Royal Pharmaceutical Society of Great Britain, London.

1922–43: Assistant, 1922–1924; 1924–1927, Instructor; 1927–1929, Assistant Professor; 1929–1935, Associate Professor; 1935–1943, Professor, Department of Pharmacology, Stanford University Medical School; 1934–1943, Professor of Pharmacology; 1940–1943, Head, Department of Physiological Sciences, College of Physicians and Surgeons Dental School, San Francisco.

1943–47: Professor of Applied Physiology, Albany Medical College.

1943–46: Director of Research, Winthrop Chemical Company.

1946–60: Founding Director, Sterling-Winthrop Research Institute.

1946 to date: Vice President, Sterling Drug Inc.

1960 to date: Vice Chairman, Sterling Research Board.

Professional and Civic Activities, Memberships, etc.

Chairman: Board of Trustees (1963–65); Life Trustee (1963 to date); Term Trustee (1954–62) Rensselaer Polytechnic Institute.

Trustee: Albany Medical College (1956–63).

Member: Board of Governors, Union University (1950–56).

Member: Board of Visitors, Harvard Medical School and School of Dental Medicine (1957–63).

Trustee: Albany College of Pharmacy (1950–65).

Member: Research Advisory Board, Columbia University School of Pharmacy (1958 to date).

Member: National Association of Manufacturers Committee on Research (1960 to date).
Member: Research and Development Section, Pharmaceutical Manufacturers Association.
Consultant: Army Chemical Center (1954–63).
Member: Advisory Council, Graduate Research Center of the Southwest (1963 to date).
Member: Industrial Advisory Committee to Cancer Chemotherapy, National Service Center (1957–60).
Member: New York State Advisory Council for the Advancement of Industrial Research and Development (1960 to date). Vice Chairman (1966 to date).
Member: New York State Commissioner of Education's Committee on Reference and Research Library Resources of New York State (1960–62).
Member: Board of Directors, Near East Foundation (1963 to date).
Member: Medical Advisory Board, Council for High Blood Pressure Research (1947 to date).
Trustee: New York Metropolitan Reference and Research Library Agency (1964 to date).
Member: Board of Directors, New York State Foundation for Science and Technology (1965 to date).
New York Academy of Sciences (President 1955; Fellow 1946 to date).
Fellow, American Medical Association (1930 to date).
New York State Medical Society (1945 to date).
Westchester County Medical Society (1961 to date).
American Physiological Society (1929 to date).
American Society of Pharmacology and Experimental Therapeutics (1927 to date).
Society of Toxicology, charter member (1961 to date).
Fellow, American College of Clinical Pharmacology and Chemotherapy, charter member (1963 to date).
American Association for the Study of Headache (1963 to date).
New York Heart Association (1955 to date).
American Society of Anesthesiology (hon.) (1938 to date).
San Francisco District Dental Society (hon.) (1937 to date).
Arizona State Dental Association (hon.) (1938 to date).
California State Dental Association (hon.) (1939 to date).
Fellow, Consular Law Society (hon.) (1957 to date).
Society for Experimental Biology and Medicine.
Society of Pharmacology & Therapeutics, Argentine Medical Association (hon.) (1946 to date).
National Society for Medical Research.
Academy of Science of Havana (hon.) (1951 to date).
Member of Board of Directors and Vice President, Albany (New York) Symphony Orchestra Association (1958–61).
Trustee: Delmar (New York) Public Library (1956–1961).
Member: Museum of Modern Art (1961 to date).
Member: American Physicians Art Association (1963; vice president 1964–66) President-elect (1966 to date).
Honor Societies: Sigma Xi (1923 to date) (scientific); Alpha Omega Alpha (1928 to date) (medical scholarship); Tau Kappa Omega (hon.) (dental); Phi Lambda Upsilon (hon.) (chemistry).
The Newcomen Society in North America.
Sons of the Revolution.
Former Editor-in-Chief, *Stanford Medical Bulletin.*
Member (past or present) Editorial Boards of:
Archives Internationales de Pharmacodynamie et die Therapie
Clinical Medicine
Toxicology & Applied Pharmacology
Author of publications on medical and dental pharmacology, therapeutics, research administration, and history of medical research.
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Business Address: 90 Park Avenue, New York, New York 10016.

Dr. TAINTER. Thank you.

This statement is of Dr. Maurice L. Tainter for Sterling Drug submitted to the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce and is consideration of section 2 of H.R. 13886.

For the information of the committee I might explain a little bit of my background so that you will know from whom your information, these comments, are coming.

I am a licensed physician in both California and New York. I was on the medical faculty of Stanford Medical School for over 20 years, ending as professor of pharmacology there where, during that period of time, I had major responsibility for teaching medical classes what they should know about the action and use of drugs, including toxicology, including, without question, of course, salicylates.

In 1943 I became the research director for Sterling Drug and have been in that capacity operating on the technical side of our company's operations since that time.

Section 2 would impose a quantity limitation on aspirin and on salicylate-containing products intended for use by children. Literally it would also apply to adult aspirin and all products containing aspirin or any other salicylate if their labeling contained directions for use by children. We understand that such a broad coverage of products was not intended by the bill's proponents. Rather, we are advised that this section is intended to cover only the children's aspirin in the 1¼-grain tablets and other salicylate-containing products primarily intended for use by children. The testimony in support of the bill presented on June 24 makes it clear and specific that the alleged problem sought to be solved by this quantity limit involves only children's products, and not the adult ones. We assume, therefore, that a clarifying amendment will be adopted at the appropriate time.

The balance of this statement is therefore based on that assumption.

Under this section, the Food and Drug Administration would be authorized to issue regulations limiting the total quantity of children's aspirins or other forms of salicyclic acid contained in a retail package to an amount to be determined arbitrarily by the Food and Drug Administration which will not be "likely to cause deaths or serious injury if ingested by a child of tender age at one time." Failure to comply with such a regulation would render the product legally adulterated and, therefore, subject to multiple seizures.

Sterling Drug does not oppose appropriate limitations on the quantity of aspirin in packages of children's products. We nevertheless question the need to handle this matter by legislation. As was done in 1955, so today, problems of this type can best be handled through voluntary cooperation of the Food and Drug Administration, the medical profession, and industry.

This method is more flexible, would permit taking prompt advantage of new packaging techniques and would encourage the development of new knowledge about the phenomenon of children's accidental ingestions of foreign substances.

As I will discuss in a moment, up to 28 percent of the children involved in accidental ingestions are "repeaters," that is, they have been poisoned one or more times. This certainly suggests that the problem is much more complex than simply the availability of a potentially harmful substance.

Research is currently going on designed to obtain greater scientific understanding of the entire phenomenon in all of its aspects.

I might say parenthetically that there is a large research study going on at Syracuse U involving the Syracuse Board of Health, on all the factors entering into the production of poisonings in homes.

Notwithstanding, Sterling Drug, Inc., does not oppose legislation in this area if such is deemed necessary. We do earnestly urge, however, that such legislation be based upon complete information and firmly established facts and that due consideration be given to the amounts of children's aspirin that doctors and mothers need to treat childhood diseases.

For many years Sterling Drug has manufactured Bayer Aspirin for Children, and we are one of this country's two leading children's aspirin manufacturers. In fact, and in order to put a dimension on this subject, Sterling Drug itself has distributed 8,639 million tablets of Bayer Aspirin for Children in the 10-year period from 1955 to 1965.

You will recall that Mr. Solmson estimated a yearly use of 50 million bottles or 2,500 million tablets in a year.

Our marketing policies and practices, including the limitation to 50 1¼-grain tables per package, have conformed strictly to the 1955 recommendations of the FDA-sponsored, Food and Drug Administration-profession-industry conference on children's aspirin. We regret that the Food and Drug Administration has not reconvened this conference instead of asking for the present far-reaching legislation. We stand ready to voluntarily follow the recommendations of such a conference today.

In testimony before this committee on June 24 it was stated that the purpose of this bill was to save the lives and the health of infants and young children who ingest an overdosage of children's aspirin, the 1¼-grain tablets. It is doubtful that further limiting the amount of children's aspirin in a single bottle will accomplish this worthy end, for reasons that I will now discuss.

What is certain is that such a limitation will seriously interfere with the proper medical use of children's aspirin. What is also certain is that such a limitation will not lessen, but will probably increase, the number of cases of accidental ingestion of children's aspirin. Until the real cause of this problem, adult negligence and carelessness, is attacked headon, no significant increase in "child safety" should be anticipated from legislation of this type.

Why is children's aspirin packaged in bottles of 50, 1¼-grain tablets? The answer is simple. This was agreed to by all interested experts, including the Food and Drug Administration, to be the right size of the bottle. Large amounts of children's aspirin are needed by mothers and are prescribed by doctors in treating childhood diseases. For example, according to Nelson's Textbook of Pediatrics (see fig. 1), which gives the doses required for different ages, you will see that in acute rheumatic fever the 2-year-old, which is the group we are most interested in here, requires 19 tablets per day; and the 5-year-old, 28 tablets per day.

After the initial saturation with the aspirin has been established, the maintenance dose for continuing medication is 14 to 21 tablets per day for rheumatic fever.

In rheumatoid arthritis the dose similarly is from 16 to 23 tablets per day.

DOSAGE OF ASPIRIN NEEDED PER DAY FOR SEVERAL PEDIATRIC INDICATIONS AND FOR SELF MEDICATION

(Source: Nelson, Waldo E., Textbook of Pediatrics, 8th Ed. W.B. Saunders Co. Phila, London 1964)

AGE (YRS)	AV. WEIGHT KILO	ACUTE RHEUMATIC FEVER				RHEUMATOID ARTHRITIS		PYREXIA		OVER-THE COUNTER DOSAGE
		INITIAL DOSE 130MG/KG/DAY GRAINS	NO 1¼ GR TAB	MAINTENANCE 90MG/KG/DAY GRAINS	NO 1¼ GR TAB	100MG/KG-Q/DAY GRAINS	NO 1¼ GR TAB	IGR 1YR Q4L(4TO6)/DA) GRAINS	NO 1¼ GR TAB	(5 DOSES PER DAY) GRAINS	NO 1½ GR TAB
2	12.4	23.3	19	17.4	14	19.4	16	12	10	NO O.T.C. DOSE	
3	14.5	27.2	22	20.4	16	22.7	18	18	14	5	
4	16.5	30.9	25	23.1	18	25.8	21	24	19	10	
5	18.4	34.5	28	25.8	21	28.8	23	30	24		
6	21.5									10-15	
7											
8	26.8										
9	29.4										
10	32.2									15-20	
11	35.4										
12	39										

FIGURE 1

In ordinary fever, which the doctor treats, the dose ranges from 10 to 24 tablets per day.

On the label of the bottle is the over-the-counter dosage. There is no over-the-counter dosage for those under 3 years old but above this age the dose ranges as you can see from 5 to 15 or 20 per day.

It might also be pointed out that in families where more than one youngster is ill, such as when a winter cold goes through a family, the daily children's aspirin requirement is multiplied several times. It is apparent that a bottle containing only 25 tablets would last only 1 day, or less than 1 day under many circumstances. A mother would therefore be compelled in an ordinary illness either to buy a new bottle every day or to purchase a number of them at one time.

I am sure you will agree with me the pharmacist will assist in this by putting two or three of them together in one package and selling three for a dollar, or something of that sort.

Since doctors, especially general practitioners and pediatricians, prescribe children's aspirin in reliance on its being in the home in adequate quantities, one thing is certain, mother will find a way to follow the doctor's orders where her children's health is concerned.

The statistics of child mortality due to accidental ingestion of aspirin are confusing and misleading, apparently even to the experts, because national figures quoted in these hearings are the total of baby aspirin, adult aspirin, combination products containing aspirin, other forms of salicylic acid, and even the highly toxic rubbing liniment, methyl salicylate or oil of wintergreen. In other words, they are all lumped into one figure under the international classification system of diseases, and heading of "Aspirin and Salicylates."

The best data available shows that about one-half of all the deaths ascribed to salicylates are due to oil of wintergreen, and here I have for example, a chart (see fig. 2) we do not have any national figures on oil of wintergreen, but this chart is representative of what seems to be the situation generally.

Dr. Jacobziner who was the director of poison control activities in New York City for many years until his death last year, reported at two different times the breakdown of fatalities by poisoning in the New York City area under his jurisdiction.

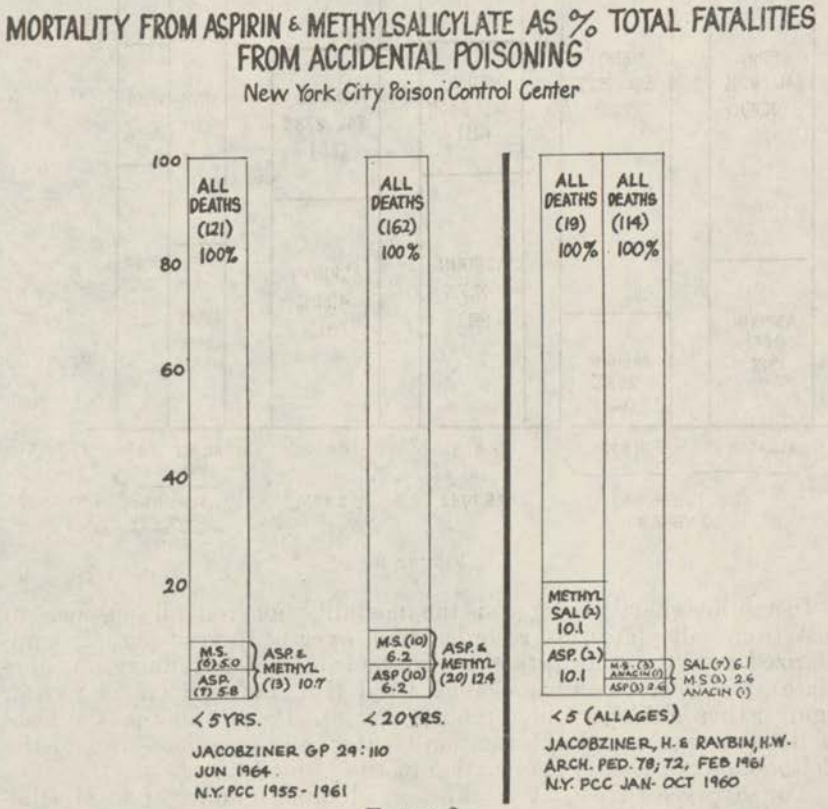

FIGURE 2

In this chart you will see that in the under-5-year group, which is the group we are concerned with, the columns on the left in both cases, that out of 121 poisoning deaths from all causes, there were 6 from methyl salicylate or oil of wintergreen and 7 from aspirin out of a total of 121. At another time, for a different time period, he reports that there were out of 19 deaths in children of this age, there were 2 from oil of wintergreen and 2 from all the other aspirin products put together. All together this chart shows that there were 21 oil of wintergeen deaths as compared to 22 from all the other aspirin products, out of a total of 416 poisoning cases.

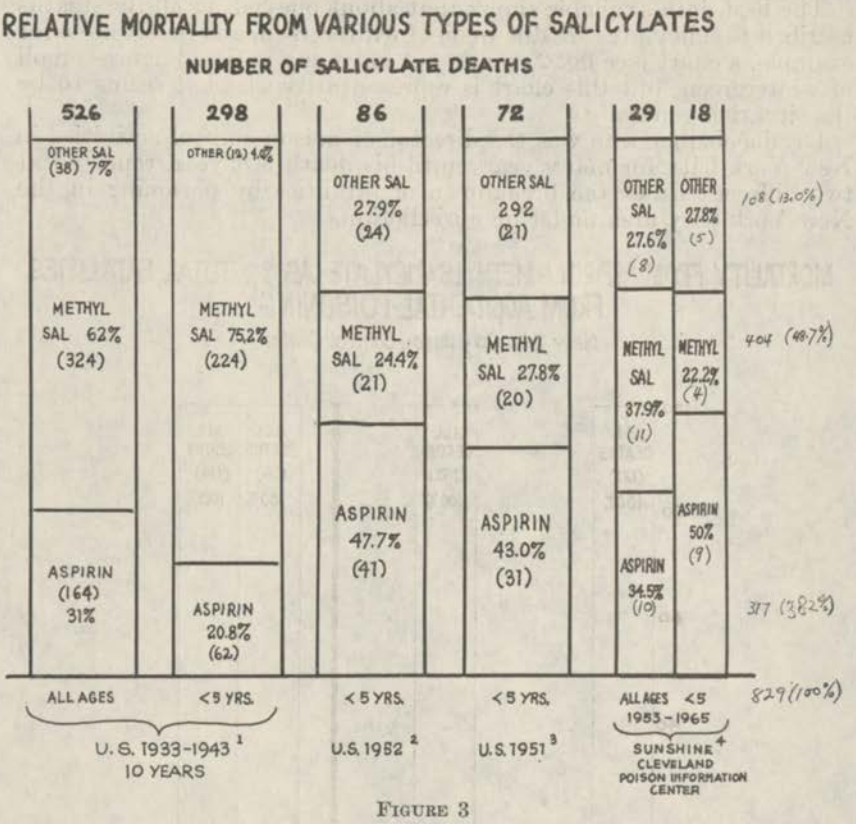

FIGURE 3

In another chart (see fig. 3) is the mortality not from all poisons, but just from salicylates, as recorded first over a 10-year period, summarized in the authoritative book by Gross and Greenberg on salicylates, the second group was 1952, total U.S. Poison Control Center figures, then a Mayo Clinic report; and finally Sunshine as the head of the Poison Control Information Center, and president-elect of the Poison Control Center Association of the United States.

You can see here that of this considerable number of total salicylate deaths methyl salicylate is at least half of the entire category.

I have totaled the under-five category separately, which totals are not shown on your charts. There were 474 deaths from salicylate in these various time periods. Of these 474 in the under-5 group, 269 or 56.8 percent were due to oil of wintergreen or methyl salicylate and not due to all other forms of aspirin combined.

It should be noted that on this latter chart the aspirin figures include all other salicylates, and that they are not broken down to show the children's aspirin share of these total salicylate deaths.

A great information gap apparently exists concerning these statistics. On June 24, at these hearings, the following statement was made:

> These statistics (the latest report of the Division of Vital Statistics, Public Health Service) lead us to one inescapable conclusion—every three days a child dies from an overdose of children's aspirin.

Since this conclusion was stated to be based on reports from the Public Health Service, a search was made by us and others of the appropriate publications of the Division of Vital Statistics, Public Health Service, U.S. Department of Health, Education, and Welfare. Our search confirmed the statement I have just made that no official published report, including the latest one of the Division of Vital Statistics, breaks down the reports of salicylate deaths into the specific salicylate or dosage forms allegedly involved

Then, written inquiry was made to this Division to determine if this information were available, although unpublished. The response, dated July 19, was "No" and the explanation follows, and I quote from the letter.

> With respect to the questions contained in your letter of July 13, the mortality tables contained in the chart (the basis for the June 24 statement) were taken from data tabulated by the Division of Vital Statistics. They obtained their information from death certificates supplied to them on a confidential basis. They tabulate in terms of chemicals or products causing fatality, not in terms of size of dosage. A death due to phenobarbital would be tabulated as a barbiturate death whether it was a 30-milligram or a 60-milligram tablet. Also in some cases the strength of the tablet may not be shown. Therefore we cannot supply data on the number of deaths that were caused by children's aspirin or adult aspirin.

Following are several typical examples of other aspects of this information gap. Here is an experience that actually occurred in the home of one of our Sterling Drug executives.

A maid who brought her child to her employer's home one day, suddenly noticed the youngster playing with an empty bottle that had contained 100 medicinal tablets. The maid, frightened, shouted to the wife that the child had swallowed the tablets. Since the child showed no symptoms, after medical consultation, no immediate action was taken except to keep the child under strict observation. A week later the maid found all the tablets behind one of the cushions on the sofa on which her child had played.

If this accident had been reported to a poison control center, and many of them just this way are, or a hospital, it would have been recorded and forever inscribed in the statistics of accidental poisonings. How many other such incidents are reflected in the statistics of accidental poisonings? No one knows, because these reports, including reports of fatalities, are rarely investigated.

Another example is the Mayo Clinic's experience with patients allegedly suffering from salicylate intoxications during the 10-year period from 1953 through 1962. Their observations are reported in the August 16, 1965, issue of the Journal of the American Medical Association.

The authors stated that during this 10-year period, 308 children under 7 years of age were seen at the Mayo Clinic because of salicylate ingestion. The records of the clinic show that only one of these children actually showed any symptoms of salicylate intoxication or poisoning. In that entire period the Mayo Clinic had only the one record of a fatility from salicylate and that was an 18-month-old child who had swallowed an undetermined amount of oil of wintergreen, which is methyl salicylate.

The problem of obtaining an accurate understanding of the situation is complicated by the fact that inaccurate terminology is frequently, though unintentionally, of course, used by those who compile or refer

to this information. For example, as examplified by the testimony already given in support of this bill on June 24, the phrase "accidental poisonings" is regularly used to refer to what are really "accidental ingestions" and/or therapeutic overdosages.

As an example, on line 14, page 5, of the June 24 report of proceedings, the following appears: "In 1965, 16,328 children over 5 were reported poisoned from the accidental ingestion of aspirin and other salicylates."

This number apparently came from table 2 of the May–June bulletin of the National Clearing House for Poison Control Centers, which is entitled "Accidental Ingestions Among Children Under 5 Years of Age."

Thus the very emotional label of poisoning is applied to all reports of actual or suspected accidental ingestions of aspirin even though the child involved had no symptoms or, in fact, had actually swallowed only a therapeutic dose or even less.

I say this because about 90 percent of the reported accidental ingestions cause no symptoms so that poisoning is definitey not present in 9 out of 10 recorded cases.

Another reason why the reliability of statistics on this subject must be questioned arises from a very human and understandable frailty. Most of these reports are necessarily based upon a mother's hasty information given at a time of high emotion and perhaps colored by her own remorse for having been negligent in administering or safeguarding the medicine involved. Experienced people know well the unreliability of the information that is obtained under such circumstances from even the best-intentioned persons.

Our company, Sterling Drug, one of the leading manufacturers of children's aspirin, does not have a single documented record in its files of a child fatality from its product. Additionally, in a recent study at one of the leading poison control centers in which all available information on salicylate fatalities in several major cities of the United States during periods of up to 13 years was reviewed, only 4 reported cases of death following overdosage of children's aspirin were found.

Furthermore, the circumstances associated with these fatalities, and the dosages, are not known.

You will also recall that in the detailed data, cited by Mr. Solmson, for Illinois in 1965 there were 45 children's deaths from all kinds of poisonings, of which 12 were ascribed to salicylates, but only 1 of these 12 was due to children's aspirin.

Medical literature contains reports of children 3 years and younger who are supposed to have taken the equivalent of as many as 278 tablets of children's size aspirin without injury. In fact, there is an even more fantastic report that a 3-year-old and his 1-year-old brother between them consumed the equivalent of 667 1¼-grain tablets without injury to either one. Some do not believe that these children consumed the amounts reported, but the report does exist and, if nothing else, it exemplifies the unreliability of much published data on this problem.

To give another example, the National Clearing House for Poison Control Centers reports that in 1965 there were 16,328 cases of ingestion of aspirin containing tablets by children under 5 years of age. Records regarding hospitalization were available for 11,308 of these

children, this is in table 5 of these reports which we have referred to several times during the hearings. Of these, 9,889, or 87.4 percent, were not hospitalized for even 1 day. This is consistent with other reports to the effect that about 90 percent of reported cases of supposed aspirin poisoning have no symptoms from ingestion of the tablets.

On June 24, Dr. Palmisano, Acting Deputy Director of the Food and Drug Administration's Bureau of Medicine, advised this subcommittee that the toxic dose, but not the lethal dose, for an average 2-year-old, and from 2 to 4 years are the ages in which most accidental ingestions occur, was about twenty-two 1¼-grain flavored tablets, and that, therefore:

> Somewhere in the neighborhood of 20 to 25 tablets of one and one-quarter grain aspirin flavored would seem to be the place where you have to cut it off.

That is page 38, report of proceedings.

Dr. Palmisano arrived at this estimate of 20 to 25 tablets by applying the age-weight method of dosage calculation. This method is undoubtedly safe and very conservative but it is not universally accepted.

For example, Dr. Harry Shirkey, director of the children's hospital in Birmingham, Ala., and a leading authority in this field has stated:

> From careful clinical observation it has been repeatedly noted that dosage based on weight is not a reliable method of dosage determination. This is especially true in the infant. If an infant is dosed proportionately using the adult dosage as standard, the infant is under-dosed.

At another place he says:

> Dosage based on age shows great limitations when one considered the variability of weight in even the normal children of a given age.

Finally, he says:

> The surface area of the body has become a valuable basis for determining drug dosage and fluid requirements not only for children but for the entire post-infantile period of life, including adults.

By application of the surface area method, and taking adult toxic dose as 140 grains, the toxic dose of aspirin for an average 2-year-old child would be 47 grains, or thirty-eight 1¼-grain tablets, which emphasizes that the 20 to 25 tablet limit suggested by Dr. Palmisano is probably lower than necessary or desirable.

Rather than relying on the somewhat indefinite opinions of those who may not have had much personal experience with the toxicology of aspirin, we have gone to the published literature to survey and summarize for this hearing the actual facts, regarding toxic doses, as they are established by the weight of the published scientific articles on this subject. We have brought together here for the first time, incidentally, the data on all published individual cases between 2 and 5 years of age in which the dosage and age were definitely given, so that we could tabulate them in their appropriate place. We reviewed over 200 medical articles for this purpose covering 20 years, the years from 1947, when this product was first used, to the present. This, incidentally, covers we think almost the entire American literature. There may be an occasional article here and there which we missed, but 200 is a very thorough coverage. In these 200 articles there were 123 cases of aspirin ingestion in the 2- to 5-year-old children described in detail.

I would like to show you at this time a chart which depicts the findings as reported in these articles. (See fig. 4.)

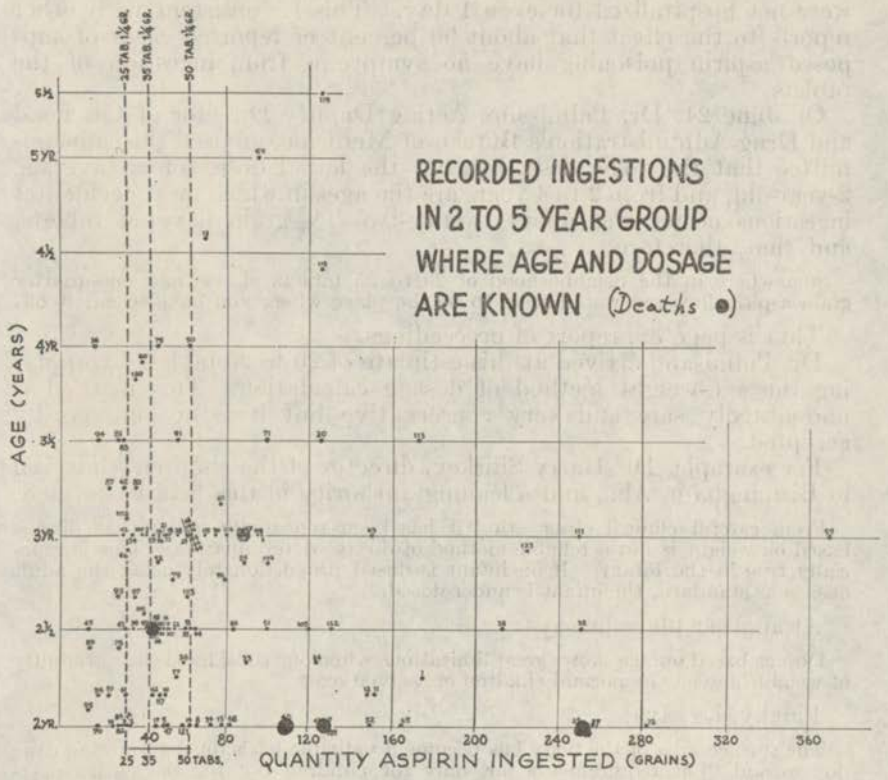

FIGURE 4

On this chart we have a scatter diagram of the age of the child going up the left side, and the quantity of aspirin ingested going across the bottom. We also have drawn on the chart for ease of understanding, 3 dotted lines which represent the dosage of 50 tablets of a 1¼-grain size, and the 35- and 25-tablet sizes so you know where they fall in relation to the reported ingestion cases.

Each one of these cases is represented on here by a dot, and you see a small number beside these dots. These numbers refer to a bibliography of the scientific articles where these case reports are printed so that you can check on any one of them you are interested in, if that is required or requested.

To make it stand out, I have taken the deaths and drawn them as large circles on this chart. The smaller dots are cases which may or may not have had symptoms, but are reported cases of children of that age that took that much aspirin.

You can see that there is 1 child reported, case No. 35, that died from a dose about the 35-tablet size. In reading the history of this case, this was a child of two and a half years of age who was in an advanced stage of deterioration from sickle cell anemia. It had a

hemoglobin content of the blood of only 2.5 grams percent as compared to a normal of 12 to 14 grams.

Sickle cell anemia is a condition where the red blood cells begin to deteriorate and develop a sickle shape with a great loss of hemoglobin and impairment of the child's health and also threat to its life.

This is one child then that died from a dose of aspirin below the 50 grains.

The next fatality recorded, No. 27, is a child that got around 90 grains of aspirin. You can see there are three others on this chart, so there are five fatalities altogether, of which four are legitimately a part of the aspirin poisoning syndrome.

You will note that on the left of the 25-tablet line, the broken line, there are 22, as I have counted the dots, cases reported. In these, 12 of the children had only mild symptoms, 7 had no symptoms at all, and in 3 of the cases, whether there were symptoms or not was not reported, and of course there were no deaths.

In the 25- to 35-tablet range, there are 15 patients. Of these, there was one severe coma, and this was a child who got no treatment for 34 hours after the drug was administered. There were eight that had mild symptoms, three that had no symptoms at all, and two in which we have no information. So we really don't have any serious symptoms at all in this 25 to 35 range.

In the 35 to 50, of course, the symptoms are a little bit heavier, as you would expect, but again there are no deaths until you get up to the 90-grain area.

This table also shows how large the doses are that children of this age can take and recover from without injury.

It might be pointed out here that aspirin is different from many other drugs or hazardous substances in that it does not damage the vital organs in such a way as to leave significant permanent injury after such overdosage. Recovery from overdosage is therefore usually prompt and complete.

Based on these data, and the total weight of the medical evidence, it is clear that the lethal dose of aspirin for a 2-year-old child is somewhat above 400 milligrams per kilogram of body weight, which calculates out to 78 grains, or sixty-two 1¼-grain tablets for our hypothetical 2-year-old child. The toxic dose for such a child is well above the 47 grains or 38 tablets suggested by the surface area dosage formula which I have just quoted.

We believe therefore that the present bottle of 50 tablets has shown itself to be very safe, particularly when you take into account the 50 million bottles a year being used with a mortality rate I estimate of only 10 to 12 per year from both accidental ingestion of these children's aspirin tablets and therapeutic overdosage. If it is felt that legislation in this matter is needed, then a 35-tablet size bottle would widen the margin of safety by about one-third. A 25-tablet bottle referred to earlier in these hearings would go still further.

However, as I have already indicated, if you decrease the size of the bottle below the amounts required for ordinary use, you create the need for multiple bottles to be kept on hand and thus increase the opportunity for accidental ingestion and reduce the safety.

There is no set pattern of how a child comes to get an excessive number of aspirin tablets. However, published studies show that in about two-thirds of the cases, it is because the bottle was not in the right place, in other words, through adult carelessness.

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LOCATION OF SUBSTANCES ACCIDENTALLY INGESTED
EXPRESSED AS PERCENT OF TOTAL CASES

	ON FLOOR OR GROUND	ON OPEN SHELF, TABLE, ETC.	IN UNLOCKED DRAWER OR CABINET	IN MEDICINE CABINET	IN "CHILD-PROOF" FURNITURE	NOT IN USUAL STORAGE PLACE
US P.H. REPORTS 1964						67.7%
CANN ET AL 1958	13%	25%				68 %
MELLINS, R.B., ET AL 1956	13.5%	32.4%	16.3%			
JENSEN, G.D. & WILSON, W.W. 1960	38 %	27%	15%	2%	2%	
CORSA, Z. & ATALLONE 1961 ASPIRIN ONLY	26.6%					10.1 %
WEHRLE ET AL 1960				7.4%		

FIGURE 5

Here we have a chart (see fig. 5) which gives what has been published on this in scientific literature. Here are six published articles which deal with where the bottles were.

On the extreme right you see a column entitled "Not in usual storage place." U.S. Public Health Reports, 1964, which reported the survey of the circumstances surrounding the cases reports a figure of 67.7 percent or in two-thirds of the cases the bottle was in the wrong place.

Dr. Cann, at another time, reported 68 percent.

Drs. Corsa and Atallone reported 10.1 percent of the bottles also not in the usual place.

Some of these authors have tried to find out exactly where the bottle was. Cann found 13 percent of his cases with bottles on the floor; 25 percent were on an open shelf or table.

Mellins had similar figures, he had 16 percent he recorded as in an unlocked drawer or cabinet.

Jensen and Wilson reported 30 percent of the bottles were on the floor and 27 percent on open tables and so on.

In other words, the carelessness of the adult in charge of the child is a very large factor in making this possible.

Very astonishing to me originally was the published data that about 25 percent or one out of every four cases were of children with previous histories of accidental ingestion. (See fig. 6.)

I referred to the Syracuse study a few moments ago. In this Syracuse study trained public health workers are going into 1,500 homes once a month to investigate all the conditions surrounding the placing of poisons and potential hazards. They are trying to educate the householders to proper systems of safety and so forth.

They have told us informally at this time because the study is not finished, that they already feel that they can predict the child and the family in which a poison case is going to occur. There is something in the environment and the presence of an active or hyperactive child, a child which demands attention and so forth that seems to lead it to get into poison scrapes.

I would like to illustrate this from some of the published literature.

THE REPEATER PROBLEM IN CHILDHOOD ACCIDENTAL POISONING

SOURCE	NO. OF CHILDREN	OBSERVATIONS
JENSEN	100	25% REPEATERS
CORSA	466	9% REPEATERS WITHIN 1 YEAR
MEYER	128	7.8% REPEATERS
GRIFFITH ET AL	174	19% REPEATERS WITHIN 1 YEAR
WEHRLE	100	28% REPEATERS (73.8% OF THESE WITHIN 1 YEAR)
KOUMANS	54	7.4% REPEATERS
SOBEL ET AL	20	20 PTS. WITH 151 EPISODES

FIGURE 6

We have seven articles written on this within recent years, and in each report the number of children involved in accidental poisoning cases from each author was a fairly large number, as you can see.

Dr. Jensen, for example, out of a hundred cases that he handled, had 25 percent who were repeaters.

The other high one is Dr. Wehrle, who in a similar group of a hundred children, had 28 percent who were repeaters; and, 73.8 percent, or three-fourths of those repeated within 1 year of their first accident episode. So roughly one-quarter of these children more or less do get into repeated trouble, because of some psychological urge on their part, or perhaps because of a family environment where these poisonings seem to them an attractive thing to get involved in.

Another very serious problem that is not written about much for fairly obvious reasons, is that from 14 to 74 percent of the aspirin poisoning cases are due to the administration of overdoses by the mother, either on her own, or on the recommendation of a physician.

I have here six scientific articles where these facts are broken down and are considered.

Apparently what happens, the doctor will tell the mother over the telephone to give the child one or two or three tablets; and mother gives them, then she gives another an then an hour or two later another, or she misunderstands the doctor and piles the dosage in, or what was an initial large beginning dose is continued. The therapeutic overdosage is a very large factor of the entire poisoning syndrome.

In this table (see fig. 7) that you are now looking at there are 220 patients recorded altogether, and in these, 86 of these got their aspirin by therapeutic overdosage, that is, 39 percent of them were therapeutic overdosages. I don't need to point out to you that this therapeutic overdosage situation would not be modified in any way by limiting the size of the bottle.

The solution to this problem is education.

Responsible heads of drug manufacturing companies are greatly concerned about the proper use of their products, especially with respect to their efficacy and safety. There can be no question but that adult carelessness with potentially toxic materials is the real culprit in childhood poisonings. But, carelessness cannot be abolished by legislation.

CONTRIBUTION OF THERAPEUTIC OVERDOSAGE TO ACCIDENTAL POISONING BY ASPIRIN IN PRE-SCHOOL CHILDREN

SOURCE	NO. PTS.	% ACCIDENTAL	% THERAPEUTIC
CRAIG, ET AL	78	85.9 (67)	14.1 (11)
SEGAR & HOLLIDAY[1]	43	25.6 (11)	74.4 (32)
RILEY & WORLEY[2]	42	31 (13)	69.0 (29)
WINTERS[3]	25	72.0 (18)	28.0 (7)
DRIVER[4]	24	87.5 (21)	12.5 (3)
ILL DEPT. P.H.[5]	8	37.5 (3)	50.0 (4)
	220	61% 133	39% 86

FIGURE 7

Realizing this, members of the drug industry recently formed the Council on Family Health. This nonprofit group was created to attack this whole problem in the most effective way—through mass education. The principal target is mother, keeper of the family health. Through all available media the council is distributing materials that alert mother, and others, to the problems of home safety—and how to overcome them.

The drug industry is in the business of helping and healing people, not of hurting them. Because the industry recognizes its responsibility in this area, it has developed many safeguards over the years to help eliminate the misuse of medicinal preparations.

The Government, the professions, and industry have been cooperating for years in the matter of children's aspirin. For example, an article in the Drug Trade News of February 28, 1955, reported the agreements reached at a conference called by the Food and Drug Administration on the accidental misuse of children's aspirin. This was attended by representatives of the American Academy of Pediatrics, the American Medical Association, various groups interested in accident prevention, the Food and Drug Administration, and industry. The recommendations of that conference have been followed exactly by Sterling Drug and all other leading manufacturers.

Today practically 100 percent of the children's aspirin tablets marketed comply with the following recommendations of that conference:

1. Children's aspirin bottles to be limited to a maximum of 50 tablets.
2. The tablets to be standardized to 1¼ grains each.
3. On the specific choice of the medical profession children's aspirin tablets will continue to be flavored.
4. The industry has urged through labeling that parents keep all medicines out of the reach of children. This you will find on the label of all aspirin bottles.
5. The industry to provide detailed dosage recommendations for specific indications and for specific ages to assure a safe and proper dosage. And, finally;

6. The best presently available safety closure to be universally used.

If we make the bottle cap too difficult to remove we defeat our purpose, for the mother will simply fail to put it back on the bottle. Even so, pharmaceutical manufacturers have never stopped their efforts to develop improved safety closures. Sterling Drug is planning to market Bayer aspirin for children with a still further improved closure very shortly. Incidentally, during these years consumer and market tests have been conducted by us to determine the acceptability of children's aspirin sold in strip packs in which each tablet is separately wrapped. Consumers did not like this type of packaging and preferred the conventional type of bottle.

At the present time, gentlemen, the Bayer aspirin for children is marketed in this sealed carton. A child would have to tear one of these cartons open in order to get at the bottle, if the bottle was fresh and contained the full amount of tablets.

Here is the modified cap which we will have on the market very shortly, it is very similar to the one which you have been shown before and have up there before you [passing sample to the chairman].

We have looked at very complicated and more difficult caps to remove than these, and believe that mothers probably will find these caps a little bit too hard to get on so that there will be a tendency for them to leave the cap off, and leave the bottle just covered loosely by the cap in their medicine cabinet. This is a danger which is very real because it ruins the efficacy of the, hopefully, safety cap.

Mr. Rogers asked Mr. Solmson if it will be possible to leave out the flavor of children's aspirin, this in on page 183 of the hearings. This question was debated at the 1955 conference. The physicians there believed that the flavor did not add appreciably to the hazard, and greatly improved the acceptability of aspirin to the sick child. They therefore preferred that the tablet be flavored. The American Medical Association, the Food and Drug Administration, and the manufacturers agreed to this decision, so such tablets are now usually flavored.

If Congress feels the necessity to reduce by legislation the quantity of children's aspirin per bottle this shoulld be 35 one and one-quarter grain tablets. Due recognition should be given to the fact that a bottle of tablets after the sealed carton has been opened for the first use, thereafter always contains less than the original number. The fact, as discussed just above, that 90 percent of the children involved in accidental ingestions of salicylates show no symptoms at all suggests that in most instances the children do not consume the entire contents of a bottle, either out of choice or because it is not full. Although adequate statistics are not presently available in this point, what there are suggests that more than two-thirds of the reported cases of accidental ingestion of children's aspirin involved taking substantially less than 50 tablets, and over one-half of them involve ingestion of 25 tablets or less.

The first portion of this statement set forth the relatively large numbers of children's aspirin tablets required to treat childhood diseases. If a quantity permitted by law in one bottle is too low, mother through necessity to meet the dosage needs of her children, will purchase several bottles at one time, thus multiplying the availability of the tablets in the home. The greater number of bottles

available in the home the greater the opportunity for children to experiment. Dr. Palmisano admitted this fallacy in the demand for an excessively small bottle when he admitted that he expected the mothers would buy a lot of the small bottles. This is on page 40 of the hearings.

Another practical and important aspect of reducing the container to even 25 tablets is the effect that such a reduction will have on the effectiveness of the smaller label as a medium of communication. The important dosage and warning information which by law and by good medicine we place on the labels of our children's aspirin would become so small in type size as to be virtually illegible. If you cut that bottle down one-half you will see that you would have great difficulty in reading what there is on the label; that is, unless the amount of text carried on the label is greatly reduced in content.

It would be a distinct disservice to the public if this information were to become unreadable or if it were removed entirely from the label, to go on a package insert or some other place, yet if the bottle size is materially reduced, what alternative is there? And will the consumer who needs this information benefit?

Mr. Rogers raised the question with Mr. Stetler of the desirability of first-aid instructions on the bottle. It would not seem wise for several reasons to put directions on the bottle of how to treat suspected aspirin overdosage. In the first place, about 9 out of every 10 reported cases of accidental ingestion never have any symptoms of overdosage, and the child may have swallowed none or only insignificant amounts of the tablets.

Secondly, in the remaining 10 percent of the children, the first treatment is to evacuate the stomach. Vomiting is not easy to induce, particularly by an excited mother in the home. There is no good emetic commonly available in the homes which can be relied on to invariably induce prompt and copious vomiting. Sirup of ipecac has been recommended for this use, but it is found in very few homes and may take as long as 30 minutes to take effect. If the mother has to go to the drugstore for it, she would be better off to take the child to the doctor's office or to the nearest hospital.

Aspirin remains in the stomach long enough without causing damage to the stomach, so that a reasonable time can be taken in getting it out. It is not like the caustic poisons in this respect.

There is no specific antidote for aspirin, which would neutralize it in the stomach like bicarbonate of soda would neutralize an acid.

In authentic poisoning cases the stomach needs to be washed out by passing a stomach tube, which can only be done by experienced personnel. Therefore, the most useful first-aid directions would be to put on the bottle the warning statement "In case of accidental overdosage call your physician or hospital at once."

Mr. Rogers also asked Mr. Stetler, at page 86 of the hearings, why first-aid directions are suitable for packages of hazardous substances but not for drugs. The materials covered by the Hazardous Substances Act are in general corrosives, irritants, caustics, et cetera, which do damage immediately on contact with the body. Speed of neutralization or removal is therefore an important factor in preventing injury. It is of much less importance with aspirin since symptoms of overdosage may take as long as 12 hours to appear.

For these and other reasons we believe the proposed legislation limiting the quantity of children's aspirin per bottle will not have the desired effect of eliminating or decreasing alleged fatalities and alleged injury due to accidental ingestion. As a matter of fact, such legislation could actually increase misuse of the product by creating greater availability in the home. Calls to the Nation's poison information centers would probably increase, and thereby further inflate these already unreliable statistics.

As a matter of high public interest, if a maximum quantity of children's aspirin per bottle is to be limited through legislation rather than the present voluntary agreement, Congress should specify the limit and not delegate this responsibility to an administrative agency which would set the limit by arbitrary regulation.

Delegation of such authority by the Congress is entirely unnecessary. No scientific question exists. Nothing can be gained through regulatory fiat in this situation. Based on FDA's own statements here, Congress can set a limit of twenty-five 1¼-grain tablets and be excessively safe, or based on this present statement and other authorities in this hearing, Congress can select a limit of thirty-five 1¼-grain tablets and also be more than safe.

The 35-tablet limit is especially preferred because it goes further toward providing enough children's aspirin per bottle to cover several days of therapeutic use in treating one child's illness. Moreover, whether the maximum limit be 25 or 35 tablets, the fact of the matter is that, on an overall average, after the bottle is first opened it will probably contain only a fraction of the maximum number specified.

Whether or not Congress specifies the maximum number, if legislation should be decided upon, the Food and Drug Administration should be empowered by Congress to increase the number of tablets when better closures become available, or if the product is made available in strips of tablets or in any single tablet dispensing forms. The regulatory process would be appropriate here because these are possible, not actual, situations and these criteria are measurable objectively.

I would like with your pleasure to read to you an editorial which just appeared in the Grants Pass, Ore., Daily Courier. I don't know how this editorial came to be written, certainly we had no hand in preparing it, but it sums up a layman's view of this situation I think in an excellent way. The editorial is labeled "Candy Flavored Aspirin Problem One for Parents":

> It seems Congress must invariably stick its nose into areas where it should be apparent that no legislation is necessary or at least attacks the wrong side of the problem when one does exist. The case in point is a current investigation in the Capitol Hill Chambers of the packaging of children's candy flavored aspirin which apparently constitutes a menace to young ones throughout the land because as one solon commented, "Every third day a child dies from an overdose of candied aspirin."
>
> We would first question a seemingly disastrous figure as highly improbable, but if true, something perhaps should be done about it. That 183 children should die each year from this form of accidental poisoning does constitute a cause for alarm if true. But the direction of the congressional investigation is along the lines of limiting the number of pills in each container so children would theoretically be unable to get enough in one bottle to poison themselves. This would obviously require pretty small bottles and as a result mothers with several children probably would have more than one bottle in the medicine chest so the limit would solve nothing.
>
> If an answer is to be found, it also won't be that of Representative Leonor K. Sullivan, the Democrat of Missouri, who uttered the flat statement about the mortality rate. She asked "Why permit these pills to be sold at all?"

Why indeed? Has she ever tried to get a large aspirin fragmented accurately for the correct dosage for a child and then get a tot to swallow the sour tasting bit? Probably not. The answer it would seem must lie in either education of, or a restrictive sort of punishment for, parents who allow medicine to be reached by children. Just placing the medicine on a high shelf won't help because somehow when compelled by his curiosity the child will attain almost any height to which an adult can climb. Rather, the only answer is to keep all medicines in a well locked place and with a key in another place unknown to the child. Even then once in a while an innocent youngster will find the one and open the other with fatal results, but it would minimize the problem. But, to blame the drug industry for our parent's stupidity seems highly unfair to say the least and an offense to our economic way of life, at best.

Gentlemen, if you will permit, I might summarize all this in a very few words.

In my opinion you have been asked to deal with the wrong problem. First, a large number of the reported instances of aspirin ingestion are not poisoning in the ordinary sense, inasmuch as 90 percent of these take too little and have no symptoms or negligible symptoms.

Secondly, among the true poisoning cases giving rise to the misused figure of 125 deaths, probably one-half the deaths are from oil of wintergreen, a rubbing liniment.

A substantial proportion of the remainder are from inadvertent overdoses during therapeutic use. Also in this group are the repeaters which form a psychological problem, maybe as many as a quarter of the total. Of those deaths properly ascribed to aspirin and all other salicylates, probably only about 8 percent, or 1 out of 12 of the deaths are from children's aspirin tablets.

You are also being asked to provide the wrong answer to this wrong question. The small bottle would contain too little for practical needs. The small bottle would lead to the purchase of several bottles at once, increasing the hazards. The small bottle would require illegible printing and reduce the effectiveness of the warning statements.

The fault is not in the bottle, it is in the negligence or ignorance of parents who do not safeguard medicines properly and do not replace safety caps properly on the bottles.

What is then the right answer?

First, these new safety closures.

Second, education of mothers by all modalities which include such things as the Council on Family Health.

Third, voluntary agreements arrived at in conference by the parties at interest.

Fourth, the 50-tablet bottle has proved itself very safe indeed, but 35 tablets can be legislated if additional safety is deemed necessary. The 25-tablet bottle is almost certain to be too small and to create more difficulties than it corrects.

If there is to be a change, it should be by legislative enactment of specific size of the bottle, rather than leaving the decision to possibly arbitrary, regulatory fiat.

Gentlemen, in my opinion this problem is too important for Congress to delegate the decisionmaking authority to other branches of the Government.

Thank you.

Mr. JARMAN. Thank you, Dr. Tainter. We appreciate your being with us this morning and adding this well documented statement to our record.

You referred several times to the 1955 conference at which the number of 50 recommended aspirins in the bottle was determined.

How thoroughly did that conference go into the problem?

Dr. TAINTER. They spent an entire day on it. It was by previous notice so that everybody there came prepared with his facts and figures and principles pretty well clarified. We believe it was a judicious conference which brought out very close to the proper answers to the questions raised.

Mr. JARMAN. Your compliance with the 50-tablet recommendation is on a voluntary basis?

Dr. TAINTER. It is on a voluntary basis at present, yes.

Mr. JARMAN. And you indicate in your statement; and I quote from page 3:

> We stand ready to follow the recommendations of such a conference today.

Dr. TAINTER. We would be delighted if such a conference were called so we could participate, present the facts and help in arriving at a sound decision.

Mr. JARMAN. Since FDA, apparently takes the position today in favor of a lesser number of tablets than the 50, let me ask this: In your informal conferences and contacts with FDA, has a recommendation been made to your company in the past year, that it be a lesser number?

Dr. TAINTER. There has been no approach to us that we reduce the size of the tablets, either formally or informally—reduce the size of the bottle.

Mr. JARMAN. The size of the tablets?

Dr. TAINTER. The size of the bottles. There has been no attempt to get us to reduce the size of our bottle below the 50 tablets of 1¼ grain size. In other words this legislation is the first move in an attempt to get the smaller size bottle on the market.

Mr. JARMAN. Are you in contact with the FDA?

Dr. TAINTER. Yes. We are. In April I believe it was, I can give you the exact date if you wish, I spent 2 hours with Dr. Goddard discussing these matters so that he knows our views very thoroughly. We told him very explicitly we would be delighted to go along with any kind of a voluntary decision of a well constituted conference.

Mr. JARMAN. Thank you.

Mr. Rogers?

Mr. ROGERS of Florida. Thank you, Mr. Chairman, excuse me a second.

I thought your testimony was well documented. I thought it very effective.

I am concerned; I wonder if you could give me a little breakdown on one figure on your chart 6, where you talk about the published reports that show that from 14 to 74 percent of the so-called aspirin poisoning cases are due to the administration of overdoses by mothers, either on her own or on the recommendation, mistaken or otherwise, of a physician? Now, I wonder how many were taken on the recommendation of a physician which was in error? Does the literature break that down?

Dr. TAINTER. The literature does not break that down in any clear way. This is a very touchy situation. A physician would not like to report that he had overdosed a patient in a published paper and subject himself to legal hazards, so this is a kind of a terra incognito.

Mr. ROGERS of Florida. There is no way of our telling that, then?

Dr. TAINTER. All that we know is that in these six reports which are published—I can get you reprints of it if you wish—the percentages of the aspirin ingestions which were due to therapeutic use by a doctor or by the mother—or I should say somebody giving it to the child, it was not the child getting it—was 39 percent of the total in the six reports.

Mr. ROGERS of Florida. What was the other percentage?

Dr. TAINTER. Seventy-four percent in one, but he had 43 patients there. He may have a special group, a selected group. On the other hand, you have to look at the article by Dr. Driver who in 24 patients had only 24.5 percent of therapeutics, or somewhere in that general rate range.

Mr. ROGERS of Florida. What do you do to give guidance to prescribing a dosage under 3 years of age?

Dr. TAINTER. We give none.

Mr. ROGERS of Florida. You give none; no suggested doses?

Dr. TAINTER. No. Because, if we did that, of course it would have to go on the bottle or the package insert and it would be available to the parents. The doctors get their knowledge about the doses to be used for these various age brackets from these formula on the age, the weight, or the surface area formula.

Mr. ROGERS of Florida. I thought you said weight was not a very good point.

Dr. TAINTER. It is not very good, that's right.

Mr. ROGERS of Florida. Yet they are using that?

Dr. TAINTER. They are using that for many compounds and for ordinary—under ordinary circumstances it is reasonably satisfactory.

Mr. ROGERS of Florida. Shouldn't you put out some literature to correct that impression, if 74 percent of these studies possibly could have come, we don't know, from the recommendation of a physician?

Dr. TAINTER. I think in many cases they did come from the recommendation of a physician.

Mr. ROGERS of Florida. Couldn't something be done there?

Dr. TAINTER. Well, there is a lot of literature on this dosage so that it is available to the doctor in published literature. We don't hand out booklets on Bayer aspirin for children to the doctors. They know that——

Mr. ROGERS of Florida. Couldn't you do that? You prescribe it enough——

Dr. TAINTER. Yes, we could.

Mr. ROGERS of Florida. Your industry I think would perhaps do a public service in making suggested formulas available.

Dr. TAINTER. We certainly could do that. We would have to develop a special booklet for the information of the medical profession. That could be done.

Mr. ROGERS of Florida. This is done in some instances, is it not, for some drugs?

Dr. TAINTER. It is for professionally prescribed drugs, prescription drugs particularly. The doctor uses the booklet as his major source of information, particularly on a new drug.

Mr. ROGERS of Florida. I would think this would be helpful to the profession, if this high a figure is possible.

Dr. TAINTER. Yes. The surface area is the most accurate way of calculating the dose. Apparently the response to drugs is determined, is more proportional to the surface area than it is to the weight or the age, although there are variations in that.

Mr. ROGERS of Florida. I think that should be made known, and I would be interested in following up if your company cares to or decides to do something like that. I think this committee would be interested in seeing about other members of the industry getting information to the doctors or else let Food and Drug do it. I don't know why they couldn't do it, after consultation with the industry and the medical people.

Dr. TAINTER. There is no real problem in developing a booklet of instructions or dosage, and that could include first aid instructions and anything else that was pertinent.

Mr. ROGERS of Florida. Let me ask—why did the industry agree in the first place to reduce its bottle size for children's aspirin?

Dr. TAINTER. Because it was the opinion of that conference group that the 50-tablet standardization was the proper size, proper number of tablets to have, and they wanted the 1¼-grain size, which is one-fourth of the full 5-grain tablet. We at that time were making a 2½-grain tablet which we were putting out in bottles of 50, so we cut our tablet size in half and still kept the same 50 bottle. There are a few minor brands, mainly locally distributed, that have other sizes. There are some bottles; a few bottles of 100's which are primarily used, I suspect, in hospitals.

Mr. ROGERS of Florida. What I wanted was the idea for the safety factor.

Dr. TAINTER. That is right.

Mr. ROGERS of Florida. For reducing the number.

Dr. TAINTER. That's right.

Mr. ROGERS of Florida. So that it has some credence then on the size of the bottle, as far as children being affected—

Dr. TAINTER. Yes. They felt that this was the ideal size from all considerations, including having enough available for use.

Mr. ROGERS of Florida. The question is then whether we should go below that. Industry has agreed that size is a factor.

Dr. TAINTER. Is a factor; right.

Mr. ROGERS of Florida. And whether we should do it or let it be done voluntarily, whether it is necessary, do you think 50 is not an unreasonable number?

Dr. TAINTER. It has turned out to be a very good number over the last 11 years.

Mr. ROGERS of Florida. I am also concerned by the fact that the Food and Drug Administration has given out a figure that some 10,000 out of 12,000 reported cases, as I recall the testimony, was from baby aspirin poisoning, or overdosage.

Dr. TAINTER. I don't know where that figure came from.

Mr. ROGERS of Florida. Well I will ask. This committee will ask them to document that statement to the committee.

Dr. TAINTER. The poison control centers have told us they have no such information in writing.

Mr. ROGERS of Florida. Now, you say oil of wintergreen is quite a problem. Should some consideration be given to that?

Dr. TAINTER. I think oil of wintergreen should be labeled as a hazardous substance if it is around the home to be used as a rubbing liniment.

Mr. ROGERS of Florida. Is that presently done?

Mr. LUTHER. There are special labeling provisions in the FDA regulations for highlighting the danger.

Dr. TAINTER. The problem here——

Mr. ROGERS of Florida. This legislation would give him authority to do something about oil of wintergreen because the wording is "or other forms of salicylic acid."

Dr. TAINTER. The problem on the oil of wintergreen can be clarified if I simply point out that if a child swallowed 1 teaspoonful of oil of wintergreen, he might get a fatal dose.

Mr. ROGERS of Florida. Just 1 teaspoon?

Dr. TAINTER. One teaspoon; yes. You see 1 teaspoon is 5 grams, and 5 grams is 5,000 milligrams, which is 62 of the tablets, so that a single swallow of oil of wintergreen can very well be fatal.

Mr. ROGERS of Florida. Well——

Dr. TAINTER. And this is why it is so hazardous a thing to have around.

Mr. ROGERS of Florida. I think we ought to go into this problem too.

This bill would give them authority under the present language?

Dr. TAINTER. Under the present language; yes.

Mr. ROGERS of Florida. Should we take any action to actually require physicians to report all cases of overdosage, or hospitals to report this to a center in order for us to get some legitimate statistics or know what action should be taken?

Dr. TAINTER. There are two ways to get the statistics, either set up field studies on a voluntary basis with cooperating groups, and this is what is being done now at Syracuse. There the Syracuse Board of Health, the University Medical School, the State board of health and the drug industry are participating in underwriting a study to go from 3 to 5 years. They have 3 groups of 500 familes each. In one family group they are following, are families where poisoning has occurred in the children.

They have another 500 group where poisoning has not occurred where they are doing intensive education of the family by monthly visits, inspections of the house, talking to the housewife about the hazards, and so forth.

The third family group they are using as an unchanged control group.

They are now going into their third year I believe, and they have all of their data on IBM cards. We have seen no tabulations, but they are investigating each entire circumstance of each poisoning incident: If we had a group of these in different parts of the country to take care of the differences in local habits and local distribution of drugs and medicines and so on, then we would have a very complete understanding of this and could really do what the best thing possible is.

Mr. ROGERS of Florida. Now I notice you say you don't think it is advisable to put any first aid treatment on it because of the size of the bottle, and because it takes 12 hours before you get the symptoms of an overdosage of aspirin.

Dr. TAINTER. Yes.

Mr. ROGERS of Florida. Now does this mean you could have death in 12 hours?

Dr. TAINTER. It would be very unusual, no. I think I either misspoke or was not understood.

Symptoms can take as long as 12 hours to develop in the case of low dosage, or threshold cases. But aspirin is a drug which has no adverse effect on the stomach, it doesn't burn the stomach the way an acid or lye would, it takes several hours for it to be completely absorbed so that you can take time and get the child into the hands of a professional who can determine how much was taken and decide whether they need to wash out the stomach or just watch the child for any symptoms. This is a kind of a decision a mother should not make because the symptoms develop so slowly. She is very apt to make a mistake and do the wrong thing.

Mr. ROGERS of Florida. Well, in any event if there is an overdose, the sooner you get it out of the stomach, the better for the child.

Dr. TAINTER. Yes, of course.

Mr. ROGERS of Florida. So, first aid, in other words if the mother could have the child vomit this would at least help to get it out of the system even before she took it to the doctor. Suppose she had a difficult time finding a doctor, and sometimes this happens nowadays. I have even had the experience myself with that.

Dr. TAINTER. Well, there is a doctor or a hospital within a half an hour of almost everybody in this country.

Mr. ROGERS of Florida. Well, sometimes it is difficult to find a doctor.

Dr. TAINTER. Except, of course, in the most rural areas.

Then there are the hospitals.

Mr. ROGERS of Florida. Well, not always the hospitals.

Dr. TAINTER. Nearly every hospital has a poison control center where they are equipped to handle these cases promptly on admission. The problem of vomiting, I think maybe I should tell you a little bit more about that.

The problem of vomiting is this, that there is nothing in the home which is a good effective vomiting agent to make the children vomit quickly.

Mr. ROGERS of Florida. Except the finger, possibly.

Dr. TAINTER. Well even that does not work with the child excited and so forth, that does not always work.

When I was a medical student I taught, and was taught that they should use a mustard infusion.

Well, the mustard seed that you get doesn't have any irritant properties until after you let it steep for 10 to 15 minutes. I know a lot of mothers would be excited with a child whom they thought had swallowed a bottle of aspirin and would not wait 15 minutes or so until the mustard developed its strength, so that it would not work.

They have tried sirup of ipecac. The trouble with ipecac is that it may take as long as a half an hour for it to work in about a third of the cases, and nobody has sirup of ipecac in their medicine cabinet anyway, so that there just isn't a good antidote, a good vomiting agent that the mother can be told to use. If she calls the doctor or the hospital and tells of the circumstances, the doctor will say to either bring the child in, or he will drop out and see it, or she does

whatever is necessary and this gives the child an opportunity to have professional protection.

Mr. ROGERS of Florida. Now, on your aspirin bottle, I don't see where you say, that for overdoses or for treatment for overdoses, immediately contact a doctor.

Dr. TAINTER. This is what we are recommending here today as being the preferred way of emphasizing the fact that you should consult or contact your physician. We will be very glad to put that on the labels, and we think it might be helpful. It would be the most helpful thing we could put on it.

Mr. ROGERS of Florida. I notice your printing about keeping the medicine out of the reach of children is blue on blue. It might be difficult for some people to see.

Dr. TAINTER. I can promise you that will be changed. I am embarrassed by that very much.

Mr. ROGERS of Florida. I think it is difficult to see.

Dr. TAINTER. Yes.

Mr. ROGERS of Florida. Now, one other question and I will conclude.

I notice that you don't want us to turn over to an administrative agency the right to set by regulation the number of aspirins in the bottle. But now suppose we require a hearing? A proper hearing where parties can be heard and evidence must be adduced, what would be your feeling on that?

Dr. TAINTER. Well, I think it would be better than letting them do it without a hearing, but I think that you have enough data in front of you now so that a decision—you have relatively few choices and a decision could be arrived at right here.

Mr. ROGERS of Florida. You think it is better for us to just say "35," than turn it over and let them go through hearings with it and get in medical evidence from both sides?

Dr. TAINTER. I think it is much better.

Mr. ROGERS of Florida. And yet you are willing for us to empower them to increase the number of tablets. Why is that? Don't you want to let them decrease the number?

Dr. TAINTER. If there is some new packaging which develops whereby a bottle comes out that is safer than any we have now, or some new way of packaging tablets, that is obviously better, then they should be empowered to take cognizance of that.

Mr. ROGERS of Florida. Don't you think probably it is always going to be difficult to get a safe cap? A child, one way or another, is going to be able to get through one, I would think.

Dr. TAINTER. Incidentally, we tried that cap you have on there in a children's home and we found that no children 2 years old could open it at all out of 20-some that tried it; and about 20 tried it in the 3-year-old category and only 2 could get it open after they had been shown how.

Mr. ROGERS of Florida. I think we should commend you for that.

Dr. TAINTER. I strongly suspect that in a good many of these children's cases that the mother just put the cap loosely on the top of the bottle and hasn't snapped it down.

Mr. ROGERS of Florida. Thank you. Your testimony has been most helpful.

Dr. TAINTER. Thank you.

Mr. JARMAN. Mr. Nelsen.

Mr. NELSEN. Thank you, Mr. Chairman.

On page 3 you make reference to the marketing policies and also for industrywide conferences, how they were held.

Now it is possible that the Food and Drug Administration feels that this is too time consuming, that it would be too difficult to get industry-wide participation and cooperation?

Dr. TAINTER. Well, if this were a court of law I wouldn't be allowed to answer that question because you would be asking me to assume what somebody else is thinking. I don't have an answer for that.

Mr. NELSEN. Let me ask you this. Has the industry cooperated on a high percentage——

Dr. TAINTER. Industry is very cooperative about this thing. In all the discussions we have had, I have never heard anyone even suggest they would not happily go along with any decision of such a conference group. In other words as I said, we are engaged in selling medicines, and we have a feeling of public responsibility. We will do what is best, as soon as that can be properly established.

Mr. JARMAN. Will the gentleman yield?

Mr. NELSEN. I yield, yes.

Mr. JARMAN. How was the decision arrived at in the 1955 conference?

Dr. TAINTER. There was a general consensus.

Mr. JARMAN. Was a vote taken?

Dr. TAINTER. I don't think they needed a vote. No, there was not enough division of opinion, they just discussed the thing very thoroughly and these were the decisions they arrived at by consensus.

The reason I quote the Drug Trade News on that was because unfortunately apparently nobody kept any minutes of this meeting. I have not been able to find any authoritative minutes. They had a Chairman, Dr. Holland, who was the medical director of food and drug at that time, but they had no secretary to take the minutes so the Drug Trade News, which attended the conference, reported it in fair detail and gave the conclusions which were arrived at and which have been lived up to, of course, ever since.

Mr. JARMAN. Based upon the difference in testimony that the committee has had on this problem, do you think that a conference of that sort whould reach a consensus?

Dr. TAINTER. Well I don't know of any difference in testimony here against the findings of that committee.

Mr. JARMAN. There has been some difference in testimony before the committee to the number of aspirins, for example, that ought to go in the bottle.

Dr. TAINTER. From the 25 to the 35 to the 50?

Mr. JARMAN. In that category, which is a big issue here.

Dr. TAINTER. I would think that if this committee were reconvened, it would consider the data that you have in front of you now, particularly the tabulation of the mortality and poison case incidence. I would think this would stimulate the poison control centers, the National Institutes of Health or HEW, Public Health or somebody to go out and get more detailed and reliable figures and statistics on what the facts actually are. Then on the basis of those facts and figures we would be able to arrive again at a proper consensus on whatever was shown to be the proper course of action.

Mr. JARMAN. What amount of time do you think that would take to come up with facts and figures to guide you?

Dr. TAINTER. The Syracuse study, because they are trying to follow these people and their families while they are in the process of waiting for poisonings to occur, is what we call a prospective study. They are looking ahead into the future. That is going to take somewhat over 3 years. They are about 2 years into it now. You could get usable information I think in 6 months to a year if you set up a group and had several investigators to go out and inquire into these cases.

Mr. LUTHER. Excuse me. Consistent with the testimony about the 35 and even the 25 tablets, if there is to be legislation, we are suggesting those numbers. We would also if there were a reconvening of the committee and the FDA came to the committee with the same thinking that they had when they endorsed this bill and appeared before you in June, we would certainly make the same offer of cooperation and would not say that 50 is fine, we won't move. Of course, we will move, even if we do not feel the facts justify it, just the source from which the suggestion is make would certainly be considered.

I just want to point out this is not a stalling device in any way. We would appear before such a committee and make the same representations as we have been making here.

Mr. JARMAN. In line with what Mr. Rogers said a moment ago with reference to a hearing, if we provided in the bill for a hearing at which time all interested groups and individuals could be heard, would that not essentially achieve the same result that a conference would achieve?

Mr. LUTHER. Well, we think first on the proposition we made here, 25 and 35, there is no scientific factual question, it is a question of policy. If you want to reduce it, it is a question of policy, you can take the 25 or 35, there's ample support for that, so we do not think that there is a hearing needed in terms of developing facts. They are pretty available and pretty clear. It is a question of setting the policy. Hearings are not useful for that purpose. We think the Congress ought to set the policy.

If, however, the committee would reconvene, it would receive the policy of FDA and that would be considered in the deliberations. Forgetting that, assuming a hearing before FDA does occur and does get involved in facts, as you know legally the burden in such a situation is really on the defendant, the industry in this case, to overwhelm in the evidence the position of the Administrator because the judgments are sustained in the courts if there is any substantial evidence to support the Administrator and his findings.

We do not feel that it is a sufficiently factual problem where you should do that. It is purely policy, Congress should set it. If Congress does not, we are perfectly willing to convene with FDA and the professions and everyone else on this matter.

Mr. NELSEN. I notice on page 21 you conclude your statement by suggesting that, if a further limitation on the number of tablets in a bottle is to be imposed, that the Congress do it, and you suggest the figure of 35 grains or we might go to 25.

Now, assume that the Congress did go to 25 and it turned out to be an utterly ridiculous number. Did it ever occur to you how cumbersome it is to get a bill through Congress to change it if we find we

have made a mistake? Is it possible that this procedure might in some way be difficult for the industry if we did make a mistake in setting it at 25?

Dr. TAINTER. I think we would prefer to take our chances with the Congress, if you will allow me to say so.

Mr. NELSEN. Thank you for the compliment.

Getting back to page 8, I think I asked a question in the earlier hearing relative to the term "accidental poisoning" and actually it should have been termed "accidental ingestion." It was your feeling that the figure dealing with accidental poisoning was taken from a report which actually was accidental ingestion. Has that ever been documented?

Dr. TAINTER. Yes, it is in table 5, I think, of the poison center control reports. They refer all the way through not to poison but to ingestion.

Mr. NELSEN. Was this a statement that came from Food and Drug or from a witness?

Dr. TAINTER. A witness of or from the Food and Drug here, used the word "poisoning" as if it were "ingestion."

Mr. NELSEN. In other words it is not exactly an accurate analogy——

Dr. TAINTER. No, sir.

Mr. NELSEN. Thank you. No more questions.

Mr. JARMAN. Mr. Satterfield.

Mr. SATTERFIELD. Thank you, Doctor. I enjoyed your remarks very much.

I have no other questions, Mr. Chairman.

Mr. JARMAN. Thank you very much, gentlemen, for being with us.

Dr. TAINTER. Thank you, sir, for the opportunity.

Mr. JARMAN. Our next witness this morning is Mr. James F. Hoge, for The Proprietary Association, and I understand he is accompanied by Mr. Paul R. Connolly, of Washington, and Dr. William D. Paul, of the University of Iowa Medical School.

We are glad to have you, Mr. Hoge.

STATEMENT OF JAMES F. HOGE, THE PROPRIETARY ASSOCIATION; ACCOMPANIED BY PAUL R. CONNOLLY, OF HOGAN & HARTSON, WASHINGTON, D.C., AND DR. WILLIAM D. PAUL, UNIVERSITY OF IOWA MEDICAL SCHOOL

Mr. HOGE. Thank you, Mr. Chairman. We want to accommodate ourselves to your time requirement and already we have contemplated means of shortening our presentations.

Let me take a moment to introduce, please, on my right, Mr. Paul R. Connolly. Mr. Connolly is a member of the firm of Hogan & Hartson, in this city, and he is a member of the bars of the State of Maryland and of the District of Columbia.

On my left is Dr. W. D. Paul of the University of Iowa Medical School. He has been with that school since about 1930. He has given me a statement of his biography and with your permission I would like for that to appear of record at the appropriate place rather than to take the time to read it now. I may be forgiven for just saying that it is a very distinguished biography and that Dr. Paul also has a very extensive bibliography. I had not thought that I would put

that of record unless the committee desires it, although I have it here. It is a very extensive one.

Mr. Chairman, I ask permission that my statement may appear in the record in full.

Mr. JARMAN. Without objection, it will be done.

(The prepared statement of James F. Hoge follows:)

STATEMENT OF JAMES F. HOGE ON BEHALF OF THE PROPRIETARY ASSOCIATION

My name is James F. Hoge. I am a member of the bar of the State of North Carolina and of the State of New York. I am a native North Carolinian and practiced law at Greensboro in that state for about eight years before moving to New York in 1930. My address now is 90 Park Avenue, New York City, where I am engaged in the active practice of the law as senior member of the firm of Rogers, Hoge & Hills.

REPRESENTATION

My appearance on H.R. 13886 is on behalf of The Proprietary Association, the offices of which are at 1700 Pennsylvania Avenue, N.W., Washington, D.C. The Association was organized in 1881 and has been in continuous existence since. Its active members—98 in number—are engaged in the manufacture and distribution of proprietary medicines—medicines which are completely compounded, packaged and labeled for use by consumers.

These medicines are classified as over-the-counter items, i.e., items not restricted by law or practice to sale on prescription. Illustrative of such articles are many well-known products, such as Vicks Vaporub, Listerine, Bayer Aspirin, Bufferin, Anacin, Alka-Seltzer, Castoria, Murine and Phillips' Milk of Magnesia. There are also 140 associate members—companies which do not manufacture and distribute proprietary medicines but which are interested therein as suppliers of materials and services.

POSITION

I would like for my first reference to be one of appreciation; to express thanks on behalf of my client, The Proprietary Association, and of myself, its General Counsel since 1934, for the privilege of this appearance.

Our appreciation is deepened by the seriousness of this legislation. For it is a very serious bill—serious in purpose and potential to both producer and consumer. I have said to my client—and, with your permission, I now say to you—that it is the most crucial legislative proposal to confront manufacturers of proprietary medicines since the introduction on June 6, 1933 of S. 1944, which—after much amendment—and after five years—was to become the Food, Drug and Cosmetic Act of June 25, 1938.

Let me interject at this point that this Association became a supporter of that bill at the time of its Senate passage in May 1935. In August of that year, I appeared before this Committee and pledged the support of this Association in the following words:

"We do not oppose the bill here today and we do not propose any amendments.

"I am particularly glad to say that, Mr. Chairman, because up until this time we have considered it necessary to be an opponent, although all the while we have realized that improved food and drug legislation was, and is, needed, not only in the interest of the public but in the interest of legitimate industry." (Hearings before the Subcommittee of Committee on Interstate and Foreign Commerce: H.R. 6906, H.R. 8805, H.R. 8941 and S. 5, 74th Congress, First Session, Saturday, August 10, 1935, page 694.)

This Association has supported this law ever since; and will continue to support it. It now opposes H.R. 13886, but only in part. It certainly supports its declared purpose "to protect children and others from accidental death or injury." To be sure, it is wholeheartedly in favor of child safety. If that were the full extent of the bill, we would have no criticism of it. But that is not the extent of it, and our purpose and position here today are to seek such amendment as will confine it to that purpose.

Our concern is that, under the heart-stirring banner of "child safety," the bill would put the packaging and labeling of over-the-counter drugs under a system of governmental licensing; would accomplish that by unlimited delegation of authority to the Food and Drug Administration.

Our concern is confined to three points: (1) limitation, by FDA regulation, of the quantity per package of aspirin—and of aspirin-containing products—

intended for use by children; (2) requirement, by FDA regulation, of safety closures for retail drug packages, whether or not intended for children; and (3) delegation of authority to FDA to prescribe the content and the manner and form of statement of labeling with respect to directions and warnings.

I. Quantity Limitation on Packaged Aspirin

Under Section 2 of the bill, a drug would be deemed to be *adulterated* if it is an aspirin or *other form of salicylic acid preparation* in a dosage form intended for use by children, and packaged in a retail container, if the aggregate quantity of the drug in such container exceeds a limit which has been established by *regulations of the FDA* as being likely—if ingested at one time by a child of tender age—to cause death or serious injury.

Manufacturers representing at least 95% of the total children's aspirin market now package the product in containers of 50 tablets of 1¼ grains. They have done this since 1955 when they adopted the recommendations of a special medical advisory panel set up under FDA direction. The panel included representatives of the American Medical Association, the American Academy of Pediatrics, representatives of industry, members of the FDA and "general interest participants."

We are not here today to argue for a continuation of packaging 50 tablets to the container. We are quite prepared to conform to contemporary thought respecting the number of tablets per package, and to reduce the number. But, for perspective, it is as important—as it is fair—to point out that the present practice was formulated by the special advisory panel referred to and that the panel operated with the participation and endorsement of the FDA, and that its recommendations were adopted and put into effect without legislation or other governmental coercion.

The action of that panel was reported in the columns of "Drug Trade News" for February 28, 1955 and a copy of that report is attached hereto as Appendix I. The recommendation of the panel were as follows:

1. Children's aspirin products should continue to be offered in flavored form.
2. Different dosage strengths of children's aspirin were "undesirable".
3. A standard dose strength per tablet of 1¼ grains of aspirin was urged.
4. All labels and packages containing salicylates should carry a clear and conspicuous warning to "keep out of the reach of children".
5. The labeling should direct parents to consult their physician concerning dosage for children under three years.
6. Manufacturers should not increase their then present maximum amount of children's flavored aspirin per package. Then and now that maximum has been 50 tablets of 1¼ grains each.
7. "Safety closures" should be developed and used.
8. Since the problem is basically one of parental negligence or ignorance, increased educational efforts concerning the dangers of accidental ingestion of aspirin-containing products was urged.

If, on the evidence adduced at these hearings, this Committee concludes that child safety will be promoted by limiting the number of tablets in containers of children's flavored aspirin, the Proprietary Association desires to cooperate in developing the legislation. It asks only that the limitation be written into the Act rather than left to determination and change by administrative regulation. And it asks that the limitation be practical and reasonable. Dr. Palmisano, a pediatrician in the Bureau of Medicine of FDA, testified at the hearing before this Committee on June 24, 1966 that:

"Somewhere in the neighborhood of 20 to 25 tablets of 1½ grain of aspirin flavored would seem to be the place where you would have to cut it off if you want to do what we are talking about." (Record, page 38)

Our recommendation is that the Committee act on that testimony and fix in the bill itself a limit of 25 tablets of 1¼ grain children's flavored aspirin, or the equivalent for liquid preparations.

II. Safety Closures

Under Section 3 of the bill, *any* drug in a retail container (including one to be dispensed on prescription), and "whether or *not* such drug is intended for children" which the FDA *by regulation* requires to be secured by safety closure, would be *adulterated* unless its container is secured in conformity with such regulations.

The difficulty on this point is that the bill here, too, is designed for yet another delegation of authority to the FDA; this time to prescribe safety closures. The objection to this further delegation is compounded by the facts presently per-

taining to the development of suitable such closures. That factual situation has been fully explained to the Committee by other witnesses.

Members of this Association—particularly those which manufacture children's flavored aspirin—have sought for a long time, with the aid of the makers of bottles, to devise safety closures. They have employed—and do now employ—such closures as have been developed. They would welcome—and are ardently seeking—more efficient closures. The objection to the bill at this point is again the delegation of unlimited authority to the FDA. Rather than make that delegation, it would be better to require that the FDA be directed to hold conferences or hearings to explore the subject and to make recommendations.

III. Basic Changes in Labeling Law

Section 4(b) of the bill includes in identical language a provision of H.R. 13885, a bill now pending before this Committee which relates to several aspects of drug regulation. What H.R. 13886 does at this point is to take *one* of those aspects (entitled in H.R. 13885 as "Drug Labeling Regulation") and incorporate it into H.R. 13886, the "Child Safety Act of 1966." Such excerpted portion would apply to *all* drugs and with respect to them the use by children would be merely *incidental*.

This excerpted portion would drastically amend Sec. 502(f)(2). That section—since 1938—has required drug labeling to bear "adequate" directions and "adequate" warnings. The manufacturer is, and has been, under the obligation to include such adequate directions and warnings on penalty of encountering—if he fails—the serious sanctions of injunction, criminal prosecution and product seizure.

Section 502(f) was a highly important provision at the time of enactment in 1938, and through the years has contributed greatly to the safe and effective use of drugs. The section has been the better for imposing the responsibility upon the manufacturer—for requiring that he meet the law's commandments and prohibitions at the risk of encountering, as above-stated, criminal prosecution, seizure of product, and injunction if he fails to meet his responsibility.

In the course of the hearings on June 24, 1966, there was testimony that the FDA had been "dealing with regulations under that section since 1938 without provision for hearing"; that

"We are regulating the entire range of drug labeling under that section without any problem without a hearing, so we didn't think it called for one to add this additional thing." (Record, pages 35 and 36 (The reference to "this additional thing" being presumably the proposed extensive rewrite of Section 502(f))).

That is not accurate. FDA has, indeed, been "regulating the entire range of drug labeling under that section," and it has been doing it "without any problem without a hearing." But that is where any analogy to the proposed amendment stops. The law requires the manufacturer to include in his labeling *adequate* directions and *adequate* warnings and imposes the responsibility on him to *comply* with the law; imposes responsibility on FDA to *enforce* the law. The proposed amendment would, in effect, empower FDA to *make* the law. For—under the amendment—every detail of the labeling as to directions and warnings would be formulated and prescribed by FDA.

For more than a quarter of a century, FDA has formulated and published—and industry has applied—a comprehensive set of suggested warnings which appear in the Code of Federal Regulations, Title 21, Chapter 1, Part 131, entitled "Interprepretive Statements Re Warnings on Drugs and Devices For Over-The-Counter Sale". A copy of such current "Interpretive Statements" is attached hereto as Appendix II. The "purpose of issuance" of these statements is stated at Section 131.1 as follows:

§ 131.1 Purpose of issuance.

The warning and caution statements suggested in Subparts B, C, and D of this part, for inclusion in the label or labeling of drugs and devices subject to section 502 (d) and (f)(2) and other relevant provisions of the Federal Food, Drug, and Cosmetic Act are *issued for the purpose of assisting industry in preparing proper labeling for these articles for over-the-counter sale and in meeting the legal requirements of the act that the label or labeling of drugs and devices bear adequate warnings, in such manner and form as are necessary for the protection of users.* Only section 502(d) of the act requires use of the specific language included in these suggested warning and caution statements. *These suggested warning or caution statements are illustrative of those that may be necessary or desirable. It is the responsibility of the manufacture, packer, shipper, or distributor in interstate commerce to see that such statements are adequate for compliance with the provisions of*

the law. Omission of any article from this suggested list does not relieve drugs and devices subject to provisions of the act from bearing adequate warning or caution statements where such statements are necessary or desirable for the protection of the user. (Emphasis added.)

Enactment of Section 4(b) would completely change the concept and application of the existing law with respect to the labeling of over-the-counter drugs. It would amend existing law so substantially and so completely as to swallow up and replace practically all other labeling requirements pertaining to over-the-counter drugs. It would put them—in so far as labeling is concerned—under a system of virtual licensing. It would accomplish this by unlimited delegation of authority to FDA to prescribe the labeling—including the manner and form of statement—with respect to directions and warnings; with respect to all matters to be included in, or omitted from, the labeling; and even to require "such other information" as FDA decrees.

The overwhelming enlargement of Section 502(f), which Section 4(b) of the bill proposes, is here shown by the new matter being capitalized:

"(b) Section 502(f) of such Act (21 U.S.C. 352(f)) is amended to read as follows: ('A drug or device shall be deemed to be misbranded—')

"'(f) Unless its labeling bears (1) adequate directions for use; (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, or against a substantial and reasonably foreseeable risk of causing accidental injury, in such manner and form, as are necessary for the protection of users, including instructions for first-aid treatment when necessary or appropriate; and (3) such other information relating to the foregoing matters and to side effects, contraindications, effectiveness, and other matters as may be required by or pursuant to regulations (applicable to the labeling of such drug) prescribed by the Secretary in order to carry out the purposes of this paragraph; and unless such labeling is in all respects in conformity (with respect to matters to be included in or omitted from such labeling, and with respect to manner and form of statement of matters included) with the requirements (applicable to the labeling of such drug) prescribed by the Secretary by or pursuant to regulation on the basis of a finding that such requirements are necessary for the safe and effective use of drugs or of the specific drug or class of drugs involved: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.'"

The sweeping extent of the proposed delegation may be analyzed by rearranging, or breaking down, the words of the section as proposed to be amended. The proposal is that the FDA have unlimited delegation to require (Page 4, line 1) "such *other* information relating to":

A. The "Foregoing Matters": to wit:
   1. Adequate directions, and
   2. Adequate warnings against—
   (a) use in pathological conditions
   (b) use by children
   (c) unsafe dosage
   (d) methods of administration
   (e) duration of administration or application
   (f) risk of accidental injury
   (g) instructions for first aid

B. "and to":
   (h) side effects
   (i) contraindications
   (j) effectiveness, and
   (k) "other matters" as may be required by regulation, and the article will be misbranded

C. "unless such labeling" conforms "in all respects" with regulations as to—
   (l) "manner" of statement, and
   (m) "form of statement" for the "safe and effective" use of the product

This breakdown speaks for itself. It both demonstrates the thoroughness of the present provisions of law and the extent of the attempted enlargement under the proposed amendment. Except for (f) and (g), the law now covers all the substantive elements in the foregoing analysis. As interpreted and applied—and as illustrated in Appendix II—it requires "adequate" warnings against—

(a) use in pathological conditions: with respect to infection, in case of burns, irritation, swelling, rash, rapid pulse, dizziness, glaucoma, kidney disease, nervous symptoms, nausea, fever, persistent coughs, high blood pressure, diabetes, heart disease, liver disease, intestinal disorders, diarrhea, sore throat;

(b) use by children: thirty-two suggested warnings with respect to children appear in Appendix II;

(c) unsafe dosage: twenty-seven suggested warnings against unsafe dosage appear in Appendix II;

(d) methods of administration: against use as a dusting powder, against internal use, use in solution, against application to large areas of the body, against bandaging extremities, for inhalation only, not for ingestion;

(e) duration of administration or application: against use if symptoms persist or recur frequently, limitation on number of days of use, against frequent or prolonged use.

We will pass over momentarily (f), risk of accidental injury and (g), instructions for first aid, and come to (h), "side effects" and (i), "contraindications." Both are covered by the present law as illustrated in the foregoing. A "side effect" is defined by Webster as—

"an effect of a drug other than the one it was administered to evoke,"

and in Stedman's Medical Dictionary as

"a result of drug or other form of therapy in addition to or in extension of the desired therapeutic effect. While technically the therapeutic effect carried beyond the desired limit (e.g., a hemorrhage from an anticoagulant is a s.), the term more often refers to pharmacologic results of therapy unrelated to the usual objective (e.g., a development of signs of Cushing's syndrome with steroid therapy). The term usually, but not necessarily, connotes an undesirable effect."

"Contraindication" is—

"an indication, sympton, or condition that makes inadvisable a particular treatment or procedure" (Webster);

"any special symptom or circumstance that renders the use of a remedy or the carrying out of a surgical procedure inadvisable." (Stedman)

As to (j), "effectiveness," the law has been strict as to over-the-counter medicines ever since enactment in 1938. A drug is defined as misbranded if "its labeling is false or misleading in any particular" (502(a)). And

"If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual." (Sec. 201(n)).

If the drug is not effective for the claims contained in its labeling, then the labeling is false or misleading and the drug is misbranded and is subject to seizure and the manufacture or distributor of it is subject to criminal prosecution and/or injunction. (Sec. 302, 303, 304).

As to (k), "other matters", as may be required by regulation, that obviously is a wide open grant of authority. As for (l) and (m), "manner and form of statement", the law now requires the warnings "in such manner and form, as are necessary for the protection of users."

So, the law now embraces—and since 1938 has embraced—the substance of everything proposed except warnings as to risk of accidental injury and instructions for first aid ((f) and (g) in the foregoing analysis). Other than those elements, the bill adds nothing to existing law except a delegation of unlimited authority to the FDA, and there has been no showing of any need for this delegation. If over-the-counter drugs are so fraught with danger, or with need for professional direction, as to require the proposed form of licensing control, they should not be sold over the counter. They should be sold only on prescription.

PRODUCT LIABILITY

Special attention may now be drawn to the proposal that the labeling of drugs should bear warnings against risk of causing accidental injury and should include instructions for first aid treatment in the event of such accidental injury. This

proposal should have most careful examination. If enacted, it would likely open wide the door to minute administrative regulation and enormous product liability.

With the passage of time there would likely be an increasing administrative demand for warnings against an increasing number of risks. The fact of the matter is, this amendment would be the answer to a negligence lawyer's prayer. The manufacturer would be liable for injury not only from *intended* use but from *unintended use* and from *abuse and misuse.*

The risk of accidental injury is dependent upon many contingencies over which the manufacturer has no control. Accidents may accompany the use of drugs in all the circumstances, ways and aspects in which they may accompany practically everything that people do: walking, riding, bathing, working, playing, etc.

The proposal for inclusion in labeling of instructions for first aid treatment is even more alarming. It may be asserted by the enforcement agency or by civil litigants that "instructions are necessary or appropriate" in a multitude of circumstances. It may be seerted that such "instructions" are "necessary" with respect to all uses—intended or unintended—and in all the conditions for which it is recommended. What is considered "necessary or appropriate" at one time may not be so considered at another. The list of conditions in which such instructions are deemed "necessary or appropriate" may lengthen with time, and the composition of the "instructions" may broaden and the nature of them may change with changing administrations.

It is quite well recognized that the Food and Drug Act is directed primarily to protecting the health of the public. So—when public health requires it—the threat of enlarged product liability must be tolerated. But must it be baited, invited, and encouraged?

First aid treatment involves questions of therapeutics; involves medical care and incidents of the practice of medicine; involves questions as to the propriety of, and the appropriate, self-medication in such cases. Thus, the manufacturer would be faced with differences of medical opinion as to whether the stated instructions were the proper ones, whether they (and/or unstated ones) were "necessary or appropriate." Uncertainty, controversy and litigation would inevitably be bred by questions of this sort, proliferated and blown into considerable proportions by cross-winds of medical opinion.

CONCLUSION

The philosophy of the Federal Food and Drug law has been to encourage private initiative and enterprise; to state in the law the commands and prohibitions; to impose upon manufacturers the responsibility for obeying such commands and prohibitions. There are in the law exceptions, but such exceptions have been justified on the basis of needed public protection. So, the new drug provisions of the law are, in effect, a form of licensing. Likewise, the certification of antibiotics. But these are exceptions which prove the rule. Unless such rule and this concept of the Food and Drug law have become outmoded and are to be discarded and the manufacture of drug products made an administered industry, the FDA should not receive the delegation of authority which this bill proposes.

The conclusion of the matter is that H.R. 13886 goes far beyond child safety, envelops controversial medical opinion, escalates legal liability and constricts industrial independence. It enlarges delegation of authority to FDA beyond anything foreseeable.

The full measure of the completeness with which H.R. 13886 locks up under Government control the labeling and packaging of drugs may be taken in the frame of reference afforded by Appendix III wherein the far-reaching controls now pertaining to these products are outlined.

Therefore, we respectfully request that H.R. 13886 and similar bills not be favorably reported in their present form, but that they be amended to overcome the objections herein set out.

APPENDIX I

[Drug Trade News, Feb. 28, 1955]

FDA, Industry Officials Agree on Children's Aspirin Policy, Recommend Label Warning

Washington.—The Food and Drug Administration is expected in time to adopt as formal policy most of the recommendations made by a medical advisory panel on accidental ingestion and misuse of salicylate preparations by children, a FDA spokesman said following a panel meeting on the subject held here.

Chief among five recommendations adopted unanimously by the panel of industry, government and other physicians and technicians interested in the subject was that labels of all bottles and packages of preparations containing salicylates carry "clearly visible and in bold face type" the following "WARNING: Keep out of reach of children."

The group also recommended that no specific dosage recommendations for children under three be carried on labels of these preparations, but that labels should bear the statement: "For children under three consult your physician."

Another recommendation was that, if possible, manufacturers agree on a standard strength of 1¼ gr. for children's aspirin. Dose forms of several strengths for children are "undesirable," the panel stated.

The group said it "looks with favor" on manufacturers refraining from increasing the present maximum amounts of children's flavored aspirin per package unit and that it encourages development of a safety closure and container.

Dr. Albert H. Holland, Jr., FDA medical director, emphasized that, while flavored aspirins probably are a factor in the salicylate hazard for children, the group recognized they have "important medical advantages" and agreed no restrictive action should be taken against the continued manufacture of such preparations.

The panel also urged "wider and more effective use" of educational means to inform physicians, pharmacists and consumers of the hazards involved in accidental ingestion of salicylate-containing preparations.

Dr. Holland said the panel's recommendations will form the basis for recommendations to be made by FDA's Medical Division to Commissioner George P. Larrick. A spokesman for Mr. Larrick said that when Dr. Holland's recommendations are received they will be considered from a legal and administrative viewpoint and a public statement will be made of the policy finally adopted. It was made clear that time will be given manufacturers and distributors to work off stocks of preparations and labels on hand at the time a policy decision is announced.

The salicylate panel, the second to be set up under Dr. Holland's direction, was headed by Dr. Charles F. McKhann, professor of pediatrics, Jefferson Medical College, Philadelphia. Dr. Holland said he was "much gratified" at the manner in which the group had attacked the problem under study and at the nature and unanimity characterizing its recommendations.

Representing industry at the Feb. 14 meeting were Drs. George R. Hazel and Edward J. Matson, Abbott; Dr. Theodore G. Klumpp and H. M. Manss, Sterling Drug; C. D. Smith Jr., and Joseph W. Kouten, Carroll Dunham Smith; Dr. Clayton G. Weigand, Lilly; Dr. James M. Shaffer and Robert L. McNeil, Jr., McNeil Laboratories; Drs. L. Eugene Daily and Paul McLeon, Norwich; Drs. E. A. Sharp and George M. Shadle, Parke-Davis; H. B. Solmson and Earl Kimzey, Plough; Dr. Douglas Remsen and J. J. Tooty, Squibb division of Mathieson; Drs. E. Gifford Upjohn and Earl L. Burbidge, Upjohn, and Dr. E. R. Neary and J. J. Feldman, White Laboratories.

Participating as consultants: Dr. Jay M. Arena, Duke University; Dr. Edward Press, American Public Health Assn.; Dr. Torald Sollman, Western Reserve University, and Dr. George M. Wheatley, Metropolitan Life Insurance Co.

"General interest" participants: Bernard Conley, Committee on Toxicology, American Medical Assn.; Dr. Harvey B. Haag, Medical College of Virginia; Dr. Justin Powers, Committee on the National Formulary; Dr. M. H. Seevers, University of Michigan, and Newell Stewart, National Pharmaceutical Council.

FDA representatives: Commissioner Larrick; Dr. Holland; Dr. Irvin Kerlan, chief, Research and Reference Branch; Dr. Kenneth B. Campbell, Drug and Device Branch; Dr. Ernest Q. King, New Drug Branch; Elizabeth C. Kelly, chief, Medical Reference Service; Dr. Arnold J. Lehman, chief, Division of Pharmacology; Dr. B. J. Vos, Division of Pharmacology; Dr. Geoffrey Woodward, Division of Pharmacology, and Morris L. Yakowitz, Office of the Commissioner.

APPENDIX II

NOTE.—Boldface roman and boldface italic type in text (excluding heads) has been added: Bold for 32 warnings as to use by children and italic for 27 warnings against unsafe dosage.

TITLE 21—FOOD AND DRUGS

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 131—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

The Commissioner of Food and Drugs has considered the comments filed on the proposed interpretative statements re warnings on drugs and devices for over-the-counter sale published in the FEDERAL REGISTER of March 26, 1959 (24 F.R. 2361), and in accordance with the authority delegated to him by the Secretary of Health, Education, and Welfare (22 F.R. 1045, 23 F.R. 9500), Title 21 is amended by adding thereto the following new part:

Subpart A—Definitions and Interpretations

Sec.
131.1 Purpose of issuance.
131.2 Definitions.
131.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503 (b)(1)(C).
131.4 Warnings suggested for drugs by formal or informal statements of policy.
131.5 Warnings required on insulin intended for over-the-counter sale.
131.6 Warnings required on certifiable antibiotics exempted from prescription-dispensing requirements.
131.7 Warnings required by official compendia.
131.8 Warning statements in relation to conditions for use.
131.9 General warnings re accidental ingestion by children.
131.10 Conspicuousness of warning statements.
131.11 Warnings on veterinary drugs intended for administration to diseased animals.

Subpart B—Drugs for Human Use

131.15 Drugs for human use; recommended warning and caution statements.
131.16 Drugs for human use; warning and caution statements required by regulations.
131.17 Drugs for human use; warning and caution statements specifically required by law.

Subpart C—Drugs for Veterinary Use

131.20 Drugs for veterinary use; recommended warning and caution statements.
131.21 Drugs for veterinary use; warning and caution statements required by regulations.

Subpart D—Devices

131.25 Devices; recommended warning and caution statements.

AUTHORITY: §§ 131.1 to 131.25 issued under secs. 503, 506, 507, 701, 52 Stat. 1052, as amended; 55 Stat. 851; 59 Stat. 463, as amended; 52 Stat. 1055, as amended; 21 U.S.C. 353, 356, 357, 371. Interprets or applies sec. 502, 52 Stat. 1050, as amended; 53 Stat. 854; 21 U.S.C. 352.

CROSS REFERENCES: For interrelated regulations issued under the Federal Food, Drug, and Cosmetic Act, see Parts 1 (Drugs), 3, 130, 146, 146c, 146d, 146e, 164, 165.

SUBPART A—DEFINITIONS AND INTERPRETATIONS

§ 131.1 Purpose of issuance.

The warning and caution statements suggested in Subparts B, C, and D of this part, for inclusion in the label or labeling of drugs and devices subject to section 502 (d) and (f)(2) and other relevant provisions of the Federal Food, Drug, and Cosmetic Act are issued for the *purpose of assisting industry in preparing proper labeling for these articles for over-the-counter sale and in meeting the legal requirements of the act that the label or labeling of drugs and devices bear adequate warnings, in such manner and form as are necessary for the protection of users.* Only section 502(d) of the act requires use of the specific language included in these suggested warning and caution statements. These suggested warning or caution statements are illustrative of those that may be necessary or desirable. *It is the responsibility of the manufacturer, packer, shipper, or distributor in interstate commerce to see that such statements are adequate for compliance with the provisions of the law.* Omission of any article from this suggested list does not relieve drugs and devices subject to provisions of the act from bearing adequate warning or

caution statements where such statements are necessary or desirable for the protection of the user.

§ 131.2 Definitions.

(a) As used in this part, the term "act" means the Federal Food, Drug, and Cosmetic Act.

(b) The terms "drugs" and "devices" are defined in section 201 (g) and (k) of the act.

(c) Official compendia are defined in section 201(j) of the act.

§ 131.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C).

Drugs exempted from prescription-dispensing requirements under section 503(b)(1)(C) of the act are subject to the labeling requirements prescribed in § 130.102(a) of this chapter. Although, for convenience, warning and caution statements for a number of the drugs named in § 130.102 of this chapter (cross-referenced in the text of this part) are included in Subpart B of this part, the inclusion of such drugs in §§ 131.15, 131.16, 131.17 in no way affects the requirements for compliance with § 130.102(a) of this chapter, or the provisions of an effective application pursuant to section 505(b) of the act.

§ 131.4 Warnings suggested for drugs by formal or informal statements of policy.

The warning and caution statements included in Subpart B in no way affect any warning statement suggested for such drugs or devices by any statement of policy or interpretation in Part 3 of this chapter.

§ 131.5 Warnings required on insulin intended for over-the-counter sale.

Warning and caution statements for insulin products sold over the counter must comply with the specific labeling provisions of the act and § 164.6 of this chapter.

§ 131.6 Warnings required on certifiable antibiotics exempted from prescription-dispensing requirements.

Certain certifiable antibiotic drugs are exempted from prescription-dispensing requirements under section 507 of the act, but are subject to the specific labeling requirements, including warning or caution statements, of the applicable section of the antibiotic regulations.

§ 131.7 Warnings required by official compendia.

Any drug included in the official compendia defined by the act shall bear such warning or caution statement as may be required by such compendia, and no statement in Subpart B or Subpart C of this part is intended to alter, modify, or permit the omission of any such statement required by such compendia.

§ 131.8 Warning statements in relation to conditions for use.

The mention in any warning or caution statement included in Subparts A, B, and C of this part, of a disease condition does not imply a finding on the part of the Food and Drug Administration that any drug or device is efficacious in such condition; nor is any drug or device bearing labeling referring to such disease condition precluded from regulatory action under the applicable provisions of the act if such claim is considered to be misbranding.

§ 131.9 General warnings re accidental ingestion by children.

Section 131.15 includes at the present time under certain items, but not all medicines, the statement **"Keep this and all medications out of the reach of children"** or "Keep out of the reach of children." However, in view of the possibility of accidental ingestion of drugs, it is not only suggested but is recommended that one of these statements be used on the label of all drug products.

§ 131.10 Conspicuousness of warning statements.

Necessary warning statements should appear in the labeling prominently and conspicuously as compared to other words, statements, designs, and devices in order to comply with the provisions of section 502 (c) and (f)(2) of the act. The warning statements should be placed in the labeling in juxtaposition with the directions for use, and in any case should appear on the label when there is sufficient label space in addition to mandatory label information.

§ 131.11 Warnings on veterinary drugs intended for administration to diseased animals.

None of the warning or caution statements recommended for use in the labeling of drugs intended for administration to diseased animals shall be construed to suggest or imply that any product of a diseased animal is suitable for food use. (See section 402(a)(5) of the act.)

SUBPART B—DRUGS FOR HUMAN USE

§ 131.15 Drugs for human use; recommended warning and caution statements.

ACETANILID.

Warning—***Do not exceed recommended dosage. Overdosage or continued use may result in serious blood disturbances.***

ACETOPHENETIDIN-CONTAINING PREPARATIONS. (See § 3.37 of this chapter.)

Warning—This medication may damage the kidneys when used in large amounts or for a long period of time. ***Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician.***

ANESTHETICS FOR EXTERNAL USE (LOCAL ANESTHETICS). See also § 130.102(a) (19) and (23) of this chapter.)

Caution—Do not use in the eyes. ***Not for prolonged use.*** If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIBIOTICS FOR EXTERNAL USE FOR PREVENTION OF INFECTION. (See also §§ 130.102(a)(5), 146c.202, 146e.402, 146e.407, 146e.409, 164e.411, 146e.422 of this chapter.)

Caution—In case of deep or puncture wounds or serious burns consult physician. If redness, irritation, swelling, or pain persists or increases or if infection occurs, discontinue use and consult physician. Do not use in the eyes.

ANTIHISTAMINICS FOR EXTERNAL USE (EXCEPT PREPARATIONS FOR OPHTHALMIC USE).

Caution—Do not use in the eyes. ***If the condition for which this preparation is used persists*** or if a rash or irritation develops, ***discontinue use and consult physician.***

*ANTIHISTAMINICS, ORAL. (See also §§ 3.29 and 130.102(a) (4), (6), (13), (24), and 25 of this chapter.)

Caution—This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. **Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician.**

The reference to drowsiness is not required on preparations for the promotion of sleep or on preparations that are shown not to produce drowsiness.

*Cyclizing-containing preparations should include the following:

Warning—Not for use by women who are pregnant or who may possible become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child.*

ANTIPERSPIRANTS.

Do not apply to broken skin. If a rash develops, discontinue use.

ANTIPYRINE.

Warning—***Do not exceed recommended dosage.*** If skin rash appears, discontinue use and consult physician.

ANTISEPTICS FOR EXTERNAL USE.

Caution—In case of deep or puncture wounds or serious burns, consult physician. If redness, irritation, swelling, or pain persists or increases or if infection occurs discontinue use and consult physician.

The reference to wounds and burns is not required on preparations intended solely for diaper rash.

ARSENIC PREPARATIONS.

Warning—***Frequent or prolonged use may cause serious injury. Do not exceed recommended dosage.*** **Keep out of the reach of children.**

BELLADONNA PREPARATIONS AND PREPARATIONS OF ITS ALKALOIDS (ATROPINE, HYOSCYAMINE, AND SCOPOLAMINE (HYOSCINE)); HYOSCYAMUS, STRAMONIUM, AND RELATED DRUG PREPARATIONS.

Warning—**Not to be used by** elderly persons or by **children under 6 years** of age unless directed by physician.

Caution—***Do not exceed recommended dosage. Not for frequent or prolonged use.*** If dryness of the mouth occurs, decrease dosage. Discontinue use if rapid pulse, dizziness, or blurring of vision occurs.

See also Rectal Preparations for additional warnings.

Scopolamine or scopolamine aminoxide preparations for insomnia should include the following warning or its equivalent:

Warning—Not to be used by persons having glaucoma or excessive pressure within the eye, by elderly persons (where undiagnosed glaucoma or excessive pressure within the eye may be present), or **by children under 12 years of age,** unless directed by a physician.

In addition to this statement, the following or its equivalent should be included:

Caution—***Do not exceed recommended dosage. Not for frequent or prolonged use.*** If dryness of the mouth occurs, decrease dosage. Discontinue use if rapid pulse, dizziness, or blurring of vision occurs.

Scopolamine or scopolamine aminoxide preparations for motion sickness should include the following:

Warning—**Not to be used by children under 6 years of age unless directed** by physician.

Caution—***Do not exceed recommended dosage.*** Discontinue use if rapid pulse, dizziness, or blurring of vision occurs.

BORIC ACID (POWDERED, CRYSTALLINE, OR GRANULAR).

Warning—**Do not use as a dusting powder, especially on infants,** or take internally. Use only as a solution. Do not apply to badly broken or raw skin, or to large areas of the body.

BROMIDES.

Caution—***Use only as directed.*** **Do not give to children** or use in the presence of kidney disease. If skin rash appears or if nervous symptoms persist, recur frequently, or are unusual, discontinue use and consult physician.

CARBOLIC ACID (PHENOL) PREPARATIONS (MORE THAN 0.5 PERCENT) FOR EXTERNAL USE.

Warning—***Use according to directions.*** Do not apply to large areas of the body. If applied to fingers or toes, do not bandage.

CATHARTICS AND LAXATIVES—IRRITANTS AND OTHER PERISTALTIC STIMULANTS.

Warning—Do not use when abdominal pain, nausea, or vomiting are present. ***Frequent or prolonged use of this*** preparation may result in dependence on laxatives.

Mercury preparations should have added to the "frequent use" statement, the words "and serious mercury poisoning."

Phenolphthalein preparations should bear, in addition to the general warning, the following statement:

Caution—If skin rash appears, do not use this or any other preparation containing phenolphthalein.

See also Mineral Oil Laxatives.

CHLORATES: MOUTH WASH OR GARGLE.

Avoid swallowing.

COBALT PREPARATIONS. (See also § 3.48 of this chapter.)

Warning—***Do not exceed the recommended dosage.*** **Do not administer to children under 12 years of age** unless directed by physician. Do not use for more than 2 months unless directed by physician.

This warning is not required on articles containing not more than 0.5 milligram of cobalt as a cobalt salt per dosage unit and which recommend administra-

tion of not more than 0.5 milligram per dose and not more than 2 milligrams per 24-hour period.

"COUGH-DUE-TO-COLD" PREPARATIONS. (See also § 130.102(a) (14) and (20) of this chapter).

Warning—Persons with a high fever or persistent cough should not use this preparation unless directed by physician.

COUNTERIRRITANTS AND RUBEFACIENTS.

Caution—Do not apply to irritated skin or if excessive irritation develops. Avoid getting into the eyes or on mucous membranes.

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

See also "Salicylates" in this section for additional warnings for preparations containing methyl salicylate.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN PREPARATIONS FOR EXTERNAL USE.

Caution—Do not apply to large areas of the body.

CREOSOTE, CRESOLS, GUAIACOL, AND SIMILAR SUBSTANCES IN DOUCHE PREPARATIONS.

Warning—The use of solutions stronger than those recommended may result in severe local irritation, burns, or serious poisoning. Mix as directed before pouring into douche bag. Do not use more often than twice weekly unless directed by physician.

DIARRHEA PREPARATIONS.

Warning—Do not use for more than 2 days or in the presence of high fever or **in infants or children under 3 years** of age unless directed by a physician.

DISPENSERS PRESSURIZED BY GASEOUS PROPELLANTS FOR DRUGS FOR EXTERNAL USE. (See also § 130.102(a) (11) and (18) of this chapter.)

Warning—Keep away from eyes or other mucous membranes. Avoid inhaling. This warning is not necessary for preparations specifically designed for use on mucous membranes.

Where indicated, in order to prevent chilling the tissues, a caution should be included against holding the dispenser too close to the body.

Warning—Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130° Fahrenheit may cause bursting. Never throw container into fire or incinerator.

DOUCHE PREPARATIONS.

Warning—Do not use more often than twice weekly unless directed by physician.

See also Creosote * * * Douche for additional warning.

DRESSINGS, PROTECTIVE SPRAY-ON TYPE. (See also § 130,102(a) (11) and (18) of this chapter.)

Warning—In case of deep or puncture wounds or serious burns consult physician. If redness, irritation, swelling or pain persists or increases or if infection occurs consult physician. Keep away from eyes or other mucous membranes. Avoid inhaling.

See also Dispensers Pressurized by Gaseous Propellants * * * for additional warnings to be included for products under pressure.

EPHEDRINE PREPARATIONS (ORAL)

Warning—Do not exceed the recommended dosage. Reduce dosage if nervousness, restlessness, or sleeplessness occurs. Do not use if high blood pressure, heart disease, diabetes, or thyroid disease is present unless directed by physician.

EPINEPHRINE INHALATION 1:100 (NOT FOR INJECTION).

Warning—For inhalation only. Reduce dosage if bronchial irritation, nervousness, restlessness, or sleeplessness occurs. Do not use if high blood pressure, heart disease, diabetes, or thyroid disease is present unless directed by physician. If prompt relief is not obtained consult physician. Do not use epinephrine inhalation if it is brown in color or contains a precipitate.

GENTIAN VIOLET (METHYLROSANILINE CHLORIDE) TABLETS.

Caution—Do not bite or chew tablets before swallowing. If nausea develops, discontinue for 1 or 2 days; then resume treatment with reduced dosage, increasing dose gradually to former level. This preparation should not be used by persons with heart, kidney, or liver disease or intestinal disorders. Abstinence from alcohol during treatment is advisable.

HEXYLRESORCINOL ANTHELMINTICS.

Warning—Do not chew or break in the mouth.

IODINE AND IODIDES (ORAL).

Caution—If a skin rash appears, discontinue use and consult physician.

MERCURY PREPARATIONS FOR EXTERNAL USE.

Warning—Discontinue use if rash or irritation develops or if condition for which used persists. ***Frequent or prolonged use,*** or application to large areas may cause serious mercury poisoning.

Ammoniated mercury bleach cream:

Warning—Discontinue use if rash or irritation develops. Do not apply to irritated or damaged skin (cuts, bruises, sunburn) or after shaving or using a depilatory. **Do not apply to children under 12 years of age.**

MINERAL OIL LAXATIVES. (See also § 3.4 of this chapter.)

Caution—Take only at bedtime. ***Avoid prolonged use.*** **Do not administer to infants or young children,** in pregnancy, or to bedridden or aged patients unless directed by physician.

NASAL PREPARATIONS: OIL BASE.

Warning—***Do not exceed recommended dosage nor use for prolonged period.*** **Do not administer to infants or children unless directed** by physician. Do not use as a spray.

NASAL PREPARATIONS IN PLASTIC SPRAY CONTAINERS.

Avoid overdosage. Follow directions for use carefully.

NASAL PREPARATIONS: VASOCONSTRICTORS (AMPHETAMINE, EPHEDRINE, EPINEPHRINE, METHAMPHETAMINE, AND OTHERS OF SIMILAR ACTIVITY). (See also § 130.102(a)(16) of this chapter.)

Caution—***Do not exceed recommended dosage. Overdosage may cause nervousness, restlessness, or sleeplessness.*** Do not use for more than 3 or 4 consecutive days unless directed by physician.

NASAL PREPARATIONS: VASOCONSTRICTORS (PHENYLEPHRINE HYDROCHLORIDE, HYDROXYAMPHETAMINE, PHENYLPROPANOLAMINE, AND OTHERS OF SIMILAR ACTIVITY).

Caution—***Do not exceed recommended dosage.***

NUX VOMICA AND STRYCHNINE PREPARATIONS.

Warning—***Do not exceed the recommended dosage.*** **Keep out of the reach of children.**

OPHTHALMIC PREPARATIONS. (See also § 3.28 of this chapter.)

Warning—If irritation persists or increases, discontinue use and consult physician. Keep container tightly closed.

Solutions should include the statement: Do not touch dropper tip (or other dispensing tip) to any surface, since this may contaminate solution.

Boric acid offered for use in the preparation of ophthalmic solutions should bear the statement: Prepare solution by boiling in water. Store in a sterile container. Prepare sufficient for one day's use and discard unused portion.

Phenacetin-containing preparations. (See Acetophenetidin.)

PHENYLEPHRINE HYDROCHLORIDE PREPARATIONS, ORAL.

Caution—Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician.

PHENYLPROPANOLAMINE HYDROCHLORIDE PREPARATIONS, ORAL.

Caution—Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician.

POTASSIUM PERMANGANATE AQUEOUS SOLUTIONS (CONTAINING NOT MORE THAN 0.04 PERCENT POTASSIUM PERMANGANATE) (See § 3.7 of this chapter.)

Warning—For esternal use on the skin only. Severe injury may result from use internally or as a douche. Avoid contact with mucous membranes. [Item added, 25 F.R. 8074, Aug. 23, 1960.]

QUININE AND OTHER CINCHONA DERIVATIVES (EXCEPT FOR USE IN MALARIA).

Caution—Discontinue use if ringing in the ears, deafness, skin rash, or visual disturbances occur.

RECTAL PREPARATIONS FOR EXTERNAL USE. (See also § 130.102(a)(3) of this chapter.)

Warning—In case of rectal bleeding, consult physician promptly.
See also Belladonna Preparations * * * for additional warnings.

RESINS, OLEORESINS, AND VOLATILE OILS.

Caution—If nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs, discontinue use and consult physician.

RESORCINOL (NOT THE MONOACETATE) HAIR PREPARATIONS.

Caution—Excessive use of this preparation may temporarily discolor blond, white, or red hair.

SALICYLATES, INCLUDING ASPIRIN AND SALICYLAMIDE (EXCEPT METHYL SALICYLATE, EFFERVESCENT SALICYLATE PREPARATIONS, AND PREPARATIONS OF PARAAMINOSALICYLIC ACID AND ITS SALTS). (See also §§ 3.43 and 3.509 of this chapter.)

Warning—**Keep out of the reach of children; or**
Warning—Keep this and all medications out of the reach of children.
The above information should appear on the label.
Caution—**For children under 3 years of age consult physician;** or
Caution—For younger children consult your physician.
One of the two statements immediately preceding is required on the label of all aspirin tablets, but such a statement is not required on the labels of other salicylates clearly offered for administration to adults only.
If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:
Caution—If pain persists for more than 10 days, or redness is present, or **in conditions affecting children under 12 years of age consult a physician immediately.**

SALICYLATES: METHYL SALICYLATE (WINTERGREEN OIL). See also §§ 3.35 and 3.509 of this chapter.

Warning—***Do not use otherwise than as directed.*** **Keep out of the reach of children to avoid accidental poisoning.**
If the preparation is a counterirritant or rubefacient the statement:
Caution—Discontinue use if excessive irritation of the skin develops. Avoid getting into the eyes or on mucous membranes.
If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:
Caution—If pain persists for more than 10 days or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

SILVER.

Caution—***Frequent or prolonged use of this preparation*** may result in permanent discoloration of skin and mucous membranes.

SODIUM PERBORATE MOUTH WASH AND GARGLE AND TOOTHPASTE.

Caution—Discontinue use if irritation or inflammation develops, or increases. Avoid swallowing.

SULFONAMIDE NOSE DROPS.

Caution—Do not use if a known allergy to sulfonamide drugs exists.

SULFUR PREPARATION FOR EXTERNAL USE.

Caution—If undue skin irritation develops or increases, discontinue use and consult physician.

THROAT PREPARATIONS FOR TEMPORARY RELIEF OF MINOR SORE THROAT: LOZENGES, TROCHES, WASHES, GARGLES, ETC. (See also § 3.510 of this chapter.)

Warning—Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult physician promptly. **Do not use** more than 2 days or **administer to children under 3 years** of age unless directed by physician.

TOOTHACHE PREPARATIONS.

For temporary use only until a dentist can be consulted.

ZINC STEARATE DUSTING POWDERS.

Warning—**Keep out of the reach of infants and children;** avoid inhaling.

§ 131.16 Drugs for human use; warning and caution statements required by regulations.

ACETAMINOPHEN (*N*-ACETYL-*p*-AMINOPHENOL). (See § 130.102(a)(1) of this chapter.)

Warning—**Do not give to children under 3 years of age** or use for more than 10 days unless directed by a physician.

If offered for use in arthritis, or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately,

ALCOHOL RUBBING COMPOUND. (See 26 CFR 182.855(a)(5); The National Formulary, Tenth Edition 1955, pp. 27–28; and section 502(g) of the act.)

Warning—For external use only. If taken internally serious gastric disturbances will result.

ANTIBIOTIC-CONTAINING DRUGS FOR EXTERNAL USE FOR PREVENTION OF INFECTION. (See § 130.102(a)(5) of this chapter.)

Caution—If redness, irritation, swelling, or pain persists or increases or if infection occurs, discontinue use and consult physician. Do not use in the eyes.

*ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE, MECLIZINE HYDROCHLORIDE, DOXYLAMINE SUCCINATE, CHLOROTHEN CITRATE, CYCLIZINE HYDROCHLORIDE, AND CHLORCYCLIZINE HYDROCHLORIDE PREPARATIONS), (See §§ 3.29 and 130.102(a) (4), (6), (13), (24), and (25) of this chapter.)

Caution—This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. **Do not give to children under 6 years of age** or exceed the recommended dosage unless directed by physician.

If offered for symptoms of colds, the statement:

Caution—If relief does not occur within 3 days, discontinue use and consult physician.

*For chlorcyclizine-, cyclizine-, or meclizine-containing preparations, the statement:

Warning—Not for use by women who are pregnant or who may possibly become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child.*

BACITRACIN-CONTAINING OINTMENTS. (See §§ 146e.402, 146e.407, 146e.411 of this chapter.)

For use only in the prevention of infection in minor cuts and abrasions.

Use of the drug should be discontinued and a physician consulted if signs of infection or irritation appear.

BACITRACIN (ZINC BACITRACIN)-POLYMYXIN OINTMENT; BACITRACIN-POLYMYXIN-NEOMYCIN OINTMENT. (See §§ 146e.409 and 146e.422 of this chapter.)

For use only in the prevention of infection in minor cuts and abrasions. Use of the drug should be discontinued and a physician consulted if signs of infection or irritation appear.

If it is in liquid form, also the statement "Not for injection."

CARBETAPENTANE CITRATE PREPARATIONS. (See Cough-Due-to-Cold Preparations.)

"COUGH-DUE-TO-COLD" PREPARATIONS (DEXTROMETHORPHAN HYDROBROMIDE AND CARBETAPENTANE CITRATE). (See § 130.102(a) (14) and (20) of this chapter.)

Warning—**Keep out of the reach of children. Do not administer to children** under 2 years of age unless directed by physician. Persistent cough may indicate the presence of a serious condition. Persons with a high fever or persistent cough should not use this preparation unless directed by physician.

DEXTROMETHORPHAN HYDROBROMIDE PREPARATIONS. (See Cough-Due-to-Cold Preparations.)

DIAMTHAZOLE DIHYDROCHLORIDE FOR EXTERNAL USE. (See § 130.102(a)(7) of this chapter.)

Warning—**Do not apply to children under 6 years of age because serious reactions may occur. Do not apply to children 6 to 12 years of age unless** directed by physician. Do not use on mucous membranes. Discontinue use and consult physician if irritation develops or relief is not obtained. Keep out of the reach of children.

DICYCLOMINE HYDROCHLORIDE WITH AN ANTACID. (See § 130.102 (a)(8) of this chapter.)

Warning—***Do not exceed the recommended dosage.*** **Do not administer to children under 12 years of age or use** for a prolonged period unless directed by physician, since persistent or recurring symptoms may indicate a serious disease requiring medical attention.

DIPHEMANIL METHYLSULFATE FOR EXTERNAL USE. (See § 130.102 (a)(22) of this chapter.)

Caution—If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

DYCLONINE HYDROCHLORIDE. (See § 130.102(a)(23) of this chapter.)

Caution—Do not use in the eyes. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by physician. Do not use, but consult physician for deep or puncture wounds or serious burns. Do not use in case of rectal bleeding, as this may indicate serious disease.

HEXADENOL. (See § 130.102(a)(11) of this chapter.)

Caution—Do not use for treatment of serious burns or skin conditions or for conditions which persist for prolonged periods. In such cases, consult your physician. Do not spray in vicinity of eyes, mouth, nose, or ears. Do not store above 120° F.

INSULIN. (See § 164.6(c) of this chapter.)

Insulin (40, 80, or 100 U.S.P. units per milliliter):

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not use if drug has become viscous or if its color has become other than water clear.

In addition to the above warnings, the following statements should be included in the labeling: "Keep in a cold place, avoid freezing. Failure to follow directions for use may lead to infection."

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Protamine zinc insulin, isophane insulin, lente insulin, semilente insulin, or ultralente insulin:

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not substitute for any other insulin-containing drug unless directed by physician. Do not use when precipitate has become lumped or granular in appearance or has formed a deposit of solid particles on the wall of the container.

In addition to the above warnings for protamine zinc insulin * * *, the following statements should be included in the labeling of these preparations: "Keep in a cold place, avoid freezing"; "Shake carefully" or "Shake well before using" or "Shake well" or "Shake carefully to suspend all particles"; "Failure to follow directions for use may lead to infection."

Globin zinc insulin:

Caution—Do not remove stopper. Not for intravenous nor intramuscular use. Do not use after expiration date shown on outside wrapper or container. Do not use if any turbidity or precipitate has developed in the solution. Do not substitute for any other insulin-containing drug unless directed by physician.

In addition to the above warnings for globin zinc insulin, the following statements should be included in the labeling: "Keep in a cold place, avoid freezing. Failure to follow directions for use may lead to infection."

*IPECAC SYRUP IN ONE-FLUID OUNCE CONTAINERS FOR EMERGENCY TREATMENT OF POISONING, TO INDUCE VOMITING. (See § 3.30 of this chapter.)

Ipecac syrup packaged for over-the-counter sale must bear statements to the following effect, in a prominent and conspicuous manner:

The following statement (boxed and in red letters):

"For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice."

The following warning: Warning—**Keep out of reach of children.** Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested.

ISOAMYLHYDROCUPREINE AND ZOLAMINE HYDROCHLORIDE RECTAL PREPARATIONS FOR EXTERNAL USE. (See § 130.102(a)(3) of this chapter.)

Warning—Do not use this preparation in case of rectal bleeding, as this may indicate serious disease.

NEOMYCIN SULFATE WITH A VASOCONSTRICTOR, IN NASAL PREPARATIONS (SPRAY OR DROPS). (See § 130.102(a)(9) of this chapter.)

Caution—***Do not exceed recommended dosage.*** **Do not administer to children under 3 years of age** unless directed by physician.

OXYTETRACYCLINE AND POLYMYXIN B SULFATE. (See Antibiotic-Containing Drugs for External Use * * *)

PRAMOXINE HYDROCHLORIDE FOR EXTERNAL USE. (See § 130.102(a)(19) of this chapter.)

Caution—Do not use in the eyes or nose. Not for prolonged use. Do not apply to large areas of the body. If redness, irritation, swelling, or pain persists or increases, discontinue use unless directed by a physician.

SODIUM FLUORIDE DENTIFRICE POWDER. (See § 130.102(a)(10) of this chapter.)

Caution—**Children under 6 years of age should not use this drug.**

SODIUM GENTISATE. (See §§ 3.43, 3.509, 130.102(a)(2) of this chapter.)

Warning—**Do not give to children under 6 years of age** or use for prolonged period unless directed by physician.

Warning—**Keep this and all medications out of the reach of children;** or

Warning—**Keep out of the reach of children.**

If offered for use in arthritis or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in **conditions affecting children under 12 years of age,** consult a physician immediately.

SODIUM MONOFLUOROPHOSPHATE DENTIFRICE SOLUTION. (See § 130.102(a)(15) of this chapter.)

Caution—**Children under 6 years of age should not use this drug.**

TUAMINOHEPTANE SULFATE NASAL PREPARATIONS (See § 130.-102(a)(16) of this chapter.)

Caution—***Do not exceed recommended dosage. Overdosage may*** cause nervousness, restlessness, or sleeplessness. Individuals with high blood pressure, heart disease, diabetes, or thyroid disease should use only as directed by physician. Do not use for more than 3 or 4 consecutive days unless directed by physician.

VIBESATE PREPARATIONS. (See § 130.102(a)(18) of this chapter.)

Caution—Do not use but consult physician for deep or puncture wounds or serious burns. If redness, irritation, swelling, or pain persists or increases, discontinue use and consult physician.

Warning—Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130° Fahrenheit may cause bursting. Never throw container into fire or incinerator.

§ 131.17 Drugs for human use; warning and caution statements specifically required by law.

PREPARATIONS CONTAINING HABIT-FORMING DERIVATIVES OF SUBSTANCES NAMED IN SECTION 502(d) OF THE ACT. (See §§ 165.1, 165.2, and 165.5 of this chapter.)

The statement "*Warning*—May be habit forming" is required to appear on the labels of all drugs containing derivatives designated in § 165.1 of this chapter as habit forming, including exempt narcotic preparations described in § 165.5(a) of this chapter and preparations containing one or more derivatives of barbituric acid, unless such drug is not suitable for internal use and is distributed and sold exclusively for such external use as involves no possibility of habit formation.

APPENDIX III

OUTLINE OF PRINCIPAL FEDERAL CONTROLS PRESENTLY PERTAINING TO PACKAGING AND LABELING OF DRUGS

1. The definition of terms in Sec. 201 of the Federal Food, Drug and Cosmetic Act are broad and elastic:

(a) "Drug" means, among other things, articles used in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

(b) "Label" means matter displayed on the immediate container.

(c) "Labeling" means matter accompanying the article.

(d) "Misbranding" includes not only representations expressly made but the failure of labeling to reveal facts material in the light of representations contained in the labeling or material with respect to consequences which may result from use of the labeled article under the conditions of use stated or under such conditions as are customary.

2. The elements of misbranding are comprehensive and the requirements are broad and precise.

(a) Labeling must not be "false or misleading in any particular," and a drug is misbranded if it is dangerous to health when used as directed in its labeling. (Sec. 502(a) and (j))

(b) The label must contain name and address of manufacturer or distributor and statement of weight, measure or numerical count. (Sec. 502(b))

Elaborate regulations, going into much detail, affect label compliance with the statutory provisions. (21 CFR 1.102)

(c) Information on labels and in labeling must be prominently placed "with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely

to be read and understood by the ordinary individual under customary conditions of purchase and use." (Sec. 502(c))

Elaborate regulations, going into much detail, affect label compliance with the statutory provisions. (21 CFR 1.103)

(d) If it contains any habit forming substance, the label must bear the name and quantity or proportion of such substance and the statement "Warning—May be habit forming." (Sec. 502(d))

(e) The label must bear the "established name" of the drug and, if it consists of two or more ingredients, the established name (and in some cases the quantity) of active ingredients. (Sec. 502(e))

Elaborate regulations, going into much detail, affect label compliance with the statutory provisions. (21 CFR 1.105)

(f) The labeling must contain (1) adequate directions for use and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. (Sec. 502(f))

(g) If it is a drug the name of which is recognized in an official compendium, it must be packaged and labeled as prescribed in the compendium. (Sec. 502(g))

(h) If a drug has been found by the Secretary to be liable to deterioration, it must be packaged in such form and manner, and its label bear such precautions as the Secretary shall by regulation require as necessary for the protection of the public health. (Sec. 502(h))

(i) The container must not be "so made, formed or filled as to be misleading"; the drug must not be an imitation of another drug; it must not be offered for sale under the name of another drug. (Sec. 502(i))

(j) Under the "Drug Abuse Control Amendments of 1965," it must not be a "counterfeit drug" which is defined (Sec. 201(g)(2)):

"The term 'counterfeit drug' means a drug which, or the container or labeling of which, without authorization, bears the trademark, tradename, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or ing of which, without authorization, bears the trademark, tradename, or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor."

(k) All depressant and stimulant drugs subject to the "Drug Abuse Control Amendments of 1965" (Sec. 511) must bear prominently on the principal panel of the label the following symbol or modifications:

The symbol in outline form is for use as a large, open-letter overprint.

(l) The advertising and labeling of prescription drugs pursuant to the 1962 Amendments, must contain the established name "printed prominently and in type at least half as large as that used for any trade or brand name thereof," the ingredients and "such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations." (Sec. 502(n))

(m) A drug which is not safe for use other than on prescription must be labeled "Caution: Federal law prohibits dispensing without prescription." (Sec. 503(b)(4))

(n) Regulations require, when appropriate, such statements as "for prescription compounding"; "Caution: For manufacturing, processing or repacking"; "For investigational use"; "Diagnostic reagent—For professional use only." (21 CFR 1.106 (j), (k), (l))

3. Packaging and labeling are subject to review and approval under the provisions of Sec. 505 as to "new drugs." The Act provides for the submission of

labeling material and the regulations make detailed requirements (21 CFR 130, et seq.).

4. Sec. 507 requires certification of antibiotics and extensive regulations prescribe numerous labeling and packaging requirements (21 CFR 141, et seq.).

5. Sec. 510 requires registration for the manufacture, processing or repackaging of drugs and requires factory inspection at least once every two years.

6. Sec. 704 provides for inspection of factories, including the materials therein and the labeling pertaining to them.

7. Sec. 801 forbids importation of any drug article which is misbranded. It permits exportation when labeled on the outside of the shipping package to show that it is intended for export.

8. S. 985 and H.R. 15440, the so-called "Fair Packaging and Labeling Act," now pending before the Committee on Interstate and Foreign Commerce—if passed in present form—will add further controls and specifications which will not be known until adoption of regulations.

Mr. HOGE. In deference to the time element which we have discussed, I will shorten a good deal by skipping. I don't want to skip, however, an expression of our appreciation, Mr. Chairman; we are grateful for this opportunity to be heard before this committee, and we are the more grateful, Mr. Chairman, because of the seriousness of this bill.

I am going to cut my statement to eliminate two of the points which I was to discuss because they have been discussed very fully: the aspirin matter just now by Dr. Tainter and safety closures recently by Mr. Fisher. I am going to come in a moment to the third element which is the matter of labeling. I want to say to you as I do that this bill is extremely serious in that respect—more serious, I think, than we have realized; certainly more serious than has been represented yet to this committee. With your permission and your patience I am going to try in my statement to analyze that part of the bill and leave with you the seriousness of it.

Mr. Chairman my statement has a reference as to who I am. My name is James F. Hoge and I am a member of the bar of the State of North Carolina and of the State of New York. I have practiced in New York for nearly 36 years and am located at 90 Park Avenue, New York City.

I appear today for my client—The Proprietary Association, located in this city. It is an association of manufacturers of proprietary medicines.

There is another thing that I would not like to skip in the matter of time, and that is the position of this association on food and drug legislation.

Mr. Chairman, I appeared before this committee on August 10, 1935, and pledged the support of this association to the bill which was then before you, and which about 3 years later became the Federal Food, Drug, and Cosmetic Act of 1938.

We were first a very ardent opponent of that bill because of reasons which were stated and argued at the time and we appeared before committees in the House and in the Senate on it. In May of 1935, when the bill passed the Senate, we had withdrawn our opposition. The bill had been amended, and we gave our support at that time. I stated our support of record in your proceedings on August 10, 1935, and I would like to quote just this sentence from my statement then:

> We do not oppose the bill here today, and we do not propose any amendments, I am particularly glad to say that, Mr. Chairman, because up until this time we

have considered it necessary to be an opponent although all the while we have realized that improved food and drug legislation was and is needed, not only in the interests of the public but in the interest of legitimate industry.

And, Mr. Chairman, that has been our position ever since, and it is our position here today; and while we are cast in the status of an opponent to this bill, H.R. 13886, our opposition is only in part. We have no objection to the hazardous substances part, the latter part of the bill. We have no objection to H.R. 13884 which was before you originally when you opened these hearings; and our opposition to H.R. 13886 relates solely to the provisions on aspirin, which we have discussed here today; to the provisions on bottle closures; and then to the third matter to which I now come.

In this matter our opposition is to the unlimited delegation of authority. We, as you have heard, have no objection to reducing the number of tablets in a bottle of aspirin. We don't know what to say specifically about bottle closures, but we will cooperate with whatever you try to work out on that. I think I would like to say this, however, about the aspirin matter right at the point where you were a moment ago, Mr. Chairman. I remember the 1955 meeting although I was not present. I have attached to my statement as appendix I (see p. 210), a copy of the "Drug Trade News" for February 28, 1955, which has been referred to several times this morning. When you have a chance to study it, I would call your attention to the people who were at the meeting, to the firms who were there, to the industry which was represented, the names of the companies, the names of the people from the Government, and the names of the people from the universities. Now as I recall, it was not so much a matter of reducing the number of tablets in a bottle of children's aspirin, as it was of encouraging the industry not to increase the number. The principal makers were then manufacturing bottles of 50 just as they are today, and the consensus of that meeting, as I remember it and as it seems to read in the "Drug Trade News" report, was that the industry was encouraged by the conference not to increase the number.

Now, with that, let me come to the matter of labeling, and that begins on page 7, I believe, of our statement, Mr. Chairman. I hope you will include in the record what I have said with respect to aspirin and bottle closures and come to page 7 which I have entitled "Basic Changes in Labeling Law."

Section 4(b) of the bill includes in identical language a provision of H.R. 13885, which is also before this committee, although you have had no hearings on it yet. What H.R. 13886 does at this point is to take one of the provisions of 13885, which in that bill is entitled "Drug Labeling Regulation," and incorporate it now into this bill, 13886, as "Child Safety Act of 1966."

Now, such excerpted portion would apply to all drugs, not just to aspirin but to all drugs and with respect to them, the use by children would be merely incidental. This excerpted portion would drastically amend section 502(f)(2). That section was put into the law in 1938 and since its enactment in 1938 it has required drug labeling to bear "adequate" directions and "adequate" warnings. The manufacturer is and has been under the obligation to include such adequate directions and warnings on penalty of encountering, if he fails, the serious sanctions of injunction, criminal prosecution and product seizure.

Section 502(f) was a highly important provision at the time of enactment in 1938. Mr. Chairman, I remember so vividly the dis-

cussions and the debates first in opposition, then finally in support of a provision of law that was to require the manufacturer to put on his labels warnings against using or against methods of using. The philosophy of it was—and it is a good philosophy—that warnings are "the other side of the coin." On one side of the coin are directions how to use; on the other side are directions how not to use. So it was really a very forward piece of legislation when it was put in this law in 1938. And, I submit to you, it has been the better for imposing the responsibility on the manufacturer, for requiring that he meet the law's commandments and prohibitions at the risk of the serious sanctions of injunction and criminal prosecution and seizure.

In the course of the hearings on June 24, 1966, before you, there was testimony that the FDA had been, I am quoting now:

> dealing with regulations under that section since 1938 without provision for hearing—

and that—

> we are regulating the entire range of drug labeling under that section without any problem without a hearing, so we didn't think it called for one to add this additional thing.

That "additional thing" I suppose was the proposed exhaustive, comprehensive rewrite of the section. Now, that statement made before you is not accurate. FDA has indeed been "regulating the entire range of drug labeling under that section," and it has been doing it "without any problem without a hearing."

But, Mr. Chairman, that is where any analogy to the proposed amendment stops. The law requires the manufacturer to include, as I just said, adequate directions and adequate warnings and imposes the responsibility on him to comply with the law; and on the FDA to enforce the law. The proposed amendment would, in effect, empower FDA to make the law, and that is the heart of our objection to this proposed rewrite of the warning section of the law.

For, under this amendment, every detail of the labeling as to directions and warnings—Mr. Chairman, when you deal with over-the-counter drugs, there are three important things: what the article is good for, and how you use it, and how you don't use it. It is important to put the weight on the label to put on the name and address and all other required things, of course. But the most important thing, if you are selling an over-the-counter medicine, without a prescription, is to tell a person what it is good for, how to use it, and how not to use it, and that is where this subject comes to a crisis. For, as I have just said, every detail now of the labeling, as to directions and warnings would be formulated by the FDA.

For more than a quarter of a century FDA has formulated and published, and industry has applied a comprehensive set of suggested warnings which appear in the Code of Federal Regulations, title 21, chapter 1, part 131, entitled "Interpretative Statements Re Warnings on Drugs and Devices for Over-the-Counter Sale."

Mr. Chairman, so that you could see what is the situation in this respect, I have attached as appendix II (see p. 211) a copy of the Code of Federal Regulations, showing the suggested warnings which now exist and to some extent have existed for 25 years. I say to some extent, because suggestions have been added through the years, of course, but this law was passed in 1938, June; it was to take effect

in June 1939, it was extended to January 1940; so, since January 1940, or very soon thereafter, there have been these suggested warnings to go on over-the-counter articles and they are now as you see them here on my statement.

Mr. NELSEN. Mr. Chairman, at that point would the gentleman yield for a question?

Mr. JARMAN. Yes.

Mr. NELSEN. In the District of Columbia Committee I introduced a bill, and the chairman introduced a bill dealing with the qualifying of the District of Columbia for rehabilitation funds on the same basis as the States, which I think it a very good bill.

The bill then went to the Education Committee and they added an elected school board to it and this addition killed the whole thing.

Now, if this section you refer to is already in the Drug Safety Act, would not this bill, which certainly has areas of merit, be jeopardized in its passage because of the additional section that is put in there?

Mr. HOGE. Well, if I understand you, Congressman, it would. I don't know whether I am familiar enough with it——

Mr. NELSEN. I am dealing with this bill.

Mr. HOGE. Yes.

Mr. NELSEN. I am using my instance as a parallel where a good bill was defeated or put on the shelf because of an additional item which was put in it. If the child safety bill is to be passed and the controversial section is added to it which is already in the law, might not the addition jeopardize the bill?

Mr. HOGE. Well, I would think so. And I appreciate your putting a point here. Let me just say this, Mr. Chairman, I have been at this a long time. I have been counsel for this association for 32 years, and I was present during the whole time that this food and drug law was worked out from June 1933 to June 1938 when it was passed, and it is a wonderful piece of legislation and it was hammered out in a democratic way, first by ardent opposition, then by support, by conferences in chambers, before you in hearings and in every way possible to exchange the views. This law as so hammered out is a good law, and we are dealing right now with one of the most important aspects of it, to wit, the command for directions and warnings on the label and the responsibility of the citizen to obey the law. This law did that; it made the Food and Drug Administration responsible for enforcing it and it left the courts to adjudicate it. Thank you, Congressman Nelsen for interrupting me at that point.

On page 9 I want to call your attention to something that is very germane. I have quoted for you there—in fact have photostated—the purpose of issuance of the suggested warning and caution statement. It is taken from the code which you will see in another section of my statement—appendix II (see p. 221). I underscored just enough so that we can move along quickly without reading it all. But I wanted you to see that the Food and Drug said itself in issuing these suggestions, that they are issued for the purpose—I am quoting now:

> issued for the purpose of assisting industry in preparing proper labeling for these articles for over-the-counter sale and in meeting the legal requirements of the Act that the label or labeling of drugs and devices bear adequate warnings in such manner and form as are necessary for the protection of users.

And three lines farther on it says:

> These suggested warning or caution statements are illustrative of those that may be necessary or desirable. It is the responsibility of the manufacturer, packer, shipper, or distributor in interstate commerce to see that such statements are adequate for compliance with the provisions of the law.

And that is a responsibility, Mr. Chairman, that every citizen ought to accept and we accept it gladly. Let me just say this, Mr. Chairman. If you will look at the labels in the drugstores, you will see that practically all of them bear the warnings or the spirit of the warnings which are suggested here. You have heard no charge that the industry stands in violation of the warning section of the act. We have made a point of that. Of course, the best, most practical thing one can do is to accept the warnings that the Government has suggested; use them or use language that says the same thing even if not in exactly the same language.

Now, enactment of section 4(b) would completely change the concept and application of the existing law with respect to the labeling of over-the-counter drugs. It would amend existing law so substantially and so completely as to swallow up and replace practically all other labeling requirements pertaining to over-the-counter drugs. It would swallow up everything except name and address and the weight and a few technical matters of that sort.

It would put these articles, insofar as labeling is concerned, under a system of virtual licensing. It would accomplish this by unlimited delegation of authority to FDA to prescribe the labeling, including the manner and the form of statement, with respect to directions and warnings; with respect to all matters, says the amendment, to be included in, or omitted from, the labeling; and even to require "such other information" as the FDA decrees.

Now, the overwhelming enlargement of the section is shown in my statement by the new matter being capitalized. In the interest of time I won't read it but I put it there for you, the bill, at this particular point, where it would amend section 502 and I have elevated into caps the new matter and I have also, on some of the copies underscored it so as bring it out the more.

Now I would like to break that down for you in a way which I think will show it a little easier than repeating so much of the language which goes into the proposal. So, I say in my statement on page 11, that the sweeping extent of the proposed delegation may be analyzed by rearranging, or breaking down, the words of the section as proposed to be amended. The proposal is that FDA have unlimited delegation to require "such other information relating to"—the bill says—"the foregoing matters."

Now, what are the "foregoing matters"? They are (1) adequate directions; and (2) adequate warnings against—(a) use in pathological conditions; (b) use by children; (c) unsafe dosage; (d) methods of administration; (e) duration of administration or application; (f) risk of accidental injury; and (g) instructions for first aid.

And then the bill continues:

"And to" (h) side effects; (i) contraindications; (j) effectiveness, and (k) "other matters" as may be required by regulation, and the article will be misbranded, says the bill, quoting again unless such labeling "conforms" in all respects with regulations as to (l) "manner"

of statement and (m) "form of statement" for the "safe and effective" use of the product.

Mr. Chairman, the breakdown speaks for itself. It both demonstrates the thoroughness of the present provisions of law and the extent of the attempted enlargement under the proposed amendment. Now except for (f) and (g), which were the risk of accidental injury, and instructions for first aid—except for those two elements—the law now covers all the substantive elements in the foregoing analysis. As interpreted and applied, and as illustrated by the suggested warnings in appendix II to my statement, the law requires "adequate" warnings against use in pathological conditions, where its use may be dangerous, says the present law. Well, the warnings suggested in appendix II will show that some of the pathological conditons against which we must warn are infection, burns, irritation, swelling, rash, rapid pluse, dizziness, glaucoma, kidney disease, neverous symptoms, nausea, fever, persistent coughs, high blood pressure, diabetes,heart disease, liver disease, intestinal disorders, diarrhea, and sore throat. And, there are more, too. I have picked out representative ones from the warnings here in appendix II. That is what we have to warn against now, they are the pathological conditions.

(b) Use by children, and there rather than try to copy some of them, knowing of the interest that we have now in this aspect of the matter, I underlined in red the warnings which now appear with respect to children. There are 32 of them if I have counted correctly, and I say again for ready reference, I put them in red so that you could see the nature of the warnings that now pertain to us and so far as this record shows, are now obeyed.

(c) Unsafe dosage, which would tie in I think, Mr. Chairman, with the matter of antidotes and accidental risk and so on. There are 27 suggested warnings against unsafe dosage and I underline those in green so as to bring them up quickly and to differentiate them from the other, and you will see the nature of them without taking the time now to read them to you.

(d) Methods of administration. Well, some of the warnings require or suggest that we should have a warning against use as a dusting powder or against internal use if it is an external matter or against use in solution or against application to large areas of the body or against bandaging the extremities, the fingers and the toes or maybe for inhalation only or maybe against inhalation, and then, of course, there are many other warnings not for ingestion, that would be again unsafe methods of administration. And then the warning law says there must be warnings against duration of administration or application where it might be dangerous, and so these suggestions deal with warning against use if the symptoms persist, or if they recur frequently, and then there are warnings which suggest that we should put on the label the limitation of the number of days in which the medicine should be used before you see a doctor, for instance.

Then there are quite a few of them against frequent or prolonged use and ever so many of them of an affirmative character, as well as negative, to use only as directed, which is a very important direction.

Mr. Chairman, it is the theory of this law when it was enacted back in 1938 that one set of drugs should have a doctor to prescribe them because of the potency and the danger of them; another set of drugs should be so labeled that the laymen could use them and as to him

then the burden, said the law, and the philosophy was, you put on that label all the material that the layman needs with which to use the drug intelligently and safely. This is the basic philosophy of this law, since 1938.

Now let me pass over momentarily (f), which was the risk of accidental injury and (g), instructions as to first aid and come to (h), which was "side effects" and (i) contraindications. The bill throws those in, Mr. Chairman, as though it was something new. It is not new. The only thing new about side effects and contraindications in the bill is that as with all of it the Secretary would be given the power to prescribe and to tell us what to do rather than impose as the law now does, the burden.

All right. A side effect is defined by Webster as "an effect of a drug other than the one it was administered to evoke."

Stedman, in his Medical Dictionary, goes to a little more length but it is a helpful definition.

> A side effect is a result of drug or other form of therapy in addition to or in extension of the desired therapeutic effect. While technically the therapeutic effect carried beyond the desired limit, for instance, a hemorrhage from an anticoagulant is a side effect, the term more often refers to pharmacologic results of therapy unrelated to the usual objective, for instance, a development of signs of Cushing's syndrome with steroid therapy. The term usually, but not necessarily, connotes an undesirable effect.

"Contraindication" is defined by Webster as "an indication, symptom, or condition that makes inadvisable a particular treatment or procedure."

And, by Stedman, as "any special sympton or circumstance that renders the use of a remedy or the carrying out of a surgical procedure inadvisable."

And I call your attention again, without reading the details of it, to appendix II which we went over a moment ago in abstract, that you will find there time after time, that we must warn against the side effects. We must warn and mention against the contraindications, so I repeat, it is all in the law now. The only thing that isn't in the law is the power of the Secretary to prescribe it literally for us.

Now, as to "effectiveness," and that was (j) in my breakdown there. The law has been strict as to over-the-counter medicines ever since enactment in 1938.

Now in the Kefauver hearings we went into a great deal of "effectiveness" with respect to prescription drugs, comparative effectiveness if you please, but with respect to these over-the-counter things which, Mr. Chairman, if they are not comparatively simple must be on prescription, they ought not to be sold unless they are capable of being handled by the layman.

Now, a drug is defined as misbranded if, and it has been since 1938, if "its labeling is false or misleading in any particular." That is 502(a).

And then this very important provision was put in in 1938 and we ought to look at it because it is very relevant to what we are talking about today. The law provides, in 201(n) that:

> If in article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading, there should be taken into account, among other things, not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations

or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

Mr. Chairman, out of your experience in hearings of this kind, you can imagine how much thought, debate, went into the working out of that section and incorporating it in the statute.

Now, if the drug is not effective for the claims contained in its labeling, then the labeling is false or misleading and drug is misbranded and is subject to seizure and the manufacturer is subject to criminal prosecution and/or injunction.

Now, as to (k) in that breakdown of a few moments ago, which was "other matters", as may be required by regulation, I can only say that that obviously is a wide open grant of authority.

As for (l) and (m), "manner and form of statement", the law now requires the warnings "in such manner and form, as are necessary for the protection of users."

So, Mr. Chairman, the law now embraces, and since 1938 has embraced, the substance of everything proposed except warnings as to risk of accidental injury and instructions for first aid, that is (f) and (g) in my analysis. Other than those elements, the bill adds nothing to existing law except a delegation of unlimited authority to the FDA, and there has been no showing of any need for this delegation. If over-the-counter drugs are so fraught with danger or with the need for professional direction as to require the proposed form of licensing control, they should not be sold over the counter. They should be sold only on prescription.

Now, I come to "product liability" and I am almost at the end of my statement as I am contracting it, Mr. Chairman.

Special attention may now be drawn to the proposal that the labeling of drugs should bear warnings against risk of causing accidental injury, and should include instructions for first aid treatment in the event of accidental injury. This proposal should have most careful examination. If enacted, it would likely open wide the door to minute administrative regulation and enormous product liability.

Let me interrupt myself here, I might forget it, yet in my study I wanted to say this to you; I said there just a moment ago that the instruction for first aid should apply to accidental injury.

The way the bill is worded, that is not correct. As I reexamine and read it, and if you will read the language of the bill, you will see that the first aid instructions would apply to everything that is in the law now, pathological conditions, unsafe dosage, use by children, everything the law now says, with this addition, the way it is put into the bill, at this particular point, would require first aid instructions with respect to all of them.

With the passage of time there would likely be an increasing administrative demand for warnings against an increasing number of risks. The fact of the matter is, this amendment would be the answer to a negligence lawyer's prayer. The manufacturer would be liable for injury not only from intended use but from unintended use and from abuse and misuse.

The risk of accidental injury is dependent upon many contingencies over which the manufacturer has no control. Accidents may accompany the use of the drugs in all the circumstances, ways, and aspects

in which they may accompany practically everything the people do: walking, riding, bathing, working, playing, and so forth.

The proposal for inclusion in labeling of instructions for first aid treatment is even more alarming. It may be asserted by the enforcement agency or by civil litigants that "instructions are necessary or appropriate" in a multitude of circumstances. It may be asserted that such "instructions" are "necessary" with respect to all uses, intended or unintended, and in all the conditions for which it is recommended. What is considered "necessary or appropriate" at one time may not be so considered at another. The list of conditions in which such instructions are deemed "necessary or appropriate" may lengthen with time, and the composition of the "instructions" may broaden and the nature of them may change with changing administrations.

It is quite well recognized that the Food and Drug Act is directed primarily to protecting the health of the public. So, Mr. Chairman, let me be clear about this, when public health requires it, the threat of enlarged product liability must be tolerated, we must assume that burden. But I ask you this morning, must it be baited, must it be invited, must it be encouraged by solemn legislation enacted by the Congress?

First aid treatment involves questions of therapeutics; involves medical care and incident of the practice of medicine; involves questions as to the propriety of, and the appropriate self-medication in such cases. Thus, the manufacturer would be faced with differences of medical opinion as to whether the stated instructions were the proper ones, whether they, and/or the unstated ones, were "necessary or appropriate." Uncertainty, controversy, and litigation would inevitably be bred by questions of this sort, proliferated and blown into considerable proportion by crosswinds of medical opinion.

Now, Mr. Chairman, at this point I would like to hesitate. I hope that the rest of my statement may be made a part of the record and if time will permit, I wish you would recognize the gentleman with me, Mr. Connolly, who has had considerable experience in the law of product liability and he is with me this morning for that purpose. I think he has a statement which he may file, but perhaps you may hear him briefly.

Dr. Paul is a physician and has had considerable experience with injuries, accidents, that sort of thing; and he has a statement which he will file too, but perhaps you would hear both of them briefly.

Mr. JARMAN. The committee will be glad to hear from them.

Mr. CONNOLLY. May I proceed, Mr. Chairman?

Mr. JARMAN. Yes.

Mr. CONNOLLY. Mr. Chairman, I am a practicing lawyer in the city of Washington. My credentials are set forth on the first page of my prepared statement. I have prepared this statement and I have also prepared a memorandum brief which supports the conclusions that I have reached. I am going to depart from that in the interest of time and try to summarize it extemporaneously and I ask however that the statement and the brief, if you care to have it, will be included in the record.

Mr. JARMAN. They will be accepted for the record.

(The prepared statement of Paul R. Connolly and memorandum brief attached thereto, follow:)

STATEMENT OF PAUL R. CONNOLLY, ESQ.

Mr. Chairman and Members of the Subcommittee: My name is Paul R. Connolly. I am a partner in the Washington law firm of Hogan & Hartson, having offices at 815 Connecticut Avenue.[1] My appearance before you today is in the capacity of consulting counsel to the Proprietary Association[2] by whom I have been requested to discuss the impact of certain language found in H.R. 13886 upon a manufacturer's liability in tort. I have specific reference to those provisions which would amend Section 502(f) of the Federal Food, Drug & Cosmetic Act [21 U.S.C. § 352(f)] to require a manufacturer to include upon its labeling "(2) such adequate warnings * * * against a substantial and reasonably foreseeable risk of causing accidental injury, in such manner and form, as are necessary for the protection of users, including instructions for first-aid treatment when necessary or appropriate; and (3) such other information relating to the foregoing matters and to side effects, contraindications, effectiveness, and other matters as may be required by or pursuant to regulations * * *"

Although there is no field of tort law which is developing as rapidly, as extensively and whose direction is more toward the imposition of new liability upon a manufacturer than in the field of products cases, there is as yet no body of judicial precedent which would impose the nature or the extent of new liability contemplated or inherent in the language proposed by this Bill. Despite the ready familiarity of the ring of the words of the Bill to the ear of the tort lawyer their arrangement and setting would create a vast new area of liability for manufacturers without regard to any fault or wrongdoing on their part. Its adoption would necessarily inhibit the development of new products; largely impose an insurer's obligation upon them, and increase the cost of their products by greatly increasing their insurance costs.

The reach and extent of the proposed amendatory language to Section 502(f) is best appreciated if it is considered in the light of the most advanced judicial and pedagogical opinion. So measured, the proposed Bill (1) would extend a manufacturer's duty to warn to four areas in which most courts have hitherto held there is no such duty; (2) would prescribe a new "good Samaritan" duty, which no court has as yet imposed and for the discharge of which a manufacturer is plainly a poor choice, and (3) would deprive a manufacturer of his common law defenses.

I. THE DUTY TO WARN EXTENDED INTO FOUR NEW AREAS

The most modern, advanced statement concerning a manufacturer's liability for marketing a defective product is to be found in Section 402A of the RESTATEMENT (SECOND), TORTS, which imposes strict liability upon a supplier of a product which is in a defective condition and unreasonably dangerous to the consumer.[3] Comment h to that section makes it clear that a product would be classified "defective" if it failed to bear an adequate warning of danger where appropriate. Comment j illustrates the extent of this duty and a substantial body of case law has defined it. The manufacturer is not an insurer against all accidental injury involving his product, and the courts have held that it is unreasonable to require a warning against every contingency which might occur in the course of use of his product.

A. Duty to Warn of Hazards Arising From An Unintended Use of the Product

Even though a manufacturer can appreciate the fact that a user of his product might put it to a purpose for which it was not intended by him, the courts have held that there is no duty to warn against such misuse. The proposed language of H.R. 13886, however, would require a warning against any reasonably foreseeable misuse. This would require a considerable degree of foresight and imagination on the part of the manufacturer to anticipate the myriad misuses of his product by the entire spectrum of humanity ranging from those of very tender years, to the blind and to the simply careless.

[1] I am a member of the American College of Trial Lawyers; the International Association of Insurnce Counsel, presently serving as a member of its Executive Committee; and the American and District of Columbia Bar Associations. I have taught and lectured extensively in the field of Trial Tactics, Negligence Law and Evidence at the Georgetown University Law Center; at the Practicing Law Institute, and elsewhere.

[2] An Association of proprietary drug manufacturers with offices at 1700 Pennsylvania Avenue, N.W., Washington, D.C.

[3] The adoption by the American Law Institute of the doctrine of strict liability has most recently been criticized as an attempt at legislating. It is argued that § 402A is not a "restatement" of existing case law but a declaration of new law. See: Dalrymple, "Brief Opposing Strict Liability in Tort," Defense Research Institute, Inc. (1966).

B. Duty to Warn Against Obvious and Patent Hazards

The courts have held that a manufacturer is required to give notice only of latent dangers inherent in his product and is not liable for a patent deficiency which should have been obvious to the consumer. The proposed Bill, however, makes no such distinction. It requires notice of every foreseeable hazard whether obvious to anyone or not.

C. Duty to Warn of the Risk of Trivial Injury

No court or commentator has thought it appropriate to require a manufacturer to warn of the danger of slight or trivial injury. Rather, the imposition of liability rests upon the immediate threat of *serious* bodily harm. Judge Prettyman, writing for the court in *Jamieson* v. *Woodward & Lothrop*, 247 F. 2d 23, 29 (D.C. Cir. 1957) put the matter well when he said:

> "But we do not find in the authorities a doctrine that, if the injury ordinarily foreseen is relatively minor and so need not be warned against, a manufacturer must nevertheless warn against any dire consequence which, also obviously, may ensue. Quite to the contrary it is well established that a manufacturer is not liable, *unless serious bodily harm is reasonably foreseeable.*"

The proposed amendatory language of H.R. 13886, however, uses the word "substantial" as modifying the risk, not the injury. Such transposition of words would require a warning against the substantial possibility of a slight or insignificant injury and the consequences which could result therefrom.

D. Duty to Warn of Side Effects, Contraindications and Effectiveness of the Product

Most courts have held that a product is not defective because it does not provide warning against a hazard or side effect of which the manufacturer could not reasonably have had knowledge. The Fifth Circuit's refual to impose liability upon a tobacco company which provided no warning of the carcinogenic quality of its cigarettes is a familiar example of this principle.[4] Likewise, there is no duty to warn of an occasional allergic or idiosyncratic reaction. There is a duty to warn only where the allergic class is sufficiently large to reflect upon the capability of the product. The reason for this rule is said to arise from the fact that most people are allergic to something; that a warning would serve no purpose since the user most probably is unaware of his allergy, and that such warnings would inhibit the use of a product which may very well be helpful to the great majority of users.[5]

H.R. 13886 would vest in the Secretary, without right of hearing, the authority to establish an absolute duty to warn against all undesirable effects arising from a product's use. This would give the Secretary the power to impose an insurer's liability upon any manufacturer subject to the Food, Drug & Cosmetic Act.

II. THE DUTY TO BE "THE GOOD SAMARITAN"

A manufacturer is not under any present duty to prescribe first-aid treatment on his product's literature. The "good Samaritan rule" rather inhibits such a practice since, if a person volunteers to provide such care, he is liable if the care turns out to be inaccurate or insufficient.

The proposed Bill would require the performance of a duty to render first aid and would undoubtedly impose additional liability upon the manufacturer if that aid were inaccurate; ill-advised, or inadequate. The variety of types of accidental injury and the disparate nature of the human response thereto make it extremely impractical to prescribe treatment in advance by means of a printed label.

III. THE DEPRIVATION OF THE COMMON LAW DEFENSES OF CONTRIBUTORY NEGLIGENCE AND ASSUMPTION OF RISK

Generally speaking, a manufacturer of a product which has caused injury may defend upon the ground that the user was himself negligent in the use of the product or else that he exposed himself to a known risk of injury in the manner in which he used it. There is a considerable body of case law, however, which holds that where legislation is enacted to protect a special class of persons thought to be incapable of protecting themselves, e.g., children and the intoxicated, the defenses of contributory negligence and assumption of risk are not available to one charged with violating the statute.

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[4] See *Lartigue* v. *R. J. Reynolds Tobacco Co.*, 317 F. 2d 19 (5th Cir. 1963).
[5] Freedman, "Allergy and Products Liability Today," 24 Ohio St. L. J. 479 (1963).

In the light of the preamble to H.R. 13886 and its common-name title, it may well be successfully argued that a manufacturer charged with a violation of its provisions is deprived of his common law defenses.

The opinions and conclusions which I have expressed concerning the present state of the law are supported by a memorandum brief which my office has prepared and which I desire to file as an addendum to these remarks.

IV. RECOMMENDATIONS

The perfectly well-intentioned motives behind H.R. 13886—to protect children and other users from substances hazardous to their bodily integrity—may be better served if the subcommittee were to follow the drafts of the American Law Institute in its RESTATEMENT, rather than attempt to employ new language and invoke new concepts of liability. If such an approach were employed, the language of H.R. 13886 should be modified to require a warning as to "risks of serious bodily harm which are reasonably foreseeable to the manufacturer from an intended use of the product but which are not reasonably obvious to an intended user."

In my opinion there should not be imposed any statutory duty to prescribe first-aid remedies. Probably the only safe and comprehensive advice which should be given in such cases is a general admonition to "contact your physician in case of misuse."

MEMORANDUM BRIEF PREPARED BY PAUL R. CONNOLLY, ESQ., CONCERNING THE LIABILITY OF A MANUFACTURER UNDER CERTAIN LANGUAGE PROPOSED BY H.R. 13886

H.R. 13886 (89th Cong., 2d Sess.) proposes to amend Section 502(f) of the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 352(f), to require that product labels bear "* * * (2) such adequate warnings * * * against a substantial and reasonably foreseeable risk of causing accidental injury, in such manner and form, as are necessary for the protection of users, including instructions for first-aid treatment when necessary or appropriate; and (3) such other information relating to the foregoing matters and to side effects, contraindications, effectiveness, and other matters as may be required by or pursuant to regulations * * * prescribed by the Secretary [of Health, Education & Welfare]."

The adoption of such statutory language would enlarge the liability of a manufacturer subject to the Act beyond any degree yet imposed by the rapidly developing case law in the field of products liability. This statement can be readily appreciated by a comparison of the liability proposed by the Bill with the most advanced present state of the law as developed in judicial opinions.

I. THE DUTY TO WARN—GENERALLY

The most advanced statement of the law concerning a manufacturer's duty to warn is to be found under Section 402A of the RESTATEMENT (SECOND), TORTS, which imposes strict liability on a supplier of a product which is in a defective condition and reasonably dangerous to the consumer. Comment h to Section 402A suggests that, where a manufacturer has reason to anticipate that danger may result from the use of his product, as for example, the ingestion of an overdose of a drug, failure to provide an adequate warning against such danger will render the product defective within the meaning of section 402A.

Comment j summarizes the law concerning the manufacturer's duty to warn, and provides as follows:

> j. *Directions or warning.*—In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required.

> But a seller is not required to warn with respect to products, or ingredients in them, which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized. Again the dangers of alcoholic beverages are an example, as are also those foods containing such substances as saturated fats, which may over a period of time have a deleterious effect upon the human heart.
>
> Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

Thus, under present case law a manufacturer must provide warnings commensurate with the potential danger of his product. *Bean* v. *Ross Manufacturing Co.*, 344 S.W. 2d 18 (Mo. 1961); *Tampa Drug Co.* v. *Wait*, 103 So. 2d 603 (Fla. 1958); *Hubbard-Hall Chemical Co.* v. *Silverman*, 340 F. 2d 402 (1st Cir. 1965) (applying Mass. Law).

However, the manufacturer is not an insurer against all accidental injury and the courts have held that it is unreasonable to require a warning against every contingency which might occur in the use of his product. Thus, for example, a manufacturer of chlorine gas was not required to warn an injured plaintiff of the dangers inherent in using an inadequate gas mask while working with chlorine gas, *May* v. *Allied Chlorine & Chemical Products, Inc.*, 168 So. 2d 784 (Fla. App. 1964).

II. THE DUTY TO WARN "AGAINST A SUBSTANTIAL AND REASONABLE FORESEEABLE RISK OF CAUSING ACCIDENTAL INJURY"

1. The duty to warn against hazards which arise from an unintended use of the product. The strict liability imposed upon a manufacturer by § 402A of the RESTATEMENT is most commonly thought to be restricted to situations where the product is used in its customary or intended manner. Comment h, for example, states, in part, that "a product is not in a defective condition when it is safe for normal handling and consumption." Consequently, a manufacturer is not under a duty to warn of the dangers inherent in using a hot catalyst with his chemical product when he intended it only to be used with a cold catalyst, *Marker* v. *Universal Oil Products Co.*, 250 F. 2d 603 (10th Cir. 1957) (applying Okla. law); nor is he required to contemplate misuse of his product by careless, ignorant, or incompetent persons, such as the use of a lawn mower in close proximity to children. *Murphy* v. *Cory Pump & Supply Co.*, 197 N.E. 2d 849 (Ill. App. 1964), or the use of a paper cutter without normal safety precautions, *Beckhusen* v. *E. P. Lawson*, 196 N.Y.S. 2d 531 (App. Div. 1960), *rev'd on other grounds*, 214 N.Y.S. 2d 342 (1961).

A manufacturer is not liable for injuries which occur when his product is not put to the use intended by the manufacturer. *Nelson* v. *Union Wire Rope Corp.*, 187 N.E.2d 425 (Ill. App. 1963), *modified on other grounds*, 199 N.E.2d 269 (Ill. 1964); *O'Donnell* v. *Asplundh Tree Expert Co.*, 99 A.2d 577 (N.J. 1963); *Boyd* v. *Frenchee Chemical Corp.*, 37 F.Supp. 306 (E.D.N.Y. 1941). Thus, in *McCready* v. *United Iron & Steel Co.*, 272 F.2d 700 (10th Cir. 1959) (applying Okla. law), a manufacturer of casement windows was not liable to construction workmen who used the moldings on these windows as a stepladder, even though there was some evidence that he knew of such use.

As a corollary to the rule of intended use, the courts have imposed liability on a manufacturer only where an injury resulted from normal use of the product. *Hentschel* v. *Baby Bathinette Corp.*, 215 F.2d 102 (2d Cir. 1954), *cert. denied*, 349 U.S. 923 (1955); *Dubbs* v. *Zak Bros. Co.*, 175 N.E. 626 (Ohio App. 1931). Thus, in *Sawyer* v. *Pine Oil Sales Co.*, 155 F.2d 855 (5th Cir. 1946), a cleansing agent manufactured by defendant splashed into plaintiff's eye. The courts, affirming a judgment for the defendant manufacturer, stated, 155 F.2d at 856:

> "Certain it is that persons in the general use of benzene, household ammonia, lysol, naptha, and other similar agents, are aware of the fact that painful consequences will result if they are used in such manner as to allow them to get into the eye, but these potential consequences do not result in a discontinuance of their use nor in the conclusion that they are unfit for the use to which they are intended to be put."

Abnormal use of the product was therefore held to be a bar to plaintiff's recovery.

The results in many of the above cited cases have been criticized by some law review authors, *e.g.*, Dillard & Hart, "Product Liability: Directions for Use and the Duty to Warn," 41 Va. L.R. 145 (1955); and Noel, "Manufacturer's Negligence of Design or Directions for Use of a Product," 71 Yale L. J. 816 (1962). These

authors advocate an extension of the manufacturer's duty to warn, and would require him to foresee abnormal and unintended uses. Dillard and Hart, for example, suggest a distinction between directions for use and warnings against the risk of harm created by a plaintiff's failure to follow directions. These authors vigorously defend the holding of the Virginia Supreme Court in *McClanahan* v. *California Spray-Chemical Corp.*, 75 S.E.2d 712 (Va. 1953), imposing liability on the manufacturer of a fungicide for the destruction of an apple crop when the product was applied by the plaintiff at the wrong time of the year, contrary to defendant's directions, on the theory that the manufacturer had a duty to warn of the dangers of failure to follow its directions.

Subsequent to these articles, some recent cases have extended the manufactsurer' liability to injury resulting from an abnormal use of the product, other than that intended by the manufacturer. These courts view "intended use" as a way to describe what the manufacturer can "reasonably foresee." If it is reasonably foreseeable that a cleansing agent will get in a plaintiff's eye, or that a child will ingest drugs carelessly left within his reach, these courts would impose liability on the manufacturer, despite the fact these uses were not specifically intended by him. Thus, where it was formerly held that a manufacturer was not liable for the death of a child who poured fingernail polish remover on his clothing and then lit a match to himself, *Lawson* v. *Benjamin Ansehl Co.*, 180 S.W.2d 751 (Mo. 1944), it has recently been held that a manufacturer is liable for the death of a child who drank furniture polish because the use was reasonably foreseeable and therefore "intended," *Spruill* v. *Boyle-Midway, Inc.*, 308 F.2d 79 (4th Cir. 1962) (applying Va. law).

The proposed amendment to Section 502(f) would appear to adopt the views expressed in the *Spruill* and *McClanahan* cases by requiring a warning wherever there is a reasonably foreseeable risk of any accidental injury. The danger exists that the courts would utilize this language as a legislative license to extend the drug manufacturer's liability and compel him to foresee and warn against the risk of any injury which might be likely to occur in a home through the use or abuse of his product. Thus, the proposed amendment to Section 502(f) goes beyond the RESTATEMENT and adopts the theory of liability espoused by isolated authors and only the most far-reaching cases.

2. The duty to warn against obvious and patent hazards: H.R. 13886 requires a manufacturer to give adequate warnings against any substantial and reasonably foreseeable risks. The courts have consistently held that a manufacturer is required to give notice of danger only of latent dangers in his product, and is not liable for injury caused by patent dangers obviously known to the consumer when using the product in an intended manner, *McDaniel* v. *Williams*, 257 N.Y.S. 2d 702 (App. Div. 1965); *Stevens* v. *Durbin-Durco, Inc.*, 377 S.W.2d 343 (Mo. 1964); *Strickler* v. *Sloan*, 141 N.E.2d 863 (Ind. 1956). Thus, in *Dempsey* v. *Virginia Dare Stores*, 186 S.W.2d 217 (Mo. 1945), the manufacturer of a loosely woven and longhaired robe was not liable for injuries when the robe caught fire because of its patently flammable qualities.

The rule is well stated in *Katz* v. *Arundel-Brooks Concrete Corp.*, 151 A. 2d 731 733 (Md. 1959):

> "We think it would be as unreasonable to require every supplier of concrete to warn of its caustic properties, as to require an electric company to warn of the danger of touching uninsulated wires. If the danger is not patent, it is at least in the realm of common knowledge which the supplier may properly take for granted."

Thus, if a dangerous condition is obvious, no warning is required. By requiring a warning against any foreseeable risks, the proposed Bill would alter this rule and require drug manufacturers to warn in every case of the consequencies of taking an overdose, or of failure to use as directed.

3. The duty to warn against the possibility of trivial injury and remote consequences: In *Jamieson* v. *Woodward & Lothrop*, 247 F. 2d 23 (D.C. Cir 1957), plaintiff brought an action against a supplier of an exercising machine for injuries to her eye resulting from a rubber stretching mechanism which slipped from her feet. In an extended discussion of the problem of the foreseeability of minor injuries, the court, refusing to impose liability on the supplier, stated, 247 F. 2d at 29:

> "But we do not find in the authorities a doctrine that, if the injury ordinarily foreseen is relatively minor and so need not be warned against, a manufacturer must nevertheless warn against any dire unusual consequence which, also obviously, may ensue. Quite to the contrary it is well established that a manufacturer is not liable, unless *serious bodily harm is reasonable foresee-*

able. Of course, so far as foreseeability is concerned, not only may the usual be foreseen, but the unusual may often be foreseen as a remote possibility. A manufacturer may foresee as a remote possibility that a metal decoration on a jewelry box may scratch one and cause an infection; the heel of a lady's shoe may break at an inopportune moment, causing serious injury; or that a stickpin may stab a man to the heart. Yet for these remote eventualities the law imposes no liability on the manufacturer. 'Reasonably foreseeable' in the rule here applicable does not encompass the far reaches of pessimistic imagination." [Emphasis added.]

H.R. 13886 would alter this rule by requiring a manufacturer to warn against a substantial and foreseeable risk of relatively minor injuries, such as an upset stomach, skin rash, temporarily blurred vision or drowsiness.

4. The duty to warn concerning side effects, contraindications and effectiveness of the product: H.R. 13886 would authorize the Secretary of Health, Education and Welfare to impose, without hearing, an absolute duty to warn of the side effects, contraindications and effectiveness of a product.

Two problems are presented by this provision. The courts have not compelled a manufacturer to warn against side effects, the existence of which he could not reasonably know, *e.g.*, the carcinogenic quality of cigarette tobacco, *Lartigue* v. *R. J. Reynolds Tobacco Co.*, 317 F. 2d 19 (5th Cir. 1963), or the allergenic quality of face cream, *Howard* v. *Avon Products*, 395 P. 2d 1007 (Colo. 1964); or the danger of radiation from a luminous watch dial, *La Porte* v. *United States Radium Corp.*, 13 F. Supp. 263 (D. N.J. 1935); Cf. *Cochran* v. *Brooke*, 409 P. 2d 904 (Ore. 1966). Some courts would, however, extend a manufacturer's liability to include unknown and unknowable side effects, subjecting him to an absolute liability for injury from side effects. See *Green* v. *American Tobacco Co.*, 154 So. 2d 169 (Fla. 1963) and *Braun* v. *Roux Distributing Co.*, 312 S.W. 2d 758 (Mo. 1958). No protection against a similar extension of this rule is found in the Bill. In fact, it would appear that liability could be imposed upon a manufacturer despite the fact that a particular hazard could not have been discovered by the most careful research and development. The manufacturer is made an insurer against untoward results. This can only inhibit the development of new products. See, Connolly, "The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product," 23 Ins. Counsel Jour. 303-307 (1965).

Secondly, a manufacturer may anticipate that his product is contraindicated to a consumer who has an allergy or an idiosyncratic reaction. Some courts have stated that a manufacturer has no duty to warn such consumers. In *Kinkead* v. *Lysol, Inc.*, 296 N.Y.S. 461 (App. N.Y. 1937), the court in a memorandum opinion stated that the manufacturer as a matter of law does not have to anticipate injuries based solely on allergic reactions. The court stated that the defective condition causing damage was in the unusual plaintiff, not the defendant's product. See also, *Cumberland* v. *Household Research Corp.*, 145 F. Supp. 782 (D. Mass. 1956); *Payne* v. *R. H. White Co.*, 49 N.E. 2d 425 (Mass. 1943). The great majority of cases hold that a manufacturer has no duty to warn of the potential allergenic qualities of his product unless a substantial number of persons will be affected adversely by that product. *E.g.*, *Merrill* v. *Beaute Vues Corp.*, 235 F. 2d 893 (10th Cir. 1956); *Wright* v. *Carter Products*, 244 F. 2d 53 (2d Cir. 1957). Thus, in *Bennett* v. *Pilot Products Co.*, 235 P. 2d 525 (Utah 1951), the court stated that the manufacturer's knowledge that some unknown few might suffer allergic reactions imposed no duty to warn upon the manufacturer when these consumers were not in an identifiable class which could be effectively warned. The court further stated that an allergic response is generally held not to be within the zone of legal foreseeability. See also, *Lehner* v. *Procter & Gamble Manufacturing Co.*, 143 N.Y.S. 2d 172 (Sup. Ct. 1955). Even where an idiosyncratic response is foreseeable in fact, the manufacturer will not be held to a duty to warn unless he can foresee that a substantial number of people will be similarly harmed. For example, in *Grau* v. *Procter & Gamble Co.*, 324 F. 2d 309 (5th Cir. 1963), even though the manufacturer knew, by virtue of a prior claim, that an ingredient of its Crest toothpaste could cause, in rare individuals, an allergic reaction, the court held that there was no duty to warn against such a remote result. H.R. 13886 would authorize regulations extending a manufacturer's duty to warn against idiosyncratic reactions to extremes which find little or no support in the case law of the various states.

The few cases which hold a manufacturer liable for the damage suffered by a unique consumer have been criticized severely, *e.g.*, *Braun* v. *Roux Distributing Co.*, 312 S.W. 2d 758 (Mo. 1958); critized in Freedman, "Allergy and Products Liability Today," 24 Ohio St. L. J. 479 (1963). Those scholars who have ap-

proved such cases have done so on the radically novel theory that the manufacturer of chemical products should be subjected to an absolute liability similar to that imposed by Section 522 of the RESTATEMENT [relating to extrahazardous activities]. *E.g.*, Elkind, "Counsel for the Plaintiff Views the Problem of the Allergic Consumer," 20 Bus. Law 179 (1964). The sound policy reasons for refusing to impose such liability are set forth in Freedman, "Allergy and Products Libility Today," *supra*. In this article, the author urges that the Federal Food, Drug & Cosmetic Act labeling provisions should not be expanded to require warnings against potential allergic responses:

> Drug products under Section 502(f) of the Act are required to be labeled so as to appropriately warn against *known dangers* in method of use or quantity of dosage. Surely no one would contend that every manufacturer must warn about a potential allergic response in that particular, susceptible individual, simply because, as Dr. Harry Swartz expressed it, "Everybody is a candidate for allergy and 50% of the population actually suffer from allergy in one form or another today." Indeed, it can be substantiated that there is no limited class of natural or artificial substances which possess a unique capacity to harm allergically a given user; nor is there a limited class of allergic users who will react adversely to natural or artificial substances.
>
> To impose liability without fault upon the manufacturer for any allergic response is to make the manufacturer the insurer of every purchaser and user of the product. There is no product to which some person at some time is not sensitive! If every product carried a caution about possible allergic responses, what economic justification would there be for such warnings when the purchaser is ordinarily unaware of his peculiar susceptibility until he has used the product! Legally, such a warning would provide the requisite notice of potential allergic response which would pertain to an infinitesimal part of the population. The reputable manufacturer who does warn may find himself at a severe disadvantage with competitors who label their products without any warning, in the hope of improving their competitive sales position. Then again, the warning itself may generate more liability, for it constitutes an admission of knowledge of danger, and must therefore stand the test of "sufficiency" and duty to warn * * *. *Id.* at 485–486.

The same policy reasons advanced by this author argue against the provisions of H.R. 13886, which would change the case law and require a warning to even the hypersensitive user of a product.

III. THE DUTY TO FURNISH FIRST-AID INSTRUCTIONS

H.R. 13886 would require a manufacturer to label his product with instructions for first aid, "when necessary or appropriate." A manufacturer is under no present legal duty to specify first-aid treatment on the labels of his product. See *Shaw* v. *Calgon, Inc.*, 114 A.2d 278 (N.J. 1955). Unlike the proposed legislation, even the rare and extreme cases which require such labeling indicate that a duty to prescribe an antidote arises only when the foreseeable risk is of extremely serious harm, cf. *Chas. Pfizer & Co.* v. *Branch*, 365 S.W.2d 832 (Tex. Civ. App. 1963). Thus, the general requirement to provide first-aid instructions included in H.R. 13886 imposes a duty upon the manufacturer which exceeds all known case law.

The implications of this labeling requirement are limited only by the bounds of imagination. It appears that the manufacturer may be required to prescribe sufficient first-aid procedures for the results of any foreseeable misuse of his product. Moreover, having undertaken to provide such instructions, he may be held liable if such instructions are found to be inaccurate or inadequate. Cf. *Johnson* v. *West Fargo Mfg. Co.*, 95 N.W.2d 497 (Minn. 1959).

Should H.R. 13886 become law, a plaintiff might effectively argue that the manufacturer should be held liable for a consumer's idiosyncratic reaction to a prescribed antidote and that he should be held liable for causing a consumer to diagnose and treat improperly a reaction as product-related when, in fact, it was an independent malady requiring immediate medical attention.

Quite possibly, the courts will impose a higher standard of care upon the manufacturer who gives first-aid treatment pursuant to a statutory duty than they would impose upon a manufacturer whose instructions were gratuitously rendered. In many jurisdictions the courts have stated that a defendant who has voluntarily assumed a duty is liable for its misperformance only if his conduct has aggravated the situation and left the plaintiff in a worse position than he would have been

had the defendant done nothing. *United States* v. *Gavangan*, 280 F. 2d 319 (5th Cir. 1960); *Therrien* v. *First Nat'l Stores, Inc.*, 6 A. 2d 731 (R.I. 1939); *Kuchynski* v. *Ukryn*, 200 A. 416 (N.H. 1938); *Kirshenbaum* v. *General Outdoor Advertising Co.*, 180 N.E. 245 (N.Y. 1932); *Erie Ry. Co.* v. *Stewart*, 40 F. 2d 855 (6th Cir. 1930); *Podespik* v. *Worcester Consol. St. Ry. Co.*, 103 N.E. 638 (Mass. 1913). This limitation on a defendant's liability is often described as an inducement to cause him to undertake voluntarily to protect another. It is not unlikely that this limitation will be discarded if the defendant's doctoring is no longer voluntary, but the result of a statutory duty.

IV. THE DEPRIVATION OF COMMON LAW DEFENSES

Under present case law, the manufacturer of a product which may cause harm to the user has a duty to warn of the dangerous propensities of his product. The question of the adequacy of the warning and the reasonableness of the notice to the user concerning dangers inherent in the use of the product are generally questions for the jury to decide. Whether plaintiff's injury was caused by his own contributory negligence or by assumption of the risk, or by an independent intervening cause are also usually questions for the jury.[1] *Tampa Drug Co.* v. *Wait*, 103 So. 2d 603 (Fla. 1958); *Martin* v. *Bengue, Inc.* 136 A. 2d 626 (N.J. 1957).

H.R. 13886 would impose a statutory duty to warn. Because this duty is imposed by statute, the defendant manufacturer may not be able to raise the defenses available to him at common law. In certain circumstances a defendant who has breached a statutory duty may not assert the plaintiff's contributory negligence or his assumption of the risk as a defense. The availability of these defenses turns upon the type of protection the statute is intended to afford. If the statutory duty is imposed to protect the public in general and not a particular or limited class of users, the manufacturer may avail himself of the defenses of contributory negligence and assumption of the risk. See *Wright* v. *Cutter Products, Inc.*, 244 F. 2d 53 (2d Cir. 1957).

In *Dart* v. *Pure Oil Co.*, 27 N.W. 2d 555 (Minn. 1947), a Minnesota statute prescribed certain precautions in the handling and labeling of volatile oils distilled from petroleum. The court held that the statute was enacted for the protection of the public in general and not for a particular or limited class of users. Hence the manufacturer was entitled to have submitted to the jury the question whether plaintiff's use of an acetelyne torch on a barrel containing flammable oils rendered the plaintiff contributorily negligent and barred his recovery. The *Dart* court recognized, however, that certain statutes are enacted to protect a limited class of persons against their inability to protect themselves. A defendant's violation of such a statute, the court continued, would preclude his use of the defense of contributory negligence. The court listed child labor statutes, statutes prohibiting sale of dangerous articles to minors, and statutes for the protection of intoxicated persons as exemplatives of this type of statute.

Many courts hold that where a protective statutory duty is limited to a certain class of persons, particularly children, the normal defenses of contributory negligence and assumption of risk do not apply. If a manufacturer violates such a statutory duty, he is made an insurer against all injuries to the plaintiff from the use of his product. Thus, in *Bennett Drug Stores, Inc.* v. *Mosely*, 20 S.E. 2d 208 (Ga. App. 1942), a statute provided that no poison could be sold unless its character was known to the purchaser. The court held that this statute evidenced a legislative intent to protect an ignorant public against the consequences of a dangerous product and precluded reliance by the manufacturer or distributor on the defense of contributory negligence.

Similarly, Section 482 of the RESTATEMENT (SECOND), TORTS, provides that:

> "The plaintiff's contributory negligence bars his recovery for the negligence of the defendant consisting of the violation of a statute, unless the effect of the statute is to place the entire responsibility for such harm as has occurred upon the defendant."

[1] It has been suggested that logically there can be no defense of contributory negligence or assumption of the risk in a duty to warn case. In Dillard and Hart, "Product Liability: Directions for Use and the Duty to Warn," 41 Va. L. Rev. 145, 163 (1955), the authors suggest that the proof that a plaintiff knew or should have known of a certain risk is proof that the defendant's failure to warn of that risk did not cause the damage complained of. Such a proof prevents recovery by the plaintiff because he has failed to establish proximate causation, an essential element of negligence. It does not constitute a proof of contributory negligence. The courts as a whole continue to use the language of contributory negligence in duty to warn cases. This memorandum adopts their language.

The RESTATEMENT would bring about the same result with respect to the defense of assumption of risk. RESTATEMENT, TORTS, §496F (1965). The RESTATEMENT further provides that:

> "Even where those for whose benefit the statute is enacted may be expected to be, and are in fact, fully able to protect themselves, it may still be found that the purpose of this legislation is to relieve them of the burden of doing so and to place the entire responsibility for avoiding the harm upon the defendant. RESTATEMENT (SECOND), TORTS, §483, comment d at 537; and § 496F, comment b at 579 (1965)."

Since H.R. 13886 is specifically a "Bill to protect children and others from accidental death or injury" it could be effectively argued that the purpose of this legislation is to protect a limited class of persons who generally are unable to exercise self-protection. It could be argued that a layman is ignorant of the harmful tendencies of the chemical preparations he uses to maintain his health and comfort. In this sense, he cannot protect himself from the dangers attending such products. The effect of this legislation well may be to place all responsibility for injuries to such consumers on the manufacturer who is presumably an expert in such matters. If the courts so read this statute, the manufacturer would be held liable to a plaintiff who was injured by an obviously negligent misuse of his product, and would thus become an insurer as against all injuries resulting from use of his product.

CONCLUSION

Fundamentally, H.R. 13886 would (1) create a new, extensive federal duty to warn on all drug manufacturers which has not hitherto been thought necessary or desirable; (2) impose an exceptional duty to write first-aid instructions in anticipation of all the vagaries of injury with such completeness as to prevent the imposition of a secondary liability, and (3) deprive the drug manufacturers of the traditional defenses of contributory negligence and assumption of risk.

Mr. CONNOLLY. Mr. Chairman, I was requested by Mr. Hoge on behalf of the Proprietary Association to express an opinion as to the manner in which section 4(b) of H.R. 13886 increases or enlarges, if any, the product liability of a manufacturer of a proprietary drug. And, I have concluded that it greatly enlarges that liability and I direct my attention almost exclusively to the proposed and mandatory language of the bill: a new section (f) which requires that the labeling bear adequate warnings "against a substantial and reasonably foreseeable risk of causing accidental injury."

Does this enlarge and increase the liability of the manufacturer? Extensively?

Mr. Chairman, over the last few years I know of no area of tort law which has so greatly increased and has received so much attention as the field of product liability. Over the last several years a new section of the restatement of the law has been hammered out by lawyers and is now section 402(f) of the Restatement of the Law of Torts.

Basically it imposes a strict liability on the manufacturer of a product which is deemed defective, irrespective of any fault or wrongdoing on the part of the manufacturer, a showing of the exercise of reasonable care on the part of the manufacturer is no defense if in fact he has marketed a defective product.

It also imposes certain duties upon the manufacturer to warn of the hazard with respect to his product.

I suggest, Mr. Chairman, and gentlemen, that section 402(a) of the Restatement of the Law of Torts is the most advanced statement of a manufacturer's liability for his product. Basically, however, the restatement does not go so far as this bill. This bill imposes a duty to warn, on a manufacturer, and four new areas which neither the Restatement of the Law of Torts nor any judicial opinion has yet sought to go.

At page 4 of my statement I outline those four new areas in which the duty to warn is imposed.

I think the most far-reaching way in which the bill goes is to require a manufacturer to warn of hazards arising from an unintended use of his product. Both the restatement and the decided cases have held that there is no duty whatsoever on the part of a manufacturer to warn against the hazards of a misuse of his product.

Now, we all know children and adults can misuse products. The propriety of misuse or the foreseeability of a misuse rather is something that we can appreciate. A manufacturer can foresee a misuse of his product but no court has yet gone so far as to say that he must nevertheless even though he can foresee a misuse, warn against it.

The courts and textwriters have not gone so far as to require manufacturers to provide warnings against obvious or patent misuses or against obvious or patent hazards. The obligation to warn has been restricted to those of which the manufacturer must have or may have knowledge, but of which the average person would not have knowledge.

Now the law would characterize such hazards as latent dangers and there is an obligation in the law now throughout the country to warn of latent hazards, but this bill would require a manufacturer not only to provide warnings as to latent hazards but also of any patent deficiencies. The list of such deficiencies, of course, would be as long as imagination could make them.

What is more, presently there is no duty to warn the user of a slight or trivial injury. The duty to warn is restricted to situations where serious bodily harm might result. This bill contains no such limitation and would impose a duty upon a manufacturer to warn against a slight, a trivial injury or even such injuries as may be remote.

Fourthly, there is presently, and this is a matter that has been very, very closely litigated, there is no duty to warn against a hazard or side effect of which the manufacturer could not reasonably have had knowledge. This bill would remove that restriction and impose an obligation upon a manufacturer to give warnings of hazards that he could not have known about, and I will give you an illustration of that.

I think most of us, if we are not familiar with the actual decided case are familiar with the newspaper coverage with respect to it.

The first test case so to speak that litigated the question of whether a tobacco company was liable in failing to give warnings of the carcinogenic effects of smoking. The Fifth Circuit Court of Appeals after much consideration decided that since a manufacturer could not reasonably have had knowledge of the carcinogenic effects of cigarette smoking, need not have provided a warning that cigarette smoking was hazardous and therefore there was no liability.

Perhaps the law is now changed, indeed it has been changed because the manufacturer is charged with that knowledge now.

Mr. ROGERS of Florida. Only wasn't it because of that deficiency in the law that Congress had to act?

Mr. CONNOLLY. No, I think not, Mr. Rogers. You see the difference is this, that the court found that a reasonably careful manufacturer, using the skill of science available to him, could not have known at the time cigarettes were manufactured and sold throughout the thirties and forties and fifties when the plaintiff was engaged in smoking, in this instance a Camel cigarette, could not have known that tobacco was a carcinogenic agent.

I think quite apart from the labeling requirement today, in view of the large body of statistics accumulated by the Department of Health, Education, and Welfare, that there would be an obligation imposed on a manufacturer, or a jury could find, I will put it that way, that a manufacturer was marketing a defective product if it did not contain the warning, irrespective of the Federal law.

Mr. ROGERS of Florida. Of course we require the warning because of the testimony presented to the Congress.

Mr. CONNOLLY. This bill would require that there would be a responsibility on the part of the manufacturer to warn of the effects of which he could not reasonably have had knowledge. In other words, if a person could prove a cause and effect relationship, a side effect coming from a particular drug, there would be liability imposed upon the manufacturer if the manufacturer had not warned of that side effect on his labeling, even though at the time the package was made he could not reasonably have known of this occurrence, this side effect.

Mr. ROGERS of Florida. I thought the wording was—as to side effects, contraindications, and effectiveness and other matters may be required or pursuant to regulations prescribed by the Secretary, under that wouldn't he have to first prescribe these before you would be held to a liability?

Mr. CONNOLLY. I think we are now coming to the way it would be regulated, but I am talking now about in a civil damage suit.

Mr. ROGERS of Florida. I mean unless you were required to put this on by regulations, you would not be held to a liability, would you? Under the law, the proposed law?

Mr. CONNOLLY. You could not be held liable for a violation of this act.

Mr. ROGERS of Florida. No, I don't think you could be held liable at all, could you, unless it had been recognized——

Mr. CONNOLLY. Question would arise as to whether or not you had a duty of——

Mr. ROGERS of Florida. It says only prescribed by the Secretary in order to carry out the purpose.

Mr. CONNOLLY. Correct.

Mr. ROGERS of Florida. Doesn't it?

Mr. CONNOLLY. Yes.

Mr. ROGERS of Florida. Doesn't that mean that he must have this finding before you would be obligated?

Mr. CONNOLLY. It depends on what the Secretary prescribes.

Mr. ROGERS of Florida. I don't care what he prescribes.

Mr. CONNOLLY. Suppose he prescribes a catchall.

Mr. ROGERS of Florida. I don't think that is intended, is it?

Mr. CONNOLLY. Well, it is solely within his discretion as to what he can prescribe.

Mr. ROGERS of Florida. Well, if we put hearings in this, for the effective and safe use of the drug, it says with respect to the manner and form of statement of matters included. I just wanted to make that point clear. I can see what you are driving at, but I wondered if the proposed language would not require that the Secretary first make a finding and require you to do this before there would be any liability upon you.

Maybe we can go into that after we come back. We have to go.

Mr. JARMAN. Mr. Connolly, we will have to suspend now. A quorum call is now in process in the House.

The committee will make an effort to get permission to sit again at 2 o'clock, and the committee will stand adjourned.

(Whereupon, at 12:25 p.m., the subcommittee stood in recess until 2 p.m. this same day.)

AFTERNOON SESSION

Mr. JARMAN. The committee will be in order.

When we adjourned, we were hearing from Mr. Paul Connolly, and we will be very glad to hear your continuation.

STATEMENT OF JAMES F. HOGE; ACCOMPANIED BY PAUL R. CONNOLLY, AND DR. WILLIAM D. PAUL—Resumed

Mr. CONNOLLY. And I was having some trouble with a question as I recall of Mr. Rogers which I would like to come back to and see if I can't answer it. The bell perhaps helped us all to reflect a little bit upon it.

Mr. Rogers, as I understood your question, you inquired as to whether or not liability could be imposed upon a manufacturer for failure to warn of unknowable side effects if there was no regulation.

Mr. ROGERS of Florida. Seeing that such——

Mr. CONNOLLY. Promulgated by the Secretary?

Mr. ROGERS of Florida. Yes.

Mr. CONNOLLY. I would like to make one thing perfectly clear. As I read the amendatory language of 502(f), the power to prescribe regulation arises only under (f)-3. I think there still exists a duty to warn irrespective of regulation with respect to the matters under 1 and 2. Under 2, although not articulated, I think by implication is contained a duty to warn of side effects and contraindications.

Mr. ROGERS of Florida. Even without regulations?

Mr. CONNOLLY. Correct.

Mr. ROGERS of Florida. Applicable to the labeling of such drug?

Mr. CONNOLLY. I think so.

Mr. ROGERS of Florida. Prescribed by the Secretary?

Mr. CONNOLLY. I think so.

Mr. ROGERS of Florida. You separate that then from the matters in (3)?

Mr. CONNOLLY. Yes.

Mr. ROGERS of Florida. You don't think (3) has anything to do with (1) and (2)?

Mr. CONNOLLY. Oh, I think it does. I think the Secretary has the right to draft in terms the warnings that are necessarily required by (2). You have a duty to warn under (2), and the Secretary under (3) may in haec verba tell you what those warnings should be.

Also, while we had the recess, I happened to read an article which appeared in yesterday's New York Times magazine, on aspirin, strangely enough, and it was somewhat interesting to me—I am not a doctor—to find out that the medical fraternity says that there are many uses of aspirin that they don't know about, and indeed there are probably many reasons for not using aspirin, and I suggest to you, Mr. Congressman, that it would be altogether appropriate when I said that one would have to know the kind of a regulation promul-

gated by the Secretary would be appropriate, or he would be authorized to promulgate a regulation which would require labels on bottles of aspirin to bear this admonition: "Continued use of this product may give rise to undesirable side effects." I don't think anyone in the courts could do anything about that under this proposed amendatory language, because you could not get witnesses to say that that was an incorrect regulation.

The second aspect of this fourth area of a duty to warn is under the proposed amendatory language there would be a duty to warn of occasional allergic or idiosyncratic election. The law as it has been developed so far imposes no such duty on a manufacturer, unless the allergic class is so large and so significant that it can be said that a manufacturer should not put in the general stream of commerce a product that may affect so many people. But if the class of persons affected by the allergy is small and insignificant, there is no duty to warn.

So to summarize and briefly, the proposed amendatory language imposes a duty to warn on a manufacturer in four areas that neither the courts nor even the text writers have seen fit to go: the duty to warn of the unanticipated or unintended use, the duty to warn with respect to obvious defects, the duty to warn with respect to the trivial injury, and the duty to warn with respect to side effects and contra indications.

Now, the amendatory language I am of the opinion also imposes a new duty, and that is the duty as I have characterized it to be the Good Samaritan. The statutory, the proposed statutory language would require a manufacturer to place on his labeling instructions for first-aid treatment when necessary or appropriate. The law does not require a manufacturer today, as it has been developed in the case law, to prescribe first-aid treatment, he would, of course, be liable, if the care turns out to be inadequate or insufficient. But this bill would require the performance of that duty; namely, to render, to provide first-aid instruction.

I suggest to you that the variety of types of accidental injury and the disparate nature of the human response thereto, make it extremely impractical to prescribe treatment in advance by means of the printed label. I suggest also that the manufacturer would really be called upon to practice medicine.

Finally, I think that this bill, unless the congressional intent were made much more manifest than is presently the case, could deprive a manufacturer of the common law defenses of contributory negligence in assumption of risk which he presently would have to a product's liability case. Generally speaking, a manufacturer may defend a product's case on the ground that the user was himself contributorily negligent or he assumed the risk of injury or damage to himself. However, there is a considerable body of case law which holds that these defenses are not available, when there is a statute enacted whose purpose is to protect a limited class of persons, such as children, for example.

It is said, and I would like to refer to the restatement, section 482 says that—

> the plaintiff's contributory negligence bars his recovery for the negligence of the defendant consisting of a statute, unless the effect of the statute is to place the entire responsibility for such harm as has occurred upon the defendant.

Continuing under 496(f):

> Even where those for whose benefit the statute is enacted may be expected to be and are in fact fully able to protect themselves it may still be found that the purpose of this legislation is to relieve them of the burden of doing so and to place the entire responsibility for avoiding the harm upon the defendant.

Now, since H.R. 13886 is specifically a "bill to protect children and others from accidental injury or death," it could be effectively argued, I contend, that the purpose of the legislation is to protect a limited class of persons who generally are unable to exercise self-protection. That being so, the courts, in deciding the liability of a manufacturer, could and most probably would conclude that defense of contributory negligence and assumption of risk were not available to a manufacturer unless, as I said, the Congress expressed its intent in specific terms.

These, then, I suggest, are far-reaching concepts that go right to the heart of the court liability of a manufacturer. These are matters which are being debated in the courts and in our country's law schools and by the text writers, and there is nothing like a unanimity of approach. I wonder whether this committee, and indeed Congress itself, should create a vast new body of tort law which would rest upon a Federal statute. It would seem to me to be wiser to let the tort law develop in the ordinary manner of a case-by-case adjudication.

I think, however, the most significant part of this proposed amendatory language is the language which requires warnings against a substantial and reasonably foreseeable risk of causing accidental injury. The single objection which I see from a manufacturer's standpoint to that language is the duty to warn against foreseeable, albeit unintended, use of the product.

If I could make a recommendation to the committee or to the subcommittee, I would suggest that it rather follow the language of the American Law Institute's restatement, rather than attempting to employ new language to express this duty. So tested, the approach would be that 13886 should be modified to require a warning as to "risks of serious bodily harm which are reasonably foreseeable to the manufacturer from an intended use of the product but which are not reasonably obvious to an intended user."

That specific language is contained at page 8 of my prepared statement. I suggest that that does follow the very carefully thought out, well hammered out language adopted by the members of the American Law Institute when they formulated their restatement.

Thank you, gentlemen.

Mr. JARMAN. Thank you, Mr. Connolly. The Chair would like to suggest that the committee now hear from Dr. Paul, after which questions can be asked of all three witnesses.

(Dr. Paul's prepared statement follows:)

STATEMENT OF WILLIAM D. PAUL, M.D.

My name is W. D. Paul, M.D., I am Professor of Physical Medicine and Rehabilitation at the College of Medicine, University of Iowa, Iowa City, Iowa. I am head of the arthritis clinic at the University Hospitals, part of the College of Medicine, and Medical director of the Iowa Chapter of the Arthritis Foundation. My interest in the Child Safety Act of 1966, H.R. 13886, stems from the fact that for many years I have devoted most of my time to the diagnosis, treatment, research and teaching of arthritis. Thursday, August 14, 1966, Surgeon General William Stewart, of the Public Health Service, released a statement to the news

media on the subject of arthritis, the foremost crippler in the United States. He stated that the National Center for Health Statistics reported that arthritis ranks second only to heart disease as the leading cause of activity limitation among persons who suffer from chronic disability. Last year (1965) the World Health Organization called an international meeting to discuss the problem of arthritis, and it was concluded that arthritis is a major disease in all countries of the world. Rheumatoid arthritis, the commonest form of arthritis, as well as the type that causes the greatest crippling, is no respecter of age, as it occurs at all ages, from infancy (1 yr or less) to the very old (90 yrs or more). The basic treatment of all forms of arthritis, except gout, is the judicious use of salicylates. Rheumatologists have found, by experience, that acetylsalicylic acid (aspirin) is the most useful antiarthritic drug, the safest, and the most economical.

Since the end of World War II, medical students have been taught to use the metric system when prescribing drugs. It is of interest that a bill to change weights and measures to the metric system, S774, has passed the senate and is pending before the House. The standard tablet of children's aspirin contains 1¼ gr of the drug, or 75 mg in the metric system. The adult tablet is 5 gr or 300 mg. Physicians are accustomed to ordering a 75 mg tablet for children, or 300 mg for an adult. The average maximum dose for very young child is 75 mg/kg/24 hrs, a kilogram (kg) being 2.2 lbs. For older children the dose is approximately 1.8 gm/24 hr. Since the weight of children of a given age may vary widely, many pediatricians feel that a more accurate method of determining dose is to base it on the surface area of the child. This is based on weight against height, the result being expressed in square meters (M^2). Rheumatic fever is a common disease in children, and treated primarily with aspirin. The therapeutic dose in this disease is 3.0 gms/M^2/24 hr. When one divides 3.0 gm by 75 mg (1¼ gr) the answer is 40. Forty 1¼ gr tablets (75 mg) would be a total of 3.0 gm of the drug. Both of these numbers are round figures, easily understood by physicians who then could calculate the number of tablets he wishes to prescribe, and he would know how long a bottle or vial of 40 tablets would last.

Children between the ages of 3 through 5, average between 14.5 to 18.4 kg in weight. When one treats acute rheumatic fever, rheumatoid arthritis or fever in children of this age, the dose of aspirin will average 25 grains in 24 hr periods. Twenty-five grains represent twenty 1¼ gr tablets which represents 1.5 gms of aspirin, or one-half the number of tablets we recommend to be packaged in a single container, or enough tablets to last only two days of treatment.

For children 3 years of age or younger, the present label informs the parent to consult a physician for the proper dosage. This is required by present regulations and should not be changed. We would recommend that under Sec. 2 of H.R. 13886, this committee state that a maximum of 40 tablets of flavored children's aspirin be packaged in any one container. This would represent a total dose of 3.0 gm. If in the future physicians and/or the commissioner of the F.D.A. decided that fewer tablets should be marketed in a single container, they could by common consent reduce the number without asking Congress to enact a new law.

We at Iowa are concerned that if fewer tablets, for instance 20–25, are required to be packaged in a single container by this act, parents will purchase several containers at one time instead of one. If there are 4 or 5 bottles of children's aspirin in the medicine chest, the parents may not realize that one is missing, or if some tablets have been removed from more than one container.

We have heard that 95% of all the children's aspirin sold are packaged with a safety closure stopper. The manufacturers are constantly seeking a better safety device and would need no coercion to adopt the new closure. On the other hand, an improved closure would make it more difficult for an individual to manipulate. As mentioned above, rheumatoid arthritis is the greatest crippler. This disease affects any joint in the body, but involves the wrists and hands early, resulting in severe crippling. One of the major functions of the fingers is grasp or pinch. Rheumatoid arthritis is a chronic progressive disease, and can only be kept under control by various antiarthritic drugs. These victims, all ages, have difficulty in opening containers, and if the safety closure poses too much of a problem will leave the bottle open in order to have easier access to the medication. If there are children or pets in the household, the open container now becomes a magnet to attract the curious.

Another group of people that interests me is the so-called elder citizen. It is in this group that one finds the largest number of people suffering from heart disease. One form of heart disease is the so-called heart attack, or myocardial infarction. If they survive the initial attack, they then, under stress of tension, excitement, overexertion, over eating etc. will develop pain in the chest, called angina pectoris.

This pain can be relieved, or another heart attack aborted, by placing nitroglycerine under the tongue. When an individual has angina pectoris he reaches for a nitroglycerine tablet, usually kept in his pocket, but now he must open a safety closure first. While he is trying to open the container, the pain becomes worse, he has difficulty breathing, his hands become weak, and he may succumb to the attack before he is able to extricate a tablet. A more common type of heart disease, is heart failure; shortness of breath, swelling of ankles, cyanosis, irregular heart beat, and enlargement of the liver. Heart failure can be kept under control with the digitalis drugs. A favorite with the physicians is digoxin, in doses of 0.25 mg twice a day. Again, if the safety closure is too difficult to manipulate, the elder citizen will keep the container uncapped, and of course it will be available to youngsters or pets. How potent is a tablet of digoxin? Four tablets of 0.25 mg equals one milligram, 1,000 milligrams equal one gram, and 30 grams equal one ounce. These tablets are more toxic than a 300 mg (5 gr) adult aspirin tablet.

The members of the College of Pharmacy, the University Hospital Pharmacy and the Poison Control Center, all of the University of Iowa, have asked me to transmit this thought to the subcommittee. The primary reason for objecting to this kind of remedial action (a better safety closure) is that it would tend to provide a false sense of security to the parent or patient. Even less care would result, regarding proper storage and general safe-guarding of medications around the house.

In 1965, the National Clearinghouse for Poison Control Centers was notified that 16,328 children, under the age of 5, accidentally ingested aspirin. Most of these were very mild as hospitalization was not necessary, even for observation, in 87.4%. During the same year 125 of these children died from all forms of all salicylates including aspirin, a deplorable figure indeed. The bright side of the picture is the fact that during 1965 there were 20,424,000 actual living children under the age of 5 (Bureau of Census). One manufacturer stated that they bottled 50 million bottles of children's aspirin tablets a year, and from this one can assume that a large number of the more than 20 million children must have been given aspirin for various illnesses, without any toxic effect.

When thinking of poisons, it is necessary to remember that the difference between the amount of a given substance needed to produce a wanted effect and the amount that may cause injury to tissue or body functions, determines the toxicity. If one takes water, as an example, we know that a glass full (200 cc) will satisfy thirst. However, during hot weather, when a large amount of water is consumed (about 10 glasses) and sweating is profuse, diarrhea may result. This causes washing out of electrolytes (salts) followed by abdominal distress and chemical alkalosis. The difference in the amounts that quench thirst and cause diarrhea, is large, and therefore we can say that water is not poisonous. Phenol or carbolic acid is very poisonous because the smallest amount that we can place on tissue, even the amount adhering to the point of a needle, will destroy the tissue on which it comes in contact. The effective dose and toxic dose are the same. Aspirin is essentially a safe drug as a dose of 150 mg (two 1¼ gr tablets) will reduce fever in infants, or 600 mg (two 5 gr tablets) will relieve a headache or painful joint in an adult. A toxic, but not necessarily a lethal dose of aspirin for infants would be in the range of 30 or more 75 mg (1¼ gr) tablets ingested at one time, or a much smaller dose taken over a period of time in a very sick child. For older children or an adult the toxic dose varies a great deal. Many arthritics can take 20 or even 30 adult size tablets every day for weeks, with only slight ringing of the ears (tinnitus).

It would appear that I am trying to paint a rosy picture ignoring the 125 deaths from aspirin or other salicylates. Two factors that are often overlooked when discussing fatal cases of salicylate poisoning is first, that many medicaments contain salicylates, either aspirin or other forms of salicylates, and secondly the role of therapeutic overdosage. This past Sunday I visited a local pharmacy located in a town of about 3,000 people, adjacent to Iowa City (The Drug Fair, Coralville, Iowa). I found 109 items on the shelves that contained salicylates ranging from aspirin, sodium salicylate, choline salicylate to methyl salicylate. These preparations are recommended for headache, muscular pains, liniments, sleeping potions, relaxants, inhalants, antifungal (athletes foot), cough mixtures, cold preparations, and corn salves. Included were tablets, liquids, ointments and plasters. Most of these state the amount of salicylate per dose on the label, but some showed no dosage, and most were mixtures of many drugs including salicylates. I have outlined these items in Appendix 1. We do not know how many deaths were actually caused by childrens aspirin, but looking over this list one can see that "other salicylates" from their large numbers, are more readily available to the curious child.

March 26, 1966 an article titled "Infants, Toddlers, and Aspirin" appeared in the British Med. Jour. (page 757). The authors showed that therapeutic overdosage is common in infants up to the age of 3, and accidental overdosage is more common from 3 to 5 years. (Appendix 2). They concluded that, "in Glasgow, during 1963–65, there were 79 cases of aspirin poisoning, of which 67 were accidental with two deaths, and 12 therapeutic (overdosage) with six deaths. Accidental and therapeutic deaths occur in different age groups, and there is reason to believe that very few therapeutic deaths are included in the accidental-poisoning returns, so the problem is even greater than the national mortality suggests.

No child died in the accidental group who was admitted within 24 hours of ingestion, and the therapeutic group had all been given aspirin for at least 24 hrs before admission. The time factor is therefore very important, and it is linked to accurate diagnosis. Not one of the eight children who died was diagnosed correctly before admission."

Why is therapeutic overdosage more dangerous than accidental poisoning? The answer lies in the symptoms that occur during overdosage. Usually the child is being treated for a disease causing fever. As salicylism starts the child breathes faster, then over breathes (hyperventilation). This causes a respiratory alkalosis, a condition in which the blood becomes too alkaline. The child becomes very fretful, has nausea and vomiting, becomes dehydrated, and then has a high fever. This is then followed by chemical acidosis. At this time the child looks as if it has pneumonia, or if the urine is examined, sugar and acetone are found. An elevated blood sugar is usually present. The child is given more aspirin in an attempt to reduce the fever and restlessness. The laboratory findings and symptoms are those typical of diabetic coma (ketosis). Hospitalization is delayed and the death rate mounts. In accidental poisoning the frantic parent calls a physician at once, the child is treated or sent to a hospital, and recovery is assured.

An antidote is a substance that neutralizes, dilutes or removes a noxious substance. When a child swallows lye, a mild acid such as vinegar (acetic acid) may neutralize the caustic. In the case of acids, milk can be given which will form a harmless protein salt when it combines with the acid. There are no antidotes for the chemical substances used as drugs. Previously, I mentioned digoxin, a drug given in an infinitesimal dose of 0.25 mg twice a day, to combat heart failure. The symptoms of toxicity are loss of appetite, nausea, fuzziness of mentality to psychosis, irregular heart beats, diarrhea, abdominal distress; the very same symptoms that occur in heart failure for which the digoxin was given. These symptoms may occur on the same dose required to keep the heart failure under control. Again there is no antidote, no method of clearing the body of the digoxin, and attempts to cause vomiting or giving something to counteract the digoxin, may cause such a burden to the already damaged heart, that it may stop beating. If one were to outline the side effects and methods of combating overdosage of any drug, it would be necessary to write a medical text on the label, or an insert, of several pages. This would be an excellent idea if every one using the drug had a medical degree.

Everyone is in agreement that hazardous substances, such as insecticides, pesticides, lye, etc. should carry warnings on the label and directions for treating burns, etc. There are regulations in effect at present that cover labeling of hazardous substances. On page 3, line 22, of H.R. 13886, we read "or against a substantial and reasonably foreseeable risk of causing accidental injury," and on page 4, line 4, "or pursuant to regulations (applicable to the labeling of such drugs) prescribed by the Secretary in order to carry out the purpose of this paragraph." A man takes a digitalis tablet, walks down stairs, trips and fractures his spine. Would this be classified as foreseeable risk? A physician prescribes a tranquilizer, the patient takes the (one) tablet, then sits down to eat dinner. His wife has prepared fried chicken which he relishes, but accidentally inhales a piece of chicken bone and is rushed to the hospital for removal of the foreign body. Is this event a foreseeable risk from ingesting one tranquilizing pill? A man who has angina pectoris was told to take nitroglycerine for the pain. While working in a machine shop, he had pain, took a nitroglycerine tablet. Shortly afterwards he became dizzy and cut his finger. Could this be called a foreseeable risk, or included in contraindications? These are a few instances that I can recall. If we were to put on the label or insert every precautionary measure that might result in a "foreseeable risk" no label would be large enough, and an insert would have to be as voluminous as a medical text. People would be afraid to us a detergent, wear clothes that were cleaned in a petroleum derivative, or add salt to their food. We know that the use of extra salt can retain

water and cause swelling in people with heart disease. The present regulations require the labeling of hazardous materials, even mentioning antidotes when necessary; therefore why add probable risks to confuse and scare the public?

We could go through a series of commonly used substances and show the difficulty of pointing out, side effects, indications and contraindications to lay persons, none of whom have a background in medicine. Adding emergency measures that might be started by a parent or relative (in the case of an adult) would not only delay adequate treatment but confuse the picture of overdosage. For instance, how should a mother cause vomiting in a child. Should she place her finger in the childs throat and gag it? This may cause vomiting, but the child may also inhale some of the vomitus and develop a serious pneumonia, not at once but hours or days later. Or the mother can be told to give syrup of Ipecac which may cause vomiting any time from 10 or 15 minutes to 30 minutes after ingestion. The mother is no longer worried because the child has vomited. Between the time of ingestion of the drug, and the time the child has vomited, a large portion of the drug has been absorbed. The next day the child has fever, over ventilation, and is fretful. Now the diagnosis becomes an acute upper respiratory infection, a pneumonia or diabetic acidosis. The child may be given more of the same drug (probably aspirin) and there is further delay before proper treatment is instituted.

The poison control center at the University Hospital in Iowa City has been in operation for the past six years. During this time they have had numerous calls about accidental poisonings. During the six year period there were only *two* occasions when it was deemed necessary to tell the parent, or person calling, what first-aid methods to carry out. The department of Pediatrics sees about 2,000 children a year, some of whom are admitted for aspirin poisoning. There are less than one death a year from salicylates, methyl salicylate being the most frequent salicylate causing death.

In conclusion we would like to submit the following suggestions for your consideration.

1. The Child Safety Act of 1966 should include a statement that each container of childrens' flavored aspirin should contain up to a maximum of forty 75 mg tablets, a total dose of 3.0 gm.

2. The safety closure used at present is adequate. Making the safety closure device more complicated would act as a hardship to the crippled, debilitated, or elderly person. It would also, we feel add to the problem of accidental poisoning. The glass container, whether it be glass or plastic, should be tall and thin so that even the absence of two or more tablets would be readily recognized. Horizontal lines could be raised on the outside of the vial, and the number 10, 20, 30, and 40 placed next to the horizonal line. This would make it easier to detect the loss of tablets.

3. The label should contain, as it does now, the notation in bold letters, "Keep all medication out of the reach of children."

At the University Hospital we have this passage imprinted on the paper sacks, called prescription bags. All pharmacists should be encouraged to do this. The label should state, "Contact your doctor, nearest hospital, or Poison Control center immediately if accidental ingestion or overdose occurs." The label should state, "always save the container and take it to your doctor in case of accidental poisoning."

4. Included in the bill should be a statement that pharmacists should label the contents and dose on all prescription lebels, unless otherwise instructed by the prescribing physician. This would help identify all drugs, and prevent a physician from prescribing a potent medicine that the patient received from another physician, and is still taking.

5. Make funds available to the F.D.A. which would be used as matching funds obtained from industry to set up an educational program on drug safety. The funds from industry could be obtained as a tax on the number of tablets sold, much like the funds obtained to promote agricultural products. The program could be carried out through the National P.T.A. and directed toward mothers. Physicians should also be included and taught how to recognize poisonings, especially due to salicylates. Architects and builders should be urged to place a metal cabinet, that has a safety lock or combination lock, in the bathroom or bedroom to be used as a locked safe for all medications.

APPENDIX 1

Aspirin and/or "other salicylates" found on shelves of the Drug Fair, Coralville, Iowa

Name	Dose	Company
Bufferin	Aspirin, 5 grain	Bristol-Myers.
Anacin	Aspirin, 3.5 grain	American Home Products Corp.
Sundra spot aspirin	Aspirin, 5 grain	Sundra Spot Co.
Norwich aspirin	do	Norwich Lab.
Pentest aspirin	do	
Tower Industries aspirin	do	Tower Industries.
Excedrin	Aspirin, salicylamide, no dose	Bristol-Myers.
Children's bufferin	Aspirin, 1¼ grain	Do.
Resolve effervescent	Aspirin, 5 grain	Do.
Fizrin effervescent	do	Glenbrook Lab.
Alka-Seltzer	do	Miles Lab.
St. Josephs children's aspirin	Aspirin, 1¼ grain	Plough, Inc.
Bayer aspirin	Aspirin, 5 grain	Bayer.
Children's aspirin	Aspirin, 1¼ grain	Do.
Aspirin	Aspirin, 1 grain (100 tablets per bottle).	Upjohn Co.
Chewable children's aspirin	Aluminum salicylate, 1¼ grain, 75 milligram (50 and 100 tablets per bottle).	Abbott Lab.
Purepac children's aspirin	Aspirin, 1¼ grain	Purepac Corp., New York.
Aspirin compound	227 milligram, 3½ grain (aspirin)	Eli Lilly.
Enseals	Aspirin, 5 grains, 325 milligrams	Do.
Do	Aspirin, 5 grains, 650 milligrams	Do.
Measurin Time Release	Aspirin, 10 grains	Chesebrough-Pond's, New York.
Aspergum	Aspirin, 3½ grains	White Co.
Calevrin	Calcium carbaspirin, equivalent to 300 milligrams of aspirin.	Dorsey Lab., Lincoln, Nebr.
Salrin	Salicylamide, 5 and 10 grains	Warren Teed.
Pabririn buffered tablets	Aspirin, 5 grains	Dorsey Lab.
Empirin compound	Aspirin, 3.5 grains	Burroughs Wellcome.
P-A-C compound	do	Upjohn.
Anodynos tabs	do	Breon.
Ascriptin	Aspirin, 5 grains	Rorer.
FOR PAIN AND ARTHRITIS		
Defencin	Aspirin, 300 milligram	Groves Lab.
Counterpain	Aspirin, 3½ grains	Squibb.
Axar	Aspirin, 2½ grains	McKesson Robbins.
Trigesic	Aspirin, 3½ grains, 0.230 milligram.	Squibb.
Dolcin, for arthritis	Aspirin, no dose	Dolcin Corp., New York.
Zarumin	Aspirin, 300 milligrams, 4 grains, potassium salicylate, 3.5 grains.	J. B. Williams, Inc., New Jersey.
Arthropan	Choline salicylate, 174 milligrams	Purdue-Frederick.
Actasol syrup drops	Choline salicylate, 105 milligrams	Do.
DeWitts (muscle pain)	Salicylamide, no dose	E. C. DeWitt, Chicago.
Phenodyne tablets	Aspirin, 3.5 grains	Blue Line.
Phenosal tablets	Aspirin, 260 milligrams	Pitman-Moore.
Falgos tablets	Aspirin, 3.5 grains	American Ferment.
Persisten	Aspirin, 2.5 grains, salicylsalicylic acid, no dose.	Sherman.
Alysine elixir	Sodium salicylate, no dose	Merrell.
Salicionyl	Sodium salicylate, 10 grains	Upjohn.
COLDS		
Coricidin	Aspirin, 1¼ grains	Schering Corp.
Congespirin	Aspirin, 80 milligrams	Grove Lab.
Coryban-D	Salicylamide, 230 milligrams	J. B. Roerig Co., New York.
Coricidin D	Aspirin, 0.32 milligram	Schering Corp.
Coricidin Medtabs, children	Aspirin, 1½ grains	Do.
Triaminicin	Aspirin, 225 milligrams	Dorsey Lab.
Fletcher's cold tabs	Aspirin, 45 milligrams	Glenbrook Lab.
666 cold tablets, also liquid	Salicylamide, no dose	Monticello Drug Co., Jacksonville, Fla.
Dricole tablets	Aspirin, 97 milligrams	Cole Pharmaceutical Co., St. Louis.
Hill's cascaro quinine cold tablets	Aspirin, no dose	Whitehall Lab.
Pyrroxate cold capsules	Aspirin, 3½ grains	Upjohn.
Coldene syrup, adult	Sodium salicylate, 216 milligrams	Pharmacraft.
Coldene syrup, children	Sodium salicylate, 108 milligram	Do.
Liquiprin	Salicylamide, 1¼ grain	Johnson & Johnson.
4-Way liquid cold syrup	Sodium salicylate, no dose	Beaumont Co., St Louis.
Ursinus inlay tabs	Calcium Carbaspirin, equal to 300 milligram aspirin.	Dorsey Lab., Lincoln, Nebr.

Aspirin and/or "other salicylates" found on shelves of the Drug Fair, Coralville, Iowa—Continued

Name	Dose	Company
ANTITENSION		
Compoz for simple tension	Salicylamide, 125 milligrams	Jeffery-Martin.
Devarex, simple nervousness	Salicylamide, 300 milligrams	J. B. Williams Co., New Jersey.
Tranquil-aid	Salicylamide, 225 milligrams	Thompson Mecical Co., New York.
Alva-Tranquil relax tension	Potassium salicylate, 085 milligram.	Chicago, Ill.
Alva-Tranquil (8 hours time release)	Potassium salicylate, 0.1944 milligram.	Do.
FOR SLEEP		
Sleep tablets	Salicylamide, 216 milligrams	McKresson Robbins.
Nytol	Salicylamide, no dose	Block Drug Co., New Jersey,
Sominex	Salicylamide, 200 milligrams	J. B. Williams Co.
LINIMENTS AND OINTMENTS		
Banalg	Methyl salicylate, no dose	Cole Chemical Co.
Inrra cel solution	Salicylamide, no dose	Tested Products Co., St. Louis.
Heet liniment	Methyl salicylate, no dose	Whitehall Lab., Inc., New York.
Omega oil	do	Omega Chemical Co., New Jersey.
Concentrated Broska	Glycol monosalicylate methyl salicylate, salicylamide.	Drug Master, St. Louis.
Anestol liniment	Methyl salicylate, no dose	Norwich Pharmacal.
Sloan's liniment	do	Standard Lab., Morris Plains.
Ben-Gay lotion	do	Charles Pfizer.
Ben-Gay balm	do	Do.
Ben-Gay greaseless	do	Do.
Ben-Gay children's	do	Do.
Analgesic balm	do	Lilly.
Musterole, regular, mild, and children.	do	Plough.
Minit Rub	do	Grove Lab.
Mentholatum deep heat rub	do	Mentholatum Co., Buffalo.
Numotizine	do	Hobart Lab., Chicago.
Surin	do	McKesson Lab.
Infrarub	Glycol monosalicylate, no dose	Whitehall Lab., New York.
Guia Camph chest rub	Methyl salicylate, no dose	Dorsey Lab., Lincoln, Nebr.
Ger-o-foam	do	Geriatric Pharmaceutical Co.
Panalgesic	Salicylates, no dose	Polythress.
Methyl-rub	Methyl salicylate, no dose	Pfeiffer.
Dr. Scholl's Solvex (athlete's foot)	Salicylic acid, no dose	Scholl Manufacturing Co., New York.
Dr. Scholl's corn salve	do	Do.
Dr. Scholl's zino-pads	do	Do.
Freezone corn remover	do	Whitehall Laboratory.
Compound W	do	Do.
Mosco (corns)	do	Mosco Chemical Co., Rochester, N.Y.
Advicin antifungal cream	do	Schering.
NP 27 antifungal cream	do	Norwich Pharmacal.
T-4-L sol antifungal	do	Sorbol Co., Mechanicsburg, Ohio.
Whitfield's ointment	do	Lilly.
Do	do	Purepac Co.
Prak-t-kal Steem Mist	Methyl salicylate, no dose	Prak-t-kal Corp., Elizabeth, N.J.
Kaz-for-colds, inhalant	do	Kaz Co., New York.
Hankscraft vaporizer fluid	do	Hankscraft Co.
Steemaid vaporizer fluid	do	Wheeler Chemical Co., Waterloo, Iowa.
MISCELLANEOUS		
Stanback tablets	Salicylamide, no dose	Stanback Co., Salisbury, N.C.
Stanback powder	do	Do.
B C	do	B C Remedy Co., Durham, N.C.
Doan's pills	Sodium salicylate, no dose	Foster Milburn Co., Buffalo.

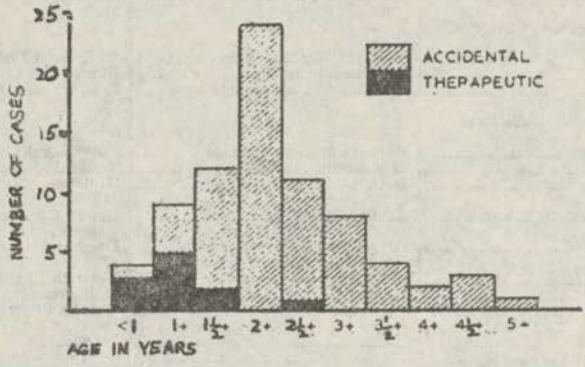
APPENDIX 2

[From the British Medical Journal]

INFANTS, TODDLERS, AND ASPIRIN

Campbell's peak age for mortality corresponds with the peak age for accidental poisoning, and is quite different from the peak age for therapeutic poisoning, which strongly suggests that the therapeutic deaths have not been registered as accidental deaths. This suggestion would not stand if there were far fewer therapeutic than accidental deaths, but it will be shown that the reverse is the case.

Number of cases of accidental and therapeutic poisoning by aspirin, in relation to age.



In the present series 2 of the 67 patients in the accidental group died, but 6 of the 12 in the therapeutic group died. Again this is similar to the findings of Riley and Worley, who had no deaths in 13 accidental cases and 5 deaths in 23 therapeutic cases. The conclusion is that many more children die of therapeutic than of accidental poisoning, and this is almost entirely due to the greater susceptibility to salicylate poisoning of the child under 2 years of age.

Even at this point the danger of aspirin may be underestimated. Children may die undiagnosed, and Arena (1962) believes that some cases of aspirin-poisoning are labelled "virus encephalitis." One need not have missed the diagnosis completely to use such a label, and indeed the cause of death in one case in the present series was certified as "toxic encephalopathy." A mother is not told that she killed her child, albeit unwittingly, if there is any doubt at all.

ACCIDENTAL POISONING

Accidental poisoning by salicylate is easier to study than therapeutic poisoning, as it involves only one episode of ingestion and is uncomplicated by disease. Winters (1959) describes three stages of poisoning, and it will be convenient to consider the present series in relation to these stages.

1. There is first an increase in pulmonary ventilation, due to the stimulant effect of salicylate on the respiratory centre. This causes alkalosis, with a rise in the blood *p*H. In the present series there were eight children, who were admitted within four hours of ingestion and who were already overbreathing. They showed no biochemical evidence of acidosis sufficient to cause this overbreathing. Wallgren, commenting on a communication by Odin (1932), quotes a striking demonstration of the initial alkalosis. He gave salicylate to two infants with spasmophilia in order to cure them by inducing acidosis. "When I tried aspirin treatment for two infants with spasmophilia," he said, "the effect was the direct opposite of what had been expected. In spite of the fact that deep respiration distinctly arose, there occurred an increase in the electrical superexcitation and the tetania became aggravated. The aspirin was at once discontinued. . . ." The initial "deep respiration" is not in fact a sign of acidosis but a toxic effect resulting in transient alkalosis. This effect may persist in the adult or schoolchild, but is present for only an hour or two in the very young child, when the acidosis of the third phase takes over. Apart from the eight mentioned above, all the children showing symptoms on admission were in the stage of acidosis (Winter's third phase). The stimulant effect of the salicylate on the respiratory

centre does of course persist while the blood salicylate is raised, and is added to rather than superseded by the hyperventilation of acidosis, so that the hyperventilation of the severely poisoned child becomes very great. This masked tendency to alkalosis should curb heroic treatment with alkali.

2. There is an increased metabolic rate related to the action of the drug in uncoupling oxidative phosphorylation, with increased CO, production and fever. The fever is potentiated by dehydration. It may be difficult to believe that an established "antipretic" drug shows fever as a toxic effect, but it has been recognized for a long time and was discussed at length by Dodd *et al.* (1937). In Segar and Holliday's (1958) 43 cases, of which 32 were therapeutic, 27 had temperatures of 103° F. (39.4° C.) or over, and 12 had temperatures of 105° F. (40.6° C.) or over. The incidence of fever was not so high in the present series, but one child had a temperature of 107° F. (41.7° C.) as the result of accidental ingestion. There are many cases in the literature where continuing fever has led to the treatment of aspirin-poisoning with heroic doses of aspirin.

3. Disturbed carbohydrate and lipid metabolism also occurs. Glycogenolysis is speeded and glycogen synthesis reduced. The blood-sugar may be normal or raised. Levels of over 200 mg./100 ml. are quite common. Blood-sugar levels are available in only four accidental poisonings in this series, being normal in three and raised (287 mg.) in one. Low blood-sugars may result from starvation in the therapeutic group, and did so in two of the present series, but are not a common feature of salicylate-poisoning. The idea that salicylate produces a low blood-sugar probably stems from the work of Reid *et al.* (1957) and Read and Lightbody (1960), who treated diabetes with aspirin, though they point out that whereas aspirin reduces the hyperglycaemia of diabetes it does not produce hypoglycaemia either in the diabetic or in the normal. Hypoglycaemia in reputed salicylate-poisioning has been described by Mortimer and Lepow (1962) and by Cotton and Fahlberg (1964), but their experience seems unusual.

Fatty-acid catabolism is accelerated and ketones are produced in excess. The precise reason for the latter is unknown, but it is very marked in the first year or two of life (Done, 1963), when acidosis is most severe.

The 67 cases of accidental poisoning in the present series can now be considered as a whole, and are summarized in Table III.

TABLE III.—*Analysis of cases of accidental poisoning*

Group	Time between ingestion and admission	Hospital	Age in months	Hours after ingestion	Blood levels on admission			Number
					Salicylate (mg./100 ml.)	HCO_3 (m.Eq/l.)	pH	
I	0 to 12 hours	[1]	[1]	[1]	[1]	[1]	[1]	[1]
II	12 to 24 hours	A	36	15	36	----------	----------	1
			24	12	48	13	----------	2
			27	16	44	6	7.14	3
			19	20	67	6	7.27	4
		B	28	16	43	10	----------	5
			26	12	58	11	----------	6
III	24 hours or more	A	27	28	52	7	7.29	7
			23	24	52	7	7.23	8
			27	44	32	5	----------	9
		B	15	24	50	14	7.20	10
			36	36	44	12	----------	11
			24	48	57	10	----------	12
			22	36	54	10	----------	13

[1] 54 cases. Average time after ingestion, 3.3 hours.

Few of the children in group I were seriously ill. Evacuation of the stomach and attention to fluid balance sufficed in most. On the other hand, group I contained the three highest salicylate levels in the series—78 mg. 100 ml. three hours after ingestion, 82 mg. at nine hours, and 95 mg. at five hours. The first was treated by exchange transfusion, the others by peritoneal dialysis, and all recovered.

Four of the six in group II were very ill, and two of the seven in group III died. It will be seen that there is no essential difference between groups II and III as regards age, salicylate level, and biochemistry. The difference lies in the time since ingestion. Done (1960) pointed out that there is no close correlation between observed salicylate level and the symptoms.

CURRICULUM VITAE—WILLIAM DARWIN PAUL, M.D.

M.B., University of Cincinnati, 1928.
M.D., University of Cincinnati, 1929.
Student Instructor in Bacteriology, University of Cincinnati School of Medicine, 1924.
Student Instructor in Hygiene, University of Cincinnati School of Medicine, 1925–27.
Friedlander Fellow in Medicine, 1926–28.
In charge of the Clinical Laboratory, Hamilton County Tuberculosis Sanatorium Cincinnati, Ohio, 1924–28.
Intern, General Hospital, Cincinnati, Ohio, 1929–30.
Resident in Internal Medicine, University Hospitals, Iowa City, Iowa, 1930–33.
Instructor in Internal Medicine, University of Iowa Medical School, 1933–36.
Associate in Internal Medicine, University of Iowa Medical School, 1936–38.
Assistant Professor of Internal Medicine, University of Iowa Medical School, 1939–45.
Professor and Head of the School of Physical Therapy, University of Iowa, 1942–present.
Associate Professor in Internal Medicine, University of Iowa Medical School, 1945–54.
Professor of Physical Medicine and Rehabilitation Division, Department of Internal Medicine, University of Iowa Medical School, 1954-present.
In charge of the Medical-Out-Clinic, University Hospitals, Iowa City, Iowa, 1938–1954.
Gastroscopist for University Hospitals, 1941–1953.
Chairman of the Division of Physical Medicine, University Hospitals, 1939-present.
Director of the Rehabilitation Unit, University Hospitals, 1954-present.
Medical Director of the Iowa Chapter of the Arthritis and Rheumatism foundation, 1956-present.
Consultant in Physical Medicine, Veterans Administration Hospital, Iowa City, Iowa, 1952-present.
Consultant in Physical Medicine, Veterans Administration Hospital, Knoxville, Iowa, 1952-present.
Diplomate of American Board of Physical Medicine, 1947.
Fellow of the American Medical Association.
Fellow of the Mississippi Valley Medical Society, 1954.
Fellow of the American College of Physicians, 1954.
Life Member of the American College of Physicians, 1958.
Member of the Editorial Board of *General Practitioner*.
Associate Editor, *International Review of Physical Medicine and Rehabilitation*.
Associate Editor, *American Journal of Physical Medicine*.
Consultant, *O. S. Digest*.
Consulting Editor of *Medical Digest*.
Member, AMA Committee on the Medical Aspects of Sports.
Past President American Society of Physical Medicine and Rehabilitation, 1946–47.
Vice-President, American Congress of Physical Medicine, 1948–1954.
President, American Congress of Physical Medicine, 1954–55.
Chairman of the Mid-Western Section, American Congress of Physical Medicine and Rehabilitation, 1945–46, 1948–50, 1951–53, 1955–56.
Executive Council of Congress of Physical Medicine.
Executive Committee of American Academy of Physical Medicine.
Editor of the Monthly Bulletin on Arthritis for Physicians, for the Iowa Chapter of Arthritis and Rheumatism Foundation, 1960–present.
Editor of the *Monthly Bulletin on Arthritis for Physical Therapists*, for the Iowa Chapter of the Arthritis and Rheumatism Foundation, 1963–present.
Supervisor of Varsity Athletics, University of Iowa, Iowa City, Iowa 1940–present.

SOCIETIES

American Academy of Physical Medicine and Rehabilitation.
American Association for the Advancement of Science.
American College of Physicians.
American College of Sports Medicine.
American Congress of Physical Medicine and Rehabilitation.
American Chemist Club.

American Diabetic Society.
American Gastroscopic Society.
American Genetics Society.
American Geriatrics Society.
American Heart Association
American Institute of Ultrasonics in Medicine.
American Medical Association.
American Rheumatism Association.
American Society for Clinical Chemists.
Arthritis and Rheumatism Foundation.
International Society for the Welfare of Cripples.
International Society for the Welfare of Crippled Children, U.S.A.
Iowa Clinical Society.
Iowa Heart Association.
Iowa State Medical Society.
Johnson County (Iowa City, Iowa) Medical Society.
Mississippi Valley Medical Society.
New York Academy of Sciences.
Sigma XI.
Society for Experimental Biology and Medicine.
World Medical Association.
Born—Brooklyn, New York, January 31, 1900—Max and Sarah (Siegfried), parents Married, September 1, 1928—Louise Nichols Ebling.

Dr. PAUL. Mr. Chairman, my name is W. D. Paul, a physician. I am professor of physical medicine and rehabilitation at the college of medicine, University of Iowa, Iowa City, Iowa. I am head of the arthritis clinic at the university hospital, part of the college of medicine, and medical director of the Iowa Chapter of the Arthritis Foundation. My interest in the Child Safety Act of 1966, H.R. 13886, stems from the fact that for many years I have devoted most of my time to the diagnosis, treatment, research, and teaching of arthritis.

Just 6 weeks ago, Thursday, August 14, 1966, Surgeon General William Stewart, of the Public Health Service, released a statement to the news media on the subject of arthritis, the foremost crippler in the United States. He stated that the National Center for Health Statistics reported that arthritis ranks second only to heart disease as the leading cause of activity limitation among persons who suffer from chronic disability. Last year (1965) the World Health Organization called an international meeting to discuss the problem of arthritis, and it was concluded that arthritis is a major disease in all countries of the world. Rheumatoid arthritis, the commonest form of arthritis, as well as the type that causes the greatest crippling, is no respecter of age, as it occurs at all ages, from infancy (1 year or less) to the very old (90 years or more). The basic treatment of all forms of arthritis, except gout, is the judicious use of salicylates. Rheumatologists have found by experience, that acetylsalicylic acid (aspirin) is the most useful antiarthritic drug, the safest, and the most economical.

I will quickly go over the next page or two. That is that we believe that a safe dose for a child over the age of 3 when treating rheumatic fever is about 3 grams on the metric system or a total of 40 tablets of the 1¼-grain as manufactured at the present time. This can be read in my written brief. We believe that this subcommittee could suggest a maximum of 40 tablets in a single package, which would be safe. That would constitute one day's treatment for an older child with rheumatic fever, or 2 days' treatment for a younger child who has rheumatic fever, rheumatoid arthritis, or fever. Forty tablets then could be the maximum and by common consent or hearing the manufacturers and the members of the Food and Drug Administration get

together if they thought that they should have less than 40 tablets without having Congress enact a new law.

We in Iowa are concerned that if fewer tablets, for instance 20 to 25 are required to be packaged in a single container by this act, parents will purchase several containers at one time instead of one. If there are four or five bottles of children's aspirin in the medicine chest, the parents may not realize that one is missing, or if some tablets have been removed from more than one container.

We have heard that 95 percent of all children's aspirin sold are packaged with a safety closure stopper. The manufacturers are constantly seeking a better safety device and would need no coercion to adopt the new closure. On the other hand, an improved closure would make it more difficult for an individual to manipulate. As mentioned above, rheumatoid arthritis is the greatest crippler. This disease affects any joint in the body, but involves the wrists and hands early. This finding is stressed by everybody throughout the world at all our international meetings, that the wrists and hands are involved early, resulting in severe crippling.

One of the major functions of the fingers is grasp or pinch. Rheumatoid arthritis is a chronic progressive disease, and can only be kept under control by various antiarthritic drugs. These victims of all ages, have difficulty in opening containers, and if the safety closure poses too much of a problem will leave the bottle open in order to have easier access to the medication. If there are children or pets in the household, the open container now becomes a magnet to attract the curious.

Another group of people that interests me is the so-called elder citizen. It is in this group that one finds the largest number of people suffering from heart disease. One form of heart disease is the so-called heart attack, or myocardial infarction. If they survive the initial attack, they then, under stress of tension, excitement, overexertion, overeating, et cetera, may develop pain in the chest, called angina pectoris. This pain can be relieved, or another heart attack aborted, by placing nitroglycerine under the tongue. When an individual has angina pectoris he reaches for a nitroglycerine tablet, usually kept in his pocket, and I keep saying "he" because it occurs three times as often in the males as the females, but now he must open a safety closure first. While he is trying to open the container, the pain becomes worse, he has difficulty breathing, his hands become weak, and he may succumb to the attack before he is able to extricate a tablet. A more common type of heart disease is heart failure; shortness of breath, swelling of ankles, cyanosis or bluish color, irregular heart beat, and enlargement of the liver. Heart failure can be kept under control with the digitalis drugs.

A favorite drug with the physicians is digoxin, in doses of 0.25 mg twice a day. Again, if the safety closure is too difficult to manipulate, the elder citizen will keep the container uncapped, and of course it will be available to youngsters or pets. How potent is a tablet of digoxin? Four tablets of 0.25 mg equals 1 milligram, 1,000 milligrams equal one gram, and 30 grams equal one ounce. These tablets are more toxic than a 300 mg (5 gr) adult aspirin tablet.

The members of the college of pharmacy, the university hospital pharmacy and the poison control center, all of the University of Iowa, have asked me to transmit this thought to the subcommittee. The primary reason for objecting to this kind of remedial action (a better

safety closure) is that it would tend to provide a false sense of security to the parent or patient. Even less care would result, regarding proper storage and general safeguarding of medications around the house.

In 1965, the National Clearinghouse for Poison Control Centers was notified that 16,328 children, under the age of 5, accidentally ingested aspirin. Most of these were very mild as hospitalization was not necessary, even for observation, in 87.4 percent. During the same year 125 of these children died from all forms of all salicylates including aspirin, a deplorable figure indeed.

The bright side of the picture is the fact that during 1965 there were 20,424,000 actual living children under the age of 5 (Bureau of Census). One manufacturer stated that they bottled 50 million bottles of childrens aspirin tablets a year, and from this one can assume that a large number of the more than 20 million children must have been given aspirin for various illnesses, without any toxic effect.

When thinking of poisons, it is necessary to remember that the difference between the amount of a given substance needed to produce a wanted effect and the amount that may cause injury to tissue or body functions, determines the toxicity. If one takes water, as an example, we know that a glass full (200 cubic centimeters) will satisfy thirst. However, during hot weather, when a large amount of water is consumed, and I may add that this is a problem with industry, that when a large amount of water is consumed (about 10 glasses), and sweating is profuse, diarrhea may result. This causes washing out of electrolytes (salts) followed by abdominal distress and chemical alkalosis, in which the blood becomes more alkaline than normal. The difference in the amounts that quench thirst and cause diarrhea, is large, and therefore we can say that water is not poisonous. Phenol or carbolic acid is very poisonous because the smallest amount that we can place on tissue, even the amount adhering to the point of a needle, or as we do in a hospital to the point of a toothpick, will destroy the tissue on which it comes in contact.

The effective dose and toxic dose are the same. Aspirin is essentially a safe drug as a dose of 150 milligrams (two 1¼-grain tablets) will reduce fever in infants, or 600 milligrams (two 5-grain tablets) will relieve a headache or painful joint in an adult. A toxic, but not necessarily a lethal dose of aspirin for infants would be in the range of 30 or more 75-milligram (1¼-grain) tablets ingested at one time, or a much smaller dose than that taken over a period of time in a very sick child. For older children, or an adult, the toxic dose varies a great deal. Many arthritics can take 20 or even 30 adult-size tablets, every day for weeks, with only slight ringing of the ears (tinnitus).

It would appear that I am trying to paint a rosy picture ignoring the 125 deaths from aspirin or other salicylates. Two factors that are often overlooked when discussing fatal cases of salicylates poisoning are first, that many medicaments contain salicylates, either aspirin or other forms of salicylates, and secondly the role of therapeutic overdosages.

This past Sunday I visited a local pharmacy located in a town of about 3,000 people, adjacent to Iowa City (the Drug Fair, Coralville, Iowa). I found 109 items on the shelves that contained salicylates ranging from aspirin, sodium salicylate, choline salicylate to methyl salicylate. These preparations are recommended for headache, muscular pains, liniments, sleeping potions, relaxants, inhalants,

antifungal (athlete's foot), cough mixtures, cold preparations, and corn salves. Included were tablets, liquids, ointments, and plasters. Most of these state the amount of salicylate per dose on the label, but some showed no dosage, and most were mixtures of many drugs including salicylates. I have outlined these items in appendix I. We do not know how many deaths were actually caused by children's aspirin, but looking over this list one can see that "other salicylates" from their large numbers, are more readily available to the curious child.

March 26, 1966, an article titled "Infants, Toddlers, and Aspirin" appeared in the British Medical Journal (p. 757). The authors showed that therapeutic overdosage is common in infants up to the age of 3, and accidental overdosage is more common from 3 to 5 years. (App. 2.) They concluded that—

> In Glasgow, during 1963–65, there were 79 cases of aspirin poisoning, of which 67 were accidental with two deaths, and 12 therapeutic (overdosage) with six deaths. Accidental and therapeutic deaths occur in different age groups, and there is reason to believe that very few therapeutic deaths are included in the accidental-poisoning returns, so the problem may be even greater than the national mortality suggests.
>
> No child died in the accidental group who was admitted within 24 hours of ingestion, and the therapeutic group had all been given aspirin for at least 24 hours before admission. The time factor is therefore very important, and it is linked to accurate diagnosis. Not one of the eight children who died was diagnosed correctly before admission.

Why is therapeutic overdosage more dangerous than accidental poisoning? The answer lies in the symptions that occur during overdosages. Usually the child is being treated for a disease causing fever. As salicylism starts the child breathes faster, then overbreathes (hyperventilation). This causes a respiratory alkalosis, a condition in which the blood becomes too alkaline. The child becomes very fretful, has nausea and vomiting, becomes dehydrated, and then has a high fever. This is then followed by chemical acidosis, or as the lay people know it, uremia.

At this time the child looks as if it has pneumonia, or if the urine is examined, sugar and acetone are found. An elevated blood sugar is usually present. The child is given more aspirin in an attempt to reduce the fever and restlessness. The laboratory findings and symptoms are those typical of diabetic coma (ketosis). Hospitalization is delayed and the death rate mounts. In accidental poisoning the frantic parent calls a physician at once, the child is treated or sent to a hospital, and if it is sent 24 hours or less after ingestion, recovery is assured.

An antidote is a substance that neutralizes, dilutes, or removes a noxious substance. When a child swallows lye, a mild acid such as vinegar (acetic acid) may neutralize the caustic. In the case of acids, milk can be given which will form a harmless protein salt when it combines with the acid. There are no antidotes for the chemical substances used as drugs. Previously, I mentioned digoxin, a drug given in an infinitesimal dose of 0.25 milligram twice a day, to combat heart failure. The symptoms of toxicity are a loss of appetite, nausea, fuzziness of mentality to psychosis, irregular heart beats, diarrhea, abdominal distress; the very same symptoms that occur in heart failure for which the digoxin was given. These symptoms may occur on the same dose required to keep the heart failure under control. This is well known by physicians in the hospitals.

Again there is no antidote, no method of clearing the body of the digoxin, and attempts to cause vomiting or giving something to counteract the digoxin, may cause such a burden to the already damaged heart, that it may stop beating. If one were to outline the side effects and methods of combating overdosage of any drug, it would be necessary to write a medical text on the label, or an insert, of several pages. This would be an excellent idea if every one using the drug had a medical degree.

Everyone is in agreement that hazardous substances, such as insecticides, pesticides, lye, and so forth, should carry warnings on the label and directions for treating burns, and so forth. There are regulations in effect at present that cover labeling of hazardous substances. On page 3, line 22, of H.R. 13886, we read "or against a substantial and reasonably foreseeable risk of causing accidental injury," and on page 4, line 4, "or pursuant to regulations (applicable to the labeling of such drugs) prescribed by the Secretary in order to carry out the purpose of this paragraph."

A man takes a digitalis tablet, walks downstairs, trips and fractures his spine. Would this be classified as a foreseeable risk? A physician prescribes a tranquilizer, the patient takes the (one) tablet, then sits down to eat dinner. His wife has prepared fried chicken which he relishes, but accidentally inhales a piece of chicken bone and is rushed to the hospital for removal of the foreign body. Is this event a foreseeable risk from ingesting one tranquilizing pill? I might add that swallowing chicken bones happens to be a common foreign body that comes in the hospital as an emergency.

A man who has angina pectoris was told to take nitroglycerine for the pain. While working in a machine shop, he had a pain, took a nitroglycerine tablet. Shortly afterward he became dizzy and cut his finger. Could this be called a foreseeable risk, or included in contraindications? We know that some people are sensitive to nitroglycerine. It is given for high blood pressure which drops precipitously and they immediately become dizzy or may have more headache after that. These are a few instances that I can recall.

If we were to put on the label or insert every precautionary measure that might result in a "foreseeable risk" no label would be large enough, and an insert would have to be a voluminous as a medical text. People would be afraid to use a detergent, wear clothes that were cleaned in a petroleum derivative, or add salt to their food. We know that the use of extra salt can retain water and cause swelling in people with heart disease. The present regulations require the labeling of hazardous materials, even mentioning antidotes when necessary; therefore why add probable risks to confuse and scare the public?

We could go through a series of commonly used substances and show the difficulty of pointing out side effects, indications, and contraindications to lay persons, none of whom have a background in medicine. As you heard, they would be practicing medicine. Adding emergency measures that might be started by a parent or relative (in the case of an adult) would not only delay adequate treatment but confuse the picture of overdosage. For instance, how should a mother cause vomiting in a child. Should she place her finger in the child's throat and gag it? This may cause vomiting, but the child may also inhale some of the vomitus and develop a serious pneumonia, not at once but hours or days later. Or the mother can

be told to give sirup of ipecac which may cause vomiting any time from 10 or 15 minutes to 30 minutes after ingestions. The mother is no longer worried because the child has vomited. Between the time of ingestion of the drug, and the time the child has vomited, or until the mother has found out this child has ingested a drug, a large portion of the drug has been absorbed. The next day the child has fever, over ventilation, and is fretful. Now the diagnosis becomes an acute upper respiratory infection, a pneumonia or diabetic acidosis. The child may be given more of the same drug (probably aspirin) and there is further delay before proper treatment is instituted.

The poison control center at the university hospital in Iowa City has been in operation for the past 6 years. During this time they have had numerous calls about accidental poisonings. During the 6-year period there were only two occasions when it was deemed necessary to tell the parent, or person calling, what first-aid methods to carry out. These were instances of people driving through and staying at a motel. The department of pediatrics sees about 2,000 children a year, some of whom are admitted for aspirin poisoning. There is less than one death a year from salicylates, methyl salicylate being the most frequent salicylate causing death.

In conclusion we would like to submit the following suggestions for your consideration.

1. The Child Safety Act of 1966 should include a statement that each container of children's flavored aspirin should contain up to a maximum of forty 75-mg. tablets, a total dose of 3 gm.

2. The safety closure used at present is adequate. Making the safety closure device more complicated would act as a hardship to the crippled, debilitated, or elderly person. It would also, we feel, add to the problem of accidental poisoning. The glass container, whether it be glass or plastic, should be tall and thin so that even the absence of two or more tablets would be readily recognized. Horizontal lines could be raised on the outside of the vial, and the numbers 10, 20, 30, and 40 placed next to the horizontal line. This would make it easier to detect the loss of tablets.

3. The label should contain, as it does now, the notation in bold letters, "Keep all medication out of the reach of children."

At the university hospital we have this passage imprinted on the paper sacks, called prescription bags. All pharmacists should be encouraged to do this. The label should state. "Always save the container and take it to your doctor in case of accidental poisoning."

4. Included in the bill should be a statement that pharmacists should label the contents and dose on all prescription labels, unless otherwise instructed by the prescribing physician. This would help identify all drugs, and prevent a physician from prescribing a potent medicine that the patient received from another physician, and is still taking.

5. Make funds available to the FDA which would be used as matching funds obtained from industry to set up an educational program on drug safety. The funds from industry could be obtained as a tax on the number of tablets sold, much like the funds obtained to promote agricultural products. You see I am from Iowa.

The program could be carried out through the national PTA and directed toward mothers. Physicians should also be included and taught how to recognize poisonings, especially due to salicylates.

Architects and builders should be urged to place a metal cabinet, that has a safety lock or combination lock, in the bathroom or bedroom to be used as a locked safe for all medications. This would solve practically all the problems.

Thank you.

Mr. JARMAN. Thank you, Dr. Paul.

Gentlemen, you have covered a lot of ground in this three-man testimony. The one question I think the Chair would like to ask now of Mr. Hoge would be in the area of packaged aspirin. In your statement, as I understand it, you take the position that a voluntary system is in force today, with manufacturers acceding to the recommendation of 1955 by FDA. You also take the position that the conclusion reached by the conference on the subject has been a good approach, and you would favor continuing that. But as I understand it, you indicate that if the Congress does feel that legislation is necessary, Congress should go ahead and write into an act the definite number of aspirin, rather than leave it to administrative regulation. I am trying to express the concern I have of the Congress getting into the business of trying to write specific limitations of that sort. Do you feel that Congress would have the necessary medical expertise, based on testimony, to do so, and would you not feel that it would be a bad precedent to set in terms of other drugs and other problems of this nature?

Mr. HOGE. Let's stay with aspirin first. It seems to me that there has been adduced here before this committee ample evidence on which you could legislate. You have heard a good deal of it here today. In my statement I relied on the evidence of the Food and Drug Administration.

When Dr. Goddard was asked by Congressman Rogers what he thought as to the number of tablets, he turned to Dr. Palmisano, his pediatrician who was with him, and asked that he might answer the question. Dr. Palmisano answered, and I have a quote in my statement, "somewhere in the neighborhood of 20 to 25 tablets of 1¼ grains of aspirin flavored would seem to be the place where you would have to cut it off if you want to do what we are talking about."

And so, Mr. Chairman, I accepted that piece of evidence as the basis for my recommendation to you that you accept it and set the number at 25.

Mr. JARMAN. Of course, we have been getting conflicting testimony on that subject, and Dr. Paul in his statement just a moment ago referred to a maximum of 40 aspirin.

Mr. HOGE. I think that is quite true; yes, sir.

Mr. JARMAN. The evidence has been conflicting.

Mr. HOGE. Well, conflicting in this sense, and maybe not conflicting. That he thinks 40 is all right, and 25, which Dr. Palmisano suggested must be even better or safer if you please.

Mr. JARMAN. Let me ask you this. If we were trying to set legislatively a number, would we not have to hold much more extensive hearings as to medical testimony to arrive at a fixed number?

Mr. HOGE. Than you have held?

Mr. JARMAN. Would you not feel that?

Mr. HOGE. No, sir, I would not, in view of the evidence that has been put before you here, and the writings.

Mr. JARMAN. Then assuming that we would have enough evidence on which to basis a decision, would you comment on the precedent

that you think we would be setting from a congressional standpoint in trying to make such a decision in legislation?

Mr. HOGE. Well, as a general matter I think I would be sympathetic to the point that you are making, Mr. Chairman. That you perhaps would be then getting into a field in which you cannot legislate specifically. But I have thought that this was an exception where the evidence has been brought forward and where a good deal has been written and a good deal known about it, so that this was an exception.

Mr. JARMAN. I am speaking only for myself, but I am concerned as to that approach in legislation of this sort. Many people die of overdoses of sleeping pills. Would the Congress not be justified then in getting into that field and others in terms of public health and perhaps a limitation on numbers of pills in a bottle? Where would we stop?

Mr. HOGE. I mustn't get into the medical field, but let me say with respect to sleeping pills and all of these other matters, the warnings now are very strict with respect to frequent or prolonged use, and also very strict with respect to seeing a physician rather than continuing the use. I just counted, as I sat here a moment ago, the warnings which I have attached as appendix II to my statement, and I counted some 15 instances in which the warning was "Discontinue use and see a physician." It seems to me that that is where we are at here with respect to this matter of accidental injury and first aid. That what we ought to do is to require every package of drugs to provide that it should be kept out of the reach of children, and that in the event of overdosage or unsafe usage, see a physician or call a physician immediately.

Mr. JARMAN. Thank you very much. Mr. O'Brien?

Mr. O'BRIEN. Mr. Chairman, I must admit at this stage I am somewhat confused. We have before us a bill that is cited as the Child's Safety Act of 1966, and then we find throughout the testimony the impact of this legislation not only on children but apparently right across the adult community. We find areas of this bill that involve us in a tortured legal situation as to consequences, and I would like to say that I attended the first hearing on this bill, and we heard the representatives of the Department, and I think that before we were through, that most of us were close to tears, weeping for the little children who apparently were being killed in vast numbers by consuming these colored aspirin.

Now perhaps it was neglect on my part, but I did not know at the time of that original testimony that this bill went far beyond child safety, went into an area which obviously required and does require extensive hearings. Now I am perfectly willing, Mr. Chairman, to go along with a Child Safety Act if we can agree upon its terms. But I do think if we are going to go much beyond that, that we should have much more extensive hearings than we have had, and I would like an opportunity, Mr. Chairman, to discuss this matter again with some representatives of HEW minus the little exhibits we had showing how much this aspirin looked like various kinds of candy and minus the emotional impact upon us.

I think what we are trying to do here in the guise of child safety is to rewrite a very broad segment of our drug laws. Now, it may be that that is necessary or will be necessary, but there has been so much

emphasis, Mr. Chairman, in this session about truth in packaging and labeling and so forth, and I think it is about time we employed a little of it to some of the legislation that comes before us.

I am not suggesting that there was any deliberate attempt to confuse the members of this committee, and perhaps my confusion is due to my own limited intelligence. But it was very strange to me that the members of the industry affected, distinguished physicians like Dr. Paul and others apparently weren't even going to be notified of our original hearing. If we had had a quorum that morning I think we would have reported out the bill.

So we have discovered by our very action here, and the length and number of these hearings, that this bill went far beyond the title "Child Safety Act of 1966." Frankly I would like to have an opportunity to ask some additional questions, based upon a much broader knowledge than I had then, of the representatives of HEW. That is all, Mr. Chairman.

Mr. JARMAN. Mr. Nelsen?

Mr. NELSEN. Thank you, Mr. Chairman. Going back to your testimony on page 10, where you refer to the new language as to labeling: "or against a substantial and reasonably foreseeable risk of causing accidental injury." Those are pretty broad terms. This gets into the same area as we are dealing with in the truth-in-packaging bill, whereby under broad general terms, some umpire sits in the ball game and makes the decision as to whether or not there has been a violation, and you are guilty until you prove you are innocent.

Now, this is pretty broad language. I wonder if you have any comment about it. I see it is underlined in your statement here.

Mr. HOGE. Well now, I underlined it, Congressman Nelsen, because it is new.

Mr. NELSEN. New language?

Mr. HOGE. That is to be added.

Mr. NELSEN. Yes.

Mr. HOGE. Now first, as to the broadness of it, I can't conceive of anything much broader than that. You will note that the language is "a reasonably foreseeable risk." Now I assume there is a foreseeable risk to almost everything we do. Every time you step in your automobile or step out on the street, anything you do I suppose presents a reasonably foreseeable risk. Of how many risks I don't know. There would be a catalog.

Mr. NELSEN. Would that language be an open invitation for all kinds of legal action?

Mr. HOGE. We think so. I said in my statement that I think this language would be the answer to a negligence lawyer's prayer—to put that into the bill, and also to put the matter of first aid instructions to go with it, not only with it but with all the rest of the section.

Now, I believe you went on a little further, Congressman Nelsen.

Mr. NELSEN. Yes.

Mr. HOGE. With respect to being guilty until proven innocent. I don't think it is quite that literal. In fact, as the law stands today, and before this amendment, that is not the situation at all. Quite the contrary. The situation today is, as I said a little while ago this morning, in my opinion, in good American tradition and concept, that the Government would charge a violation of the law, to wit, that we did not have adequate directions or adequate warnings.

It would have the burden of proving its charge, and if it did, then it won.

Mr. NELSEN. I see.

Mr. HOGE. Now what has happened here is not only the injection of this matter of first aid treatment, and reasonable foreseeable risks of causing accidental injury; Mr. Rogers had this a moment ago. If you will pardon me I will put the two things together if I may.

You are looking at page 10 of my statement. If you will draw a line after the semicolon, "necessary or appropriate" just before you get to "and (3)," and will lay aside for the moment the matter of foreseeable risks and first aid and all of that, and just read it down to that semicolon, you will see that the bill would require warnings against pathological conditions or by children where its use may be dangerous or against unsafe dosage or methods or duration of administration, or against a reasonably foreseeable risk of causing injury, in such manner and form as are necessary for the protection of users, including instructions for first aid treatment when necessary or appropriate.

Now, Mr. Rogers, when you get there, the burden is put on us by the statute without any regard to regulations at all, appropos of your question a moment ago. It is from that point on that you get the regulations. And you will see that it says, "and (3), such other information relating to the foregoing matters," to wit, pathological, use by children, and on through the rest of that language including the manner and formal statement "as required by regulations." So the regulations don't come in until you get to the words "such other information."

Now there, Congressman Nelsen, there does come an application of your question about guilty until proven innocent; not literally, no, but the difficulty with administrative law is that while it preserves the form of due process, it doesn't animate the spirit of it. In fact, the spirit of due process dies under administrative law because usually your accuser is also your finder of fact and your judge, and the courts don't disturb him if there is any evidence to support what he does.

Mr. NELSEN. Now, on the instructions for first aid, an earlier witness brought out some statements that were very interesting to me. The premise was that if instructions for first aid were provided, that the parent might, in a clumsy way, attempt to provide this first aid when a doctor should be doing it. This is very interesting to me. It is quite logical. Do you have any comment about that?

Mr. HOGE. Well, now, I wonder if I could defer to the doctor on that?

Mr. NELSEN. Yes.

Mr. HOGE. Dr. Paul is with me for this very sort of thing.

Mr. NELSEN. Yes.

Mr. HOGE. Dr. Paul.

Dr. PAUL. In the first place, you must remember the inside of the stomach looks like a bath towel. It has many, many projections. If you take tablets, and I have watched these tablets through a gastroscope, a scope we put into the stomach, and I have seen them breakup within a minute. Some tablets are made so that they do not break up at all. As they disintegrate, they get caught in this tissue.

Even if you wash out the stomach, there is a great deal of material still left within the folds of the stomach, unless you put a tube in and

wash it out very thoroughly which a mother cannot do. The other thing is that if you do this frantically, even a medical student, intern, or resident or even a staffman tries to do this very rapidly, you are apt to get the tube into the trachea and allow fluid to go into the lungs and cause pneumonia. So it should be done under good control in a hospital.

Now, even if the child vomits, they have enough of this material left underneath these folds in the stomach so that they can absorb it at a later time. The thing that worries us at Iowa, if you tell a mother to cause the vomiting, the child vomits. According to the label the child is better, when all the time there is enough material left to be absorbed so that later that evening or the next day, the child then becomes sick, and they think it is something entirely different. If they would call the physician or the poison control center, then the condition would be known and something done immediately, and it has been shown by physicians, even though it may be very serious, you can even put them on an artificial kidney and wash the drug out from the blood, and the child will recover.

We feel that by leaving all of this off the label, and saying "Call the doctor, call the poison control center," then there is a followup because the hospital who calls the physician then knows that something has happened and they inquire "What have you done about it?"

Mr. NELSEN. I noticed on page 11 the reference to side effects and contraindications. On your labels now you must provide adequate warnings on drugs as to side effects and contraindications. I wonder what would be your judgment as to having this in this bill when it is already in your food and drug laws?

Mr. HOGE. The only difference, Congressman Nelsen, is that the bill would permit the Secretary to write and prescribe definitely what we are to do. As it is now, the law puts the burden upon us to indicate these contraindications and the side effects, and all the rest that you see here we must do, as I said a moment ago, on the peril of incurring the sanctions of the law if we fail, seizure, criminal prosecution, and injunction. Now, that is the only difference.

Mr. NELSEN. Getting back to the number of tablets in a bottle, in the hearings last week, I had the same feeling that the chairman expressed, that we might get into a long series of congressional determinations as to how many pills and various kinds of drugs would be in a bottle, which would be a rather tedious and long-drawn-out affair. But I am advised by people who should know something about this that in this particular case of aspirin, there is a pretty general across-the-board opinion in the drug industry that this is one area that could be established by a congressional action and come close to at least a reasonable mark. Would you have any comment about that?

Mr. HOGE. That is my understanding, Congressman Nelsen. I think I ought to say this, and you will understand my saying it. I am a lawyer. I am not a doctor. And we lawyers have to rely a good deal on what our clients tell us when we present our causes. I am told just what you said, that the state of knowledge in the drug industry is such that a number could be legislated, and the number has been indicated here by Dr. Palmisano as 25, Dr. Tainter thinks it could be higher, Dr. Paul thinks it could be higher. But Dr. Palmisano fixed it at 20 to 25. I think that is what he said.

Mr. NELSEN. However, if a conference could be arranged where the industry could agree on something, you would also cooperate in that instance?

Mr. HOGE. We certainly would, and I wanted to say to you that a conference could have been had on this subject just as it was in 1955. When the testimony was put before you on the 24th of June—and I say this without any invidious implication, please understand me—it almost appeared as a unilateral action of the Food and Drug Administration that brought about the policy statement for 50 tablets to the bottle, for keeping medicine out of the reach of children, and fixing uniform dosage at one and a quarter grains.

The fact of the matter is that there was no emergency presented. It was a matter of getting the industry together, and I want again to call your attention to appendix I, which is attached to my statement. It is a photostat of the Drug Trade News report of that conference, and I do want you to study, not necessarily at the moment, but later, the names of the people and the companies who were present at that conference. Abbott Laboratories, Sterling Drug, McNeil Laboratories, Norwich, Eli Lily, Parke-Davis, Plough, Upjohn, White Laboratories, Squibb—all blue chip names. And then likewise from the Government and from the colleges.

Congressman Nelsen, indeed there could be such a conference, and if there were such a conference, you would find the industry attending by knowledgeable, representative people and participating, and I think it is a foregone conclusion that you would get their cooperation, and you would come out just as you did in 1955 with an understanding.

Mr. NELSEN. I would like to point out that under the Federal Trade Act, getting into other fields of merchandise, the machinery is set up there whereby an industrywide conference could be set up on many of the trade practices. Yet we find that this opportunity has not been overly exercised. I would also point out that in our hearings on the truth in packaging bill, some members of industry have moved, because of the fact that the bill is being considered, in making uniform some of their practices it does prove that it can be done. So I want to thank the gentleman for his statement, Mr. Chairman, and to thank the chairman for yielding to me.

Mr. HOGE. I am so interested in what Congressman Nelsen is saying. He is ever so right. It should be done, and this is an area in which cooperation is very essential. Of course, medicine is technical and complicated. We have heard that here. These companies don't need to be policed. They are very law-abiding people, and very high minded and very much interested in the public health. There is no difficulty ever to get a conference with the industry and the Food and Drug and the doctors and the colleges. It can be done at any time and it ought to be done. As medicine grows and as our population grows and as our regulation gets more complicated, we ought to have more and more cooperative conferences and consideration rather than always just legislation.

Off the record.

(Discussion off the record.)

Mr. NELSEN. That is all, Mr. Chairman.

Mr. JARMAN. Mr. Hoge, did the Food and Drug Administration set up the conference of 1955?

Mr. HOGE. I think that is a fair way to put it. In my statement I believe I put it that it was under the direction of the Food and Drug. Dr. Holland, who was then the Medical Director of the Food and Drug Administration, had a main hand in organizing and gathering the people. And we know, from what is written here, that the conference was held under FDA auspices.

Mr. JARMAN. There has been no conference since 1955?

Mr. HOGE. Well, there have been conferences.

Mr. JARMAN. On this subject?

Mr. HOGE. Not on this subject that I know of; no, sir.

Mr. O'BRIEN. Will the chairman yield? There has been no conference with the industry on this legislation at all?

Mr. HOGE. I think I am right in saying that. I don't know of any, Mr. O'Brien.

Mr. O'BRIEN. In other words, the effort was made to come in and get a law before an attempt was made to bring it about on a voluntary basis?

Mr. HOGE. I want to be fair in my answer, of course. I know of no invitation to a meeting or any approaches. I know of these ideas having been thrown out in speeches by the Administration. In fact, some of them I think have been reflected in legislation introduced in previous Congresses, but not acted upon. But I think I am correct in answering you. There has been no invitation or any setup of a meeting or any suggestion of a setup of a meeting. I hope I am right about that. I mean to be.

Mr. JARMAN. I might say to the gentleman from New York that earlier in the hearing today I asked Dr. Tainter if his company had been contacted by FDA for a conference on this subject, and my understanding of his response was that it had not been. Mr. Rogers?

Mr. ROGERS of Florida. Thank you, Mr. Chairman. I notice that on page 8, one reason I was wondering whether it would have to be prescribed by regulation and somewhat going into the question of liability, the statement is made: "For 'under the amendment' every detail of the labeling as to directions and warnings would be formulated and prescribed by FDA."

That is why I wondered whether they would have to set this before any liability would play.

Mr. HOGE. Mr. Rogers, I appreciate your remark about that, and after your interrogation of Mr. Connolly this morning, I reverted in my mind to that, to the fact that I had said that. I can see how you would have a question about it now. But I think what I said is accurate.

Mr. ROGERS of Florida. They have the right to if they desire.

Mr. HOGE. That is right. I think that if you require, as this statute would provide, at (3), "such other information" as the Secretary demands, and let him prescribe the form and manner of statement, I think with that authority, the Secretary could very well get into about as much detail as he wanted to. I don't know what he would do, but I think the authority would be there. So that while I might have written a little differently if we had had that colloquy before I wrote it, I think we would come back to it.

Mr. ROGERS of Florida. Now let me ask you about this. On your voluntary agreement, I notice that the actual agreement was that the wording should be "Warning" in double-spaced lettering, in relation

to "Keep out of reach of children." "Warning" was the terminology that the industry had agreed upon for aspirin. Also I notice that same wordage in the Food and Drug title as suggested. It says, "Warning: Keep out of the reach of children." Or "Warning: Keep this and all medications out of the reach of children."

Now just looking at the bottle that was given to us, Bayer Aspirin, that really isn't basically carried out here. This is the wordage——

Dr. PAUL. Would you look at the top of the cap?

Mr. ROGERS of Florida. Keep out of children's reach.

Dr. PAUL. It is on the cap and on the label.

Mr. ROGERS of Florida. Here it is on the label. "Parents: Please keep this and all medicines out of the reach of children." Now I think there is a difference in significance to it where you just say "parents," or where you have the word "warning." There is a great difference. I would hope that the industry in itself would relook at their agreement, as was clearly stated, and yet not really carried out in labeling at least in this one instance. I don't know if this prevails, but I would think you would agree that the word "warning" should appear.

Mr. HOGE. No, I don't know that I would, Mr. Rogers.

Mr. ROGERS of Florida. I thought they agreed to that according to the opinions that you gave us.

Mr. HOGE. Now the news story we are looking at does say the following, "Warning, keep out of the reach of children."

Mr. ROGERS of Florida. Yes, and so does the FDA agreement.

Mr. HOGE. Yes, that is right.

Mr. ROGERS of Florida. Yes.

Mr. HOGE. But the warnings which I have set up in appendix II, which include all of these, I can't lay my finger——

Mr. ROGERS of Florida. On page 6.

Mr. HOGE. Yes, I know, but I can't put my finger on the exact wording that I want now, but all during these 25-years, the Food and Drug Administration has accepted the word "warning," or the word "caution" synonymously, and they have not considered that we have violated any law or agreement when sometimes we didn't have the word actually "warning" or "caution" provided we did have the warning statement or the cautionary statement. Now that is somewhere in writing, and here at the moment I don't seem to put my finger on it exactly. What you are reading did say "warning," Mr. Rogers, I see that.

Mr. ROGERS of Florida. In both instances?

Mr. HOGE. Yes, there is no question about that. I think I am quite right in saying to you and I believe the Food and Drug would back me up that all through the years, they haven't insisted; maybe sometimes. In 502(d) yes, the hypnotics must say "Warning, may be habit-forming." That is prescribed. That is not suggested as these warnings are. That is prescribed. But under these as I have given you in the statement by the Food and Drug are suggested warnings.

Mr. ROGERS of Florida. Well, I realize that and also industry agreed up, that is the point I was making, that the industry itself agreed upon the warning in double caps, and to keep out of the reach of children. In other words, it has a different significance to me if you see something with a "warning" and simply something saying "Parents, please

keep this out * * * ." I think it has more impact than the word "warning."

Mr. HOGE. It does, and I am not arguing with you about it. I am simply trying to say, and I think the Food and Drug would agree, we had not breached any agreement by not doing it. They would recognize the validity of what you are saying, but I don't think they would charge us with any violation upon that basis. I may say this to you. It is a matter in which the industry would take the word "warning," but they have taken the other language with the understanding of the Food and Drug.

Mr. ROGERS of Florida. So Food and Drug has approved the wordage that you use?

Mr. HOGE. Well, I don't want to be misunderstood, sir. If you look, when you have a chance, in red I have put the warnings with respect to "Keep this and all medications out of the reach of children." You will find there that sometimes the word is "caution," and that is the Food and Drug suggestion. For instance——

Mr. ROGERS of Florida. But caution isn't even on here. You see, that is the point I was making. There is no caution warning.

Mr. HOGE. I am looking, sir, at their own——

Mr. ROGERS of Florida. I was looking at one specifically for aspirin, which said, "Warning," and your agreement "warning" that you have pointed out that industry agreed on. In other words, I just think that if we are going to agree to something, and there are some suggestions, we ought to live up to it all the way, that is all.

Mr. HOGE. Well, if there is any question——

Mr. ROGERS of Florida. I just don't think "Parents: Please keep out of the reach of children" has the same impact as a warning in caps and "Keep out of the reach of children" as you have agreed should be placed on them. That was the only point I wanted to make. I won't argue with you.

Mr. HOGE. I don't want to argue with you, sir, but I will call your attention with respect to salicylates that the Food and Drug itself has one that varies a little, "Caution: for children under 3 years of age consult physician," or "Caution: for younger children, consult your physician." Here is another one, "If pain persists or in conditions affecting children under 12 years consult a physician." I don't mean to argue with you, Mr. Rogers.

Mr. ROGERS of Florida. But there is no caution even on here you see, which is less than a warning I presume. But nevertheless, I am concerned with the fact that I think I too would be interested in questioning Food and Drug again on some of the impressions I was given about the little change that was being made in this law, and why it is all lumped under child care too.

Now, on the good Samaritan approach, we do this in hazardous substances, don't we?

Mr. CONNOLLY. Yes, Mr. Rogers.

Mr. ROGERS of Florida. Why would it be any different under those circumstances than here?

Mr. CONNOLLY. I would think that a doctor would tell you that those are fairly well identifiable.

Mr. ROGERS of Florida. I mean the principle, the good Samaritan principle is the same, isn't it? Basically you are giving some advice on what to do in the case of a hazardous substance.

Mr. CONNOLLY. Well, your advice can be pretty unmistakable and pretty certain because these hazardous substances are readily identifiable and the antidote or treatment is fairly specific. But with respect to the vast variety of over-the-counter drugs, your antidotes are not that specific, and the ways they can be misused are almost legion, I would suggest, and that being so, I think that you have to be most exhaustive then in the writing of your first-aid instructions. If you are not fulsome and you undertake to do so, there would then be imposed liability upon you. Or if you are compelled to write first-aid instructions and they turn out not to be specific enough or are inadequate or not fulsome enough there would be liability imposed upon you.

Mr. ROGERS of Florida. That would be so in hazardous substances, too?

Mr. CONNOLLY. It would.

Mr. ROGERS of Florida. Now on the restatement of the law, do you give us all of the full restatements in your statement, the four points?

Mr. CONNOLLY. The text?

Mr. ROGERS of Florida. Yes.

Mr. CONNOLLY. Yes.

Mr. ROGERS of Florida. Those are included in your statement?

Mr. CONNOLLY. Yes.

Mr. ROGERS of Florida. I would just like to have those.

Mr. CONNOLLY. I direct your attention to page 2 of my brief which is the actual quote of the restatement section (j) concerning directions of warning. That, I think, states the present state of the law with respect to the duty to warn.

Mr. ROGERS of Florida. Dr. Paul, I believe from your testimony evidently this cautionary labeling requirement would go to prescription drugs as well as over-the-counter drugs?

Dr. PAUL. Yes, we in Iowa feel very definitely about that, that there should be a label on all prescription drugs, saying, for instance, on the ones used for arthritis, "Take Butazolidin."

You would say Butazolidin, 100 milligrams, so a physician would know when an individual came to him or he went to their home that they were using this particular drug and wouldn't reorder this drug again, say "You take this."

We have seen this happen where they take prescriptions from two different physicians and have trouble.

Mr. ROGERS of Florida. There are the directions and adequate warnings and first-aid treatment, if we would require that on the over-the-counter drugs, then this would also be required on prescription drugs?

Dr. PAUL. Yes. On prescription drugs.

Mr. ROGERS of Florida. Who would give this? Would the druggist?

Dr. PAUL. Well, that is the question.

Mr. ROGERS of Florida. Would it have to be passed on there, or where?

Dr. PAUL. I don't know how you would write this. For instance, I was thinking while this discussion was going on about the use of the Cortisone-like drugs. They came into being in 1950, and it wasn't until 1955 that we first began to recognize peripheral neuritis, a

paralysis of the arms and legs. It is an accentuation of part of the rheumatoid disease caused by the Cortisone-like drugs. It took a 5-year period before we were actually sure that this is what was going on and began to recognize this.

Therefore, how could we bring precautionary labels or say what might happen. For instance, take tetanus toxoid as an example, I give it to all the athletes at the University of Iowa and have no trouble. A few years ago I was going to Europe and I talked my wife into taking tetanus toxoid. She promptly developed an arthraligia. All her joints blew up from the tetanus toxoid and that is the only case I have had so far with this particular brand of tetanus toxoid that we use.

Mr. ROGERS of Florida. Also, I was impressed with your figures which you used on page 7, saying that up to the age of 3 it is a therapeutic overdosage that is most common.

Dr. PAUL. Yes, sir.

Mr. ROGERS of Florida. And the figures that you later gave, 12 therapeutic deaths. This was taking prescriptions given by the doctors?

Dr. PAUL. A physician treated the child. What happens is that a physician orders something which contains salicylates. And then over the phone or while he is examining the child, say to the mother, "Now, if the temperature goes above 104 you give him two tablets of aspirin." This child is reacting to the aspirin but the mother doesn't know this. Then according to the doctor's prescription she gives more aspirin, this is what usually happens. We used to see this very frequently when we had polio epidemics. We would get infants sent in to us for acute poliomyelitis only to find they were overdosed with aspirin.

I would see them when they first came in overbreathing, and would find out that what they actually had was overdosage of salycilates prescribed by physicians, and then added to by the family.

Mr. ROGERS of Florida. What do you do for this?

Dr. PAUL. We stop the salicylates immediately, and then start giving them large amounts of fluids, usually in the vein, which gets rid of most of the salicylates. So if you see this within an early period after ingestion, you can save practically all the children.

Mr. ROGERS of Florida. I noticed that you say in one instance here, "Not one of eight children who died was diagnosed correctly before admission to the hospital."

Dr. PAUL. Yes, sir; because these children became dehydrated. They lost water. They vomited. They had an increased urinary output at first, and then they look like they have pneumonia, or they have sugar in the urine and a high blood sugar. This is why they think they are diabetics. But the point I want to make, if we educated physicians to this, all they would have to do is take this piece of paper, which every pediatrician has now, because this is a test for phenylketonuria (the metabolic defect in children who later become mentally retarded). This particular chemical on here reacts very quickly to salicylate. All you have to do is dip this in the urine, it turns black and you know this child has had aspirin.

Mr. ROGERS of Florida. And yet this is called an improper diagnosis?

Dr. PAUL. Yes, sir; that is called a Phenistix.

Mr. ROGERS of Florida. What is the best way to get the doctors educated on that?

Dr. PAUL. We start in the medical schools and try to teach our students about this.

Mr. ROGERS of Florida. Could the drug companies do this in the materials that they put out?

Dr. PAUL. Yes.

Mr. ROGERS of Florida. Labeling for doctors?

Dr. PAUL. I think they should make notice that one can test for salicylate with a Phenistix. As I say, every pediatrician now has these to test for phenylketonuria. Dr. Carter will agree with me. Every hospital has these, and it is so simple. You can even do this with the gastric washings. You wash the stomach out and you dip this into the gastric washing. It turns black, and you know that this is not due to sugar, it is due to aspirin.

Mr. ROGERS of Florida. What is your formal procedure, and I won't pursue this any more, what is the normal procedure of getting this out to the medical fraternity?

Dr. PAUL. There have been two articles now.

Mr. ROGERS of Florida. Could Food and Drug put this out?

Dr. PAUL. Food and Drug could put this out. For instance, there are two articles in the medical literature, called a new method of determining salycilate in the urine.

Mr. ROGERS of Florida. Would you let us have a memo on this?

Dr. PAUL. Surely. Pardon me, I was just going to continue saying I put out a bulletin on arthritis information. I abstract foreign literature for doctors. In one of my monthly bulletins to physicians I mention the fact that salicylates could be tested with the phenacetin. I think that is the way we could educate the doctors.

Mr. ROGERS of Florida. Thank you. It has been most helpful. Thank you very much, Mr. Chairman.

Mr. CARTER. I certainly want to compliment Dr. Paul on his excellent presentation. He is one of the most astute and articulate physicians that we have seen. I would like to ask a few questions. Do you find many cases of rheumatoid arthritis under the age of 6?

Dr. PAUL. Oh, yes. Dr. Gouchat in our Department of Pediatrics, has a standing grant from our Iowa chapter of the Arthritis Foundation, now has a group of about 190 children that he has been watching over a period of years, all under the age of about 6 or 7 who have rheumatoid arthritis.

The other thing we find, that these very young children of 2 or 3 years of age, come in looking like rheumatic fever with enlarged hearts and pericardial effusion, looking like rheumatic fever. It may take you a few months to convince one's self that this is rheumatoid arthritis instead of rheumatic fever. Time tells you that, as they develop the deformities, but we see quite a number of them.

Mr. CARTER. What is your average dose of aspirin for a 2-year-old child with rheumatoid arthritis?

Dr. PAUL. Somewhere around a gram and a half a day.

Mr. CARTER. A gram and a half?

Dr. PAUL. That would be——

Mr. CARTER. Twenty-two and a half grains?

Dr. PAUL. Yes, about 22 tablets of 1¼ gr., and for older children we go sometimes all the way up to 3 grams if necessary, depending on their surface area. That would be about 40 to 44 tablets.

Mr. CARTER. About how much per pound would you say the dose is for 24 hours?

Dr. PAUL. Sir?

Mr. CARTER. How many grains or how many milligrams per pound of body weight?

Dr. PAUL. In children of 3 or under it is about a grain per pound which is 27 grains (average weight 27 pounds). In children older than that, we may go up to 1½, 2 grains per pound and sometimes even more, depending on their fever and how much inflammation they have in the joints at the time, and then start cutting it down.

Mr. CARTER. Yes, sir. What do you consider a minimal lethal dose of acetylsalicylic acid for a child of 2 years, 3 years and 5 years?

Dr. PAUL. I don't know, because these British writers have shown blood salicylate levels of 78 and 90 milligrams percent, a figure that I have never obtained in anybody, and I have been doing blood salicylate levels since about 1938 when we first tried to get a method for this; yet both those children recovered. On the other hand, they had some that were much lower than that that had died. I think this depends on what is going on in the child at the moment. If a child has a fever from unknown origin or from something else, they may be rather sensitive. You take another child with rheumatoid arthritis, and they may be able to take a lot more salicylates. We see this in adults also, where they may get ringing in the ears very quickly with a small dose, but in rheumatoid arthritis we find they can take twice as much before they develop this. So I am a little hard put to answer that question. I have seen all sorts of figures and in the literature I have read anything.

Mr. CARTER. You don't know the minimum lethal dose then for these different age groups? I haven't been able to find it either. I checked two pharmacologies and have another one that I haven't got to read since Friday. I didn't find a minimum lethal dose in any of them. However, I don't think that a bottle should contain more than the minimum lethal dose, do you? That way our babies wouldn't get too much, if we would keep it below what would kill one of them.

Dr. PAUL. That is the problem. What is the minimal lethal dose?

Mr. CARTER. Yes, sir, that is the problem.

Dr. PAUL. In any given child.

Mr. CARTER. You would be willing to limit it to that, the minimum lethal dose, is that right?

Dr. PAUL. That is why I said if we take the average dose of 3 grams for a child who has rheumatic fever (and it has about a square meter of body surface) if you put that number in a bottle, make this the maximum, then in conference you could come down to any figure below that without having to have another act of Congress.

Mr. CARTER. Yes, sir. Now let's see, for a child of 2 years, I believe you said one grain of aspirin per pound, is that right?

Dr. PAUL. Yes.

Mr. CARTER. And then a child of 2 years at an average weight would be around 30 pounds, wouldn't it, something like that?

Dr. PAUL. Yes.

Mr. CARTER. Then that would be approximately 30 grains, wouldn't it?

Dr. PAUL. That is right.

Mr. CARTER. Thirty grains, that wouldn't take much of a bottle, would it?

Dr. PAUL. No.

Mr. CARTER. All right, sir. Now let's go up to 3 years. The average weight of a child of three would be about how much? About 35 to 40 pounds?

Dr. PAUL. The figures I saw were somewhere around 40 to 45 pounds.

Mr. CARTER. Forty to forty-five pounds.

Dr. PAUL. I came out with 45 grains for those children.

Mr. CARTER. Forty-five grain dose?

Dr. PAUL. Total for 24 hours. That would be 37 tablets of 1¼ gr. for a child of 45 pounds.

Mr. CARTER. That is for a 3-year-old?

Dr. PAUL. Yes, sir.

Mr. CARTER. And a 4-year-old would require about how much, then?

Dr. PAUL. About the same or maybe just a little more. You could probably go up to say 37 or 40 tablets or thereabouts.

Mr. CARTER. Thirty-seven or forty tablets, of course, would be 50 grains, I believe, wouldn't it? I think if we are going to go into this and do it right, we should definitely find more out about the minimum lethal dose, and if we have less in the bottle than that, we know our children are safe, is that not true?

Dr. PAUL. Yes, sir.

Mr. CARTER. That is all. Thank you, sir.

Mr. JARMAN. Are there any further questions?

Mr. HOGE. Mr. Chairman, may I just say a closing word?

Mr. JARMAN. Yes, Mr. Hoge.

Mr. HOGE. I should like to express appreciation for your giving us this hearing today and sitting this afternoon as you have, and if you will pardon me, in view of my age, I would like to say appreciation not only for the hearing on this bill but for hearings on the many bills that you have heard in this field, and I have had the privilege of appearing before you for some 35 years, and we are grateful to you. Mr. Rogers, I believe you were on the subject of prescription. These warnings would apply to prescription drugs as well as to over-the-counter. Of course, I have been speaking for the over-the-counter people.

My closing words to you are these: One of the best things that ever happened to the drug industry and particularly to the over-the-counter drug industry was the passage of the Federal Food, Drug, and Cosmetic Act of 1938. That was one of the best things that ever happened to them and in happening to them it happened to the whole country. My plea to you here on this bill is that we keep that law, which is a good law, and we not spoil it by some wanton, unbridled delegation of administration authority which this bill proposes particularly with respect to the labeling. We are certainly in favor of child safety, Mr. Chairman, just as much as anybody, and we only ask let's keep this bill on child safety and not rewrite the whole food and drug law under the pretense that we are protecting the children. Thank you again.

Mr. JARMAN. Thank you. For the committee I would like to thank you gentlemen and Dr. Tainter for your testimony today and for adding in a very real way to the hearing that we are having on this proposed legislation.

The committee stands adjourned.

(Whereupon, at 4:20 p.m. the committee was adjourned, to reconvene subject to the call of the Chair.)

CHILD SAFETY ACT AND PERSONNEL TRAINING

MONDAY, SEPTEMBER 19, 1966

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to recess, in room 2218, Rayburn House Office Building, Hon. John Jarman (chairman of the subcommittee) presiding.

Mr. JARMAN. The subcommittee will come to order. We are pleased to have back with us Dr. James Goddard, Commissioner of Food and Drugs, and his associates to comment further on the child safety bills that are before the subcommittee.

Dr. GODDARD. Thank you, Mr. Chairman.

On my left is Mr. William W. Goodrich, General Counsel for Food and Drugs and on my right is Dr. Basil G. Delta, a pediatrician who has been working on this problem of child safety.

We appreciate this opportunity to appear again in support of H.R. 13886, the Child Safety Act.

FURTHER STATEMENT OF HON. JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS; ACCOMPANIED BY WILLIAM W. GOODRICH, ASSISTANT GENERAL COUNSEL FOR FOOD AND DRUGS; AND BASIL G. DELTA, M.D., MEDICAL OFFICER, BUREAU OF MEDICINE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Dr. GODDARD. Our study of the testimony which has been presented to you since we last appeared here on June 24 indicates that the following issues have been raised:

1. Whether the extent of the hazard from children's aspirin has been overstated;

2. Whether the maximum number of children's aspirin to be permitted in a container should be fixed by law or left to regulation by the Secretary;

3. Whether a practical safety closure for drug containers is available;

4. Whether warning labels as to accidental injury are needed for drugs and cosmetics; the argument being that drugs are already adequately labeled, and that cosmetics have not been involved in any serious accidental poisonings;

5. Whether there is any need or basis for giving us authority to require increased warnings on drugs and additional labeling in-

formation to assure the safe and effective use of over-the-counter drugs;

6. Whether the provision for improved labeling warnings and instructions should be conditioned upon a notice and opportunity for hearing before the labeling changes may be placed into effect; and

7. Whether improved labeling warnings should not be required because they may increase the product liability of drug firms.

We would like, Mr. Chairman, to take these points up one by one.

The hazard from children's aspirin:

When I appeared here in June, I provided figures from the National Clearinghouse for Poison Control Centers on reported fatalities due to aspirin and other salicylates.

These figures showed that 125 fatalities to children under 5 years of age due to ingestion of aspirin and other salicylates occurred during 1964, the last year for which there are complete figures. The type of salicylates involved in all cases of death was not recorded, and is not known.

We also provided the committee with the statistics from the National Clearinghouse on oil of wintergreen, another of the salicylates frequently involved in poisonings of children under age five.

In addition, we provided the committee with data on the accidential ingestion of aspirin in 1965. Children's aspirin accounted for 10,854 of the 12,102 ingestions of aspirin where the dosage form was specified; there are, in addition, 4,226 instances where the dosage form was unspecified, or a total of 16,328.

Thus, as we stated in our testimony, where information on dosage form was reported, 90 percent of the cases of accidental ingestion of aspirin by children under five involved children's aspirin—78.5 percent of these cases were reported to have been treated by physicians.

This pattern of accidental ingestion of children's aspirin has been the consistent experience over a period of time. For example, in 1963, as reported by the New York City Poison Control Center, "Flavored aspirin preparation was most frequently incriminated, primarily because of their frequent use for children under 5 years of age. Children under five are the chief victims of flavored aspirin poisoning."

Thus, it is clear that children's aspirin was by far the most frequently implicated in these cases of accidental ingestion—the overwnelming majority of which required medical attention.

Since the type of aspirin involved in fatalities was not recorded in all cases, it is not possible to say with any certainty that the fatality experience followed the ingestion experience. Two possible assumptions might be made:

First, that the fatality experience followed, in general, the ingestion experience, or

Second, that the fatalities occurred primarily from the 10 percent of the ingestions of adult aspirin.

If the children's aspirin were too low in strength to cause a fatality, the latter assumption could be made. But we know that children's aspirin do cause fatalities and that the assumption cannot be made.

We continue to believe that the available data demonstrate that there is a substantial risk of serious illness or death to young children through the accidental ingestion of children's aspirin.

How many more of the ingestions might have been deaths, but for prompt action by physicians? The poison control centers in fact prevent serious illness or deaths by quickly furnishing accurate information to physicians and parents. The fact that more lives are not lost hardly proves there was no risk.

We think that the number of reported instances and the danger inherent in this situation warrant congressional action to protect children from these risks by limiting the availability of children's aspirin in retail packages which now contain enough aspirin to kill or cause serious illness to a child of tender age.

Limitation of the number of aspirin in containers:

We had not understood that there was any serious dispute about what may constitute a toxic dose of aspirin to a young child. We think the figures supplied by Dr. Palmisano, who accompanied me at the opening hearing, represent the consensus of medical opinion on this point.

Our pediatricians do not agree with the implications of one chart presented here to show that children have ingested large amounts of aspirin without serious adverse effects.

The medical reports do not bear this out. Since the chart entitled "Recorded Ingestions in 2- to 5-year Group Where Age and Dosages Are Known" was submitted to the committee on September 12 we have been able to review 22 of the 24 literature references cited in which the children were alleged to have ingested 120 or more grains of aspirin.

Two of the cited articles were not available either in our library or the National Library of Medicine at the time of the review.

In each case we found that the children invloved received significant medical treatment and in some cases heroic therapy to save their lives.

The treatment ranged from gastric lavage, intravenous fluids, and oxygen, to exchange blood transfusions, use of an artificial kidney, and peritoneal dialysis, the last three of which are available only in large medical centers.

Rather than minimizing the significance of massive ingestion of aspirin by small children, we believe the data submitted by the witness who presented this chart confirms that a very serious hazard does exist when large quantities of aspirin are ingested by young children. And without prompt medical treatment, the number of fatalities would unquestionably be much higher.

I have here, Mr. Chairman, which will be available for the record if you wish, a tabulation of those cases in which the dosage was above 120 grains, the management of the cases showing the use of intravenous fluids, gastric lavage or in some instances it is simply cited as heroic therapy and the outcome and the places where the cases occurred.

Mr. JARMAN. That will be accepted for the record.

(The document referred to follows:)

Tabulation of children 2 to 5 years of age who ingested 120 or more grains of aspirin

Case No.	Age in months	Sex	Weight	Amount ingested (gr)		Time elapsed (hours)[1]	Blood salicylate mg. per-cent[2]	Symptoms[3]	Management	Outcome	Locality
				Total	Per pound body weight						
1	27	M	.....	175	.....	19	73	+	Intravenous fluids	Recovered	Minnesota.
7	30	.....	.....	[4] 130	.....	[5] +30	45	++	Oxygen, intravenous fluids	Expired	Tennessee.
11	26	.....	28.0	[4] 150	.....	24	43	+	....do	Recovered	Do.
12	26	.....	25.0	150	6.0	20	70	+	....do	....do	Do.
20	42	.....	.....	8gm.	.....	(6)	(6)	(6)	(6)	....do	Europe.
24	28	F	25.0	125	5.0	3	160	+, ++	Oxygen, intravenous fluids, exchange transfusion	....do	Washington, D.C.
25	24	M	25.0	250	10.0	[5] 1	73	+, ++	Induced vomiting, gastric lavage, oxygen, intravenous fluids, exchange transfusion.	....do	Connecticut.
32	30	F	28.5	250	8.5	1–23	30–60	−, ++	Intravenous fluids, hemodialysis	....do	(6).
37	24	M	.....	250	.....	1/24	−/90	−, +	Intravenous fluids	Expired	New York.
38	30	F	.....	215	.....	11	50	+	....do	Recovered	Do.
41	24	F	.....	110	.....	2	(6)	−, ++	Gastric lavage, heroic therapy	Expired	Do.
72	24	.....	.....	285	.....	(6)	(6)	(6)	(6)	Recovered	Do.
101	24	F	.....	125	.....	1/4	(6)	−/+	Heroic therapy	Expired	Do.
122	30	M	.....	130	.....	.....	.....	.....	This is a table, not a case report; management not stated.	Recovered	Do.
52	30	F	.....	[4] 150	.....	(6)	61.8	+	Peritoneal dialysis	....do	Canada.
59	36	M	30.0	360	12.0	3	40.1	+	Oxygen, intravenous fluids	....do	Michigan.
63	36	F	28.0	150	5.3	2	15.6	−	Oxygen, intravenous fluids, gastric lavage	....do	Do.
65	24	F	26.0	[4] 165	6.7	14	75	+	Oxygen, intravenous fluids	....do	Do.
105	30	.....	28.5	120	4.2	.....	(6)	−	Gastric lavage	....do	South Africa.
111	36	.....	33.0	250	7.6	36	(6)	+	Intravenous fluids	....do	Do.
113	42	.....	32.0	170	5.3	.....	(6)	−	Gastric lavage	....do	Do.
118	53	.....	36.0	125	3.3	.....	(6)	−	....do	....do	Do.
119	66	.....	46.0	125	2.7	.....	(6)	−	....do	....do	Do.
123	35	M	.....	225	.....	22	52	+, ++	Prompt therapy (intravenous fluids, oxygen)	....do	(6).

[1] Time elapsed between actual ingestion and arrival to the hospital.
[2] Blood salicylate level at the time of admission.
[3] Symptoms:
− Asymptomatic.
+ Mild to moderate.
++ Severe.
[4] In cases 7, 11, 52, 65 the amounts stated do not coincide with those of the articles referred to:
7—Ingested amount unknown.
11—Ingested amount unknown.
52—Ingested perhaps 20–5 gr. tablets (100 gr.).
65—Ingested 6.6 grams (100 gr.).
[5] In cases 7 and 25 the child was receiving prescribed aspirin therapeutically prior to accidental ingestion.
[6] Reference could not be found in National Library of Medicine.

Dr. GODDARD. Thank you.

Thus we conclude that 1 grain of aspirin per pound of body weight is about the point of danger, and we would propose to restrict contents of bottles accordingly.

The problem presented to you is whether the maximum content of the containers should be written into the law or left to regulations. The argument is that we may fix the figure at 25 aspirin today and reduce it to 10 tomorrow.

This is not at all likely. We would plan to start the program at 20 to 25 1¼ grain tablets after full consultation with pediatric authorities, and with representatives of the affected industry.

We would maintain the quantity at that point so long as it seemed to assure safety. As we indicated when we testified before, the established procedure under which we would issue regulations to set the quantity limitation on children's aspirin permits all interested parties, including both the scientific community and the affected industry, to submit comments and views on such a proposed rule.

But we think we should have the authority to reduce the figure if experience proves necessary without asking that the entire medical problem on which a reduction would have to turn, be reexamined by the Congress.

We believe the desirability of this approach is borne out by a review of the testimony which the committee has already received. Already you have had recommendations ranging from an outright ban of children's aspirin to suggestions that the limit be no lower than 25, 35, 40 tablets per bottle. As we stated before, we do not believe the problem warrants a total ban of this product but neither do we believe a limit set at 35 or 40 tablets of 1¼ grains is adequate to deal with the problem.

We respectfully submit that full and complete consultation with pediatric experts and the industry affected will provide us the best guidance in this matter.

SAFETY CLOSURES

We are not now sure that there are entirely satisfactory safety closures. We have seen some that appear to do a good job and there are others which warrant further study and consideration as to practicability.

What the bill would do, and what we would expect to do under it, is to encourage the development of suitable and practicable safety closures for the drugs for which they may be needed.

We could not and would not require an impractical safety closure. But we cannot agree that this is a problem that can be solved by a joint industry-government study group with no mandate for action and no means of making its recommendations effective.

There will be resistance to safety closures—even practicable ones—and we recommend legislation that would allow us to move ahead to require them on drugs where needed as soon as practicable closures are developed.

Given such authority, it seems to us that the determination whether a sufficiently satisfactory closure has been developed and its use should be required involves, not so much issues that can best be resolved

through plenary hearings, but rather, issues that can better be dealt with through a process which permits consultation and conference with expert consultants and interested industry groups and provides adequate opportunity for the submission of views on proposed regulations.

COSMETICS INVOLVED IN ACCIDENTAL INGESTIONS

Representatives of the Toilet Goods Association contend that experience with cosmetics does not establish a need for label warnings information as to accidental ingestions.

In 1964 there were 3,058 cases of the accidental ingestion of cosmetics by children under 5 years of age reported to the national clearinghouse. In 1965 this figure has risen to 3,271. In both years over 20 percent of the children ingesting the cosmetics received medical treatment.

Thus, we believe it is clear that the accidental ingestion of cosmetics is not a rare occurrence as was suggested to the committee by one witness. In fact, we must recall that these are cases reported to local poison control centers and to the national clearinghouse and thus do not reflect the total picture in regard to the risk.

And irrespective of how one defines whether such an ingestion is serious, I'm sure the parents of the 620 youngsters who were treated, some of whom were hospitalized, considered this a serious matter.

Further, we know from reports made to us, to the national clearinghouse, and in the scientific literature, that some children have been seriously ill and others have died from the ingestion or inhalation of cosmetics.

You may recall that I discussed one such case at prior hearings.

At present the labels of cosmetics are not required to bear any ingredient information, aside from certain information on hair dyes. But now the physician in an emergency room with a child who has ingested a cosmetic has no data on which to act, and the parent has no label information to help avoid accidental ingestions of cosmetics which contain ingredients that may be dangerous to the child.

The bill does not, as one witness suggested, require warning against wholly or consequential ingestions. The warnings must be presented when there is a substantial risk of injury or death.

If the risk is one that should be avoided and involves the need to seek emergency treatment for the child, we think it should be stated on the label.

DRUG LABELING AS TO ACCIDENTAL INGESTION

Drugs play a major role in accidental ingestions. Yet they are exempt from the Federal Hazardous Substances Labeling Act. We think that plainly this is a serious defect in existing law. Certainly, more care would be exercised in storing drugs out of the reach of children, if the parent were informed by the label of the hazards that may be associated with accidental ingestion.

And first aid information, where needed, would provide an extra margin to avoid serious injury from accidental ingestion. It would also assist the physician called to treat a child who has ingested a drug product.

When the Hazardous Substances Labeling Act was enacted in 1960, drugs were exempt primarily because of the argument that any drug

warning should be required under the Federal Food, Drug, and Cosmetic Act, and not the Federal Hazardous Substances Labeling Act.

In each of the succeeding Congresses we have requested that this gap in consumer protection be closed. But as yet, 6 years later, the problem has not been remedied.

DRUG LABELING WITH ADDITIONAL WARNINGS, CONTRAINDICATIONS AND INFORMATION AS TO SAFE AND EFFECTIVE USE

It has been contended that this provision makes sweeping changes in labeling controls, on points not relevant to child safety and under conditions that would deprive the drug producer of hearing on the need for the labeling changes.

Actually, both this bill and H.R. 13885, the Drug Safety bill, which is also pending before your committee, involve amendment to section 502(f) of the Federal Food, Drug, and Cosmetic Act. And because they do, the same amendments were offered to the same section in both bills.

Thus, we agree that some of the amendments to section 502(f) are relevant to general drug safety and effectiveness as well as to child safety. This is no reason, we believe, for postponing action on these necessary amendments in the context of this bill.

We strongly support these changes, and we do not agree that they rob any drug producer of any important labeling rights. Nor can we agree that it makes good sense to require that before a needed labeling change to add a new warning of danger or a new contraindication or a new instruction as to effectiveness could be called for, the long process of hearing would have to be completed.

Many times the new warning, the new contraindication, and the new effectiveness information is needed at the earliest possible time by the person who is attempting to treat himself.

We have seen several instances where drugs long considered safe for self-medication or in broad usage on the advice of physicians called for new warnings of newly discovered hazards.

Phenacetin and dipyrone are but two examples.

Phenacetin, a drug used in many analgesic products, was found to be associated with kidney damage in excessive dosage or in prolonged use.

Dipyrone, a drug used for relieving high fever in children, was learned to be a cause of fatal arganulocytosis.

Both required labeling changes. Both required changes in the indications for use and the warnings against misuse. In both cases, we issued statements of policy calling for relabeling to make the drugs safe.

In the case of dipyrone, we reclassified it as a new drug because it was not generally recognized as safe and effective under the new labeling recommended to us by an ad hoc committee of medical experts.

What the bill does is provide an orderly means to bring about these needed changes in drug labeling, in a way that would be applicable to all producers and distributors of the drug.

In the past, when statements of policy or interpretive regulations have been issued on drug warnings, most firms affected have promptly complied. But not all have.

This has caused dissatisfaction among the better firms who made the changes, when their competitors dragged their feet. We have been told repeatedly that firm A, for example, would change its labeling, but that it couldn't do so until all other firms did the same.

The regulation procedure we have recommended would make the labeling change for all concerned at the same time; and at an early time when the change was such as to require it.

The point that this is a rewrite of regulatory procedures without the requirement of a hearing is not true. As we have shown, it formalizes and reinforced the statement of policy procedure that we have long followed.

And in more than 25 years of experience with regulations under section 502(f)—the section here involved—no hearings have been required even though it specified the labeling details for essentially every drug that is marketed today—those in final dosage form as well as those intended for manufacturing or processing.

These regulations, which spell out the conditions for exemption from the requirement of section 502(f) that the label bear adequate directions for use, have been amended from time to time.

In 1961, they were broadly amended to require full disclosure in the labeling of prescription drugs. No hearing was required or conducted. Instead, we utilized the public participation provisions of the Administrative Procedure Act to solicit the views of the affected industry.

Moreover, most drugs that will require labeling changes of the type called for in section 502(f) will also require new drug clearance for the new labeling.

The Court of Appeals for the 10th Circuit has held that labeling changes take the product out of its grandfather clause protection and subject it to reclearance from the standpoint of safety and effectiveness under its new labeling.

The case is now pending on a petition for certiorari in the Supreme Court. When subjected to reclearance as a new drug, full opportunity for a hearing is allowed.

What we need here is a prompt, efficient method of requiring drug labeling improvement across the board when a new danger arises or when effectiveness cannot be assured under the existing pattern of labeling. All would be treated alike.

If the committee should decide to write in a hearing provision—where none has been found necessary in the past, we would strongly urge that we be allowed to require interim labeling changes to be complied with while the hearing procedure is underway.

Otherwise, we risk unnecessary drug injuries and drug failures.

PRODUCT LIABILITY

The argument that increased warnings would increase product liability completely escapes us.

Product liability arises out of a failure to warn—not out of more adequate warnings which this bill would require.

A warning on the label against accidental ingestion or known hazards should benefit both the patient and the drug producer—the patient by helping to avoid injury and the producer by calling attention to hazards which can be avoided.

Under no reasonable construction would this bill require warnings against insignificant or trifling injuries, first aid instructions that are not necessary for the protection of the public health, or warnings against hazards that could not be discovered by the highest degree of care.

To conclude, Mr. Chairman, we think that this bill is an important measure for the protection of the public health. We feel that the problems to which it is addressed have not been exaggerated.

Like all other laws, it would have to be administered reasonably; and so administered, we are confident it would not unduly inhibit the legitimate sale of these products. And we do believe its enactment will help to protect children from unnecessary risks of injury, serious illness, or death.

I would be happy to answer any questions you or members of your committee may have.

Mr. JARMAN. Thank you, Dr. Goddard.

One particular question that the Chair would like to ask is this: It has been our understanding during the course of the hearings that the 50-aspirin limitation on children's aspirin was achieved on a voluntary basis as a result of a 1955 conference with Government and manufacturers and a good many organizations and individuals participating.

Dr. GODDARD. Yes.

Mr. JARMAN. During the course of the hearings, it has been asked of witnesses, particularly the manufacturing witnesses if they have been contacted for a conference as the basis for a voluntary reduction of the number of aspirin and the response was that they had not been contacted.

The thing that the Chair was particularly interested in hearing from you is why the Government has not decided on approaching this problem from a conference standpoint as in 1955 and trying to achieve this reduction on a voluntary rather than a legislative basis.

Dr. GODDARD. Going back to 1955, it is true that there was a conference held. Now, I would not want the chairman and members of the committee to have the impression that all as principal manufacturers have voluntarily reduced the total tablets to 50.

This is not so. We have firms packaging them in 100-tablet bottles. Many times they are repackaged this way. The major firms have gone along with the 50-tablet limit. Because of this and because we felt the very strong need to get at this problem of children's accidental poisoning with flavored aspirin in particular, we felt that we would ask for the legislative authority.

The past experience has not been proven to be successful in those terms. In fact, if one looks at the statistics just taking deaths alone, admitting that deaths cannot be directly related to children's aspirin because we do not have the detailed knowledge of the product involved—just taking deaths due to aspirin and salicylates in children under 5 from 1955 through 1964, we have seen an increase from 72 cases to a maximum of 144 in that period of time.

What I am saying is that to the extent that there are correlations between deaths and ingestion and the presence of children's aspirin in the marketplace in these dosage forms, I feel that this is another rationale for proceeding on the assumption that we have to have a limitation fixed by the Secretary.

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Mr. JARMAN. Could you make any estimate as to the percentage of children's aspirin that is not in the 50 per bottle?

Dr. GODDARD. We do not get marketing data from any of the drug firms and this is a handicap.

We don't know that is in the marketplace. I can't even give you an estimate. I am told by Mr. Kinslow that the industry estimates that 95 percent of it is in the 50 tablet.

Mr. JARMAN. Ninety five percent of the production?

Dr. GODDARD. Yes; and that is the best I can provide you on that.

Mr. JARMAN. We have had it very firmly stated in the testimony, as you know, that those who produce the great percentage, the 95 percent to which we refer, would willingly accede to any decision reached in a conference such as the one held in 1955. I am particularly interested in hearing your comment on that because, in light of the testimony that the subcommittee has had, it just seemed or at least I wanted to raise the question as to whether it was not logical to ask for legislative authority if you failed to achieve the results through a voluntary meeting?

Dr. GODDARD. I think we have already failed to achieve the results through the voluntary meeting. They reduced in 1955 to a total of 50, 95 percent of them. Yet, we have seen the number of ingestions and we have, I think, good data that 10,000 out of 12,000 cases where the tvpe of aspirin was known was due to children's aspirin being ingested.

To me, this plus the fact that 5 percent of the aspirin marketed does not conform to it simply means that we need a stronger handle on this problem.

Mr. JARMAN. Have you had any conferences with the firms that manufacture the 5 percent in terms of reduction?

Dr. GODDARD. I will have to ask and find out whether any of the staff has.

Of course, this has preceded my assumption of the commissionership. Mr. Goodrich says he has no knowledge of this. In many of these instances it would be almost impossible, Mr. Chairman, because some of these are repackagers, small firms which purchase in bulk and put it out under their own label, and they are located in many parts of the United States. It is difficult to have knowledge of all of these products in the marketplace.

Mr. JARMAN. Then you take the position that you feel that you could not achieve the results that you think are needed on a voluntary conference basis?

Dr. GODDARD. Well, I am simply of the opinion that in the interest of consistency if it is worth doing for 95 percent of the product market, it is worth going the other 5 percent of the way too, and in the light of past experience we feel that 50 tablets in a bottle is too high.

Mr. JARMAN. I am not really following you there because the testimony has been here that if such a conference were called and if a lesser number of aspirin were recommended as a result of that conference that the major manufacturers of the 95 percent would cooperate in reducing to that number.

Dr. GODDARD. The bill would require that too and we would get the other 5 percent and thus afford more protection for all those entering the market.

Mr. JARMAN. I understand.

I am just surprised that an effort has not been made to achieve this reduction in aspirin; if you feel as obviously you do that it should be reduced, that a real effort has not been made to achieve it on a voluntary cooperative basis since it seemed to work with such a large percentage of the product was a result of the 1955 conference.

Dr. GODDARD. I don't believe that the manufacturers have been unaware of these statistics since 1955 either, Mr. Jarman, and if they felt that further reductions were indicated, I don't see why they didn't take the action.

They are not unaware of these statistics. They watch them very closely.

Mr. JARMAN. I understand.

Of course, in your testimony on June 24, before the subcommittee, with reference to the number of aspirin you said:

> This is strictly a scientific issue of how many 1¼-grain aspirins can safely be allowed below the lethal dose. We think that is not a matter that would involve great controversy and it would involve delay to call for hearings under those circumstances.

We have had a good bit of expression of difference of opinion in the hearings as to what different people and organizations feel that number should be.

You take the position that a hearing is not necessary but that you should be authorized to go ahead and set the number without a hearing.

Dr. GODDARD. After consultation with the pediatric profession, which is largely involved in this, and members of the affected industry, we feel that we should be given the responsibility of setting the total number of tablets, the grainage, to be offered in childrens' aspirin.

Mr. JARMAN. Mr. Gilligan?

Mr. GILLIGAN. Thank you, Mr. Chairman. No questions.

Mr. JARMAN. Mr. Springer?

Mr. SPRINGER. Doctor, this was my understanding from your testimony: that it is your scientific opinion that a child can absorb about 1 grain per pound; is that correct?

Dr. GODDARD. That is approximately correct.

Mr. SPRINGER. Now, the average child of approximately 5 weighs how much? Do we know, roughly?

Dr. DELTA. About 40 pounds.

Mr. SPRINGER. Now, is it your theory at this point, and this is your position, that you have to have less than 50 tablets in order to meet this problem?

Dr. GODDARD. That is correct.

Mr. SPRINGER. Have you come to any primary conclusions as to what you think it ought to be?

Dr. GODDARD. As I indicated in the testimony, sir, somewhere between 20 and 25 1¼-grain tablets. This won't completely solve the problem. This plus safety closures plus better information to the public about the inherent dangers, all of these and many other steps will be required.

Mr. SPRINGER. Now, at the present time, can you label that under the Federal Food, Drug, and Cosmetic Act?

Mr. GOODRICH. As we indicated in our prior testimony, we did require on the basis of the voluntary meeting in 1955 a statement warning: "Keep this and other medicines out of the reach of children."

There was a doubt as to whether that could be legally done but we resolved those doubts in favor of the authority. We did put the statement of policy out. As has been indicated not everyone complied. We still have had as recently as 1965 an enforcement case to try to require that.

We are asking here for clear authority to provide warnings against accidental hazards as well as the hazards that go with the expected dosage.

Mr. SPRINGER. Do you feel that you don't have, or at the present time have, no way of limiting the number?

Mr. GOODRICH. We don't think we have.

Mr. SPRINGER. Well now, let me ask you this: Under the act, can't you call these people in if this is a dangerous thing? I am talking about not industry but company by company.

Mr. GOODRICH. Certainly. We could invite them to come to Washington any time and frequently do that on issues on which we have no authority and on which we are trying to work out a satisfactory solution.

Mr. SPRINGER. This is purely on a voluntary basis.

Dr. GODDARD. Yes.

Mr. SPRINGER. You don't think you would have authority to issue any regulation of any kind?

Dr. GODDARD. It is my understanding we do not.

Mr. SPRINGER. You are sure about that?

Mr. GOODRICH. As sure as I can be. The packaging limitations on drugs are fixed in what is called an official compendium. That is the only authority we have. If the U.S. Pharmacopoeia or one of the other compendia which are publications of voluntary organizations do that, we could enforce it, but we have no packaging authority in the drug section.

Mr. SPRINGER. Even though you feel it is dangerous you still don't have that authority?

Mr. GOODRICH. No, sir.

Mr. SPRINGER. On a person-by-person basis?

Mr. GOODRICH. No, sir.

Mr. SPRINGER. Are you the legal counsel?

Mr. GOODRICH. Yes.

Mr. SPRINGER. Now, let me ask you this: In this bill, H.R. 13886, tell me how many things, would you please, that you are doing under that bill, very shortly, not in 15 minutes but give it to me one, two, three.

Mr. GOODRICH. The authority we now have?

Mr. SPRINGER. No; the authority you are seeking under H.R. 13886.

Mr. GOODRICH. All right.

Dr. GODDARD. You are asking what we are now doing?

Mr. SPRINGER. No; I am asking what authority you are asking under H.R. 13886.

Mr. GOODRICH. We are asking the authority to limit the number of aspirins in the container, asking the authority to require safety closures, asking the authority to require increased warnings and information on drug labeling.

Mr. SPRINGER. Just a minute. Stop there just a second. What is the nature of the warnings you are asking for?

Mr. GOODRICH. Asking for addition to section 502(f)(1) to warn against the substantial or reasonably foreseeable risk of causing accidental injury in such manner and form as is necessary for protection and use.

Mr. SPRINGER. On aspirin?

Mr. GOODRICH. No; this is drugs in general.

Mr. SPRINGER. Will you repeat that again because this is a broader authority.

Mr. GOODRICH. This is the warning against accidental ingestion of drugs along with first aid instructions where necessary.

Mr. SPRINGER. You are asking this for all drugs?

Mr. GOODRICH. Right.

Mr. SPRINGER. That is the third one?

Mr. GOODRICH. We are asking for the authority to require added warnings against new dangers, added contraindications where they come up and added instructions to insure safe and effective use, where there is a finding that these added labeling provisions are necessary for the safe and effective use of the drug.

Mr. SPRINGER. I don't get the difference between No. 3 and No. 4.

Mr. GOODRICH. Well, accidental injuries in No. 3 and this is the use that is normally expected.

Mr. SPRINGER. All right.

This would be the contraindications.

Mr. GOODRICH. Contraindications, warnings, and additional instructions as in the case of Phenacetin. You find a drug that has been on the market over the counter for a long time, presumably safe. Suddenly, out of the medical experience comes a new finding that it is causing injury by being a poison to the kidney.

It is necessary to revise the label.

Mr. SPRINGER. What else?

Mr. GOODRICH. No. 4 would require warnings against accidental ingestion of cosmetics.

Mr. SPRINGER. That is No. 5.

Mr. GOODRICH. Yes, sir.

Mr. SPRINGER. In cosmetics.

Mr. GOODRICH. Yes, sir, and along with first aid instructions where necessary.

Mr. SPRINGER. As I understand it from Dr. Goddard's testimony, you did not have any deaths but you did have some injuries; is that correct?

Mr. GOODRICH. Right.

Dr. GODDARD. We have had at least one death reported from ingestion of cosmetics.

Mr. SPRINGER. You are seeking, then, on this one the accidental possibilities, right?

Mr. GOODRICH. Right, along with first aid.

Mr. SPRINGER. Along with first aid?

Mr. GOODRICH. Yes, sir, on the basis of a finding that this is necessary for protecting against accidental injury.

Mr. SPRINGER. Would this apply to all cosmetics?

Mr. GOODRICH. It would be based on finding that the nature, composition and packaging of this particular cosmetic involves a risk and make it applicable.

Mr. SPRINGER. Anything else?

Mr GOODRICH. Require the same kind of warnings on pressurized containers of foods as are now required on pressurized containers of pesticides, don't puncture or incinerate because they might explode.

Mr. SPRINGER. What else?

Mr. GOODRICH. We are asking for increased authority on making sure that the Hazardous Substances Labeling Act applies to a toy which has been treated by a pesticide chemical. We are proposing to apply the Federal Hazardous Substances Labeling Act to unlabeled containers.

We are proposing to ban the sale of toys which are or which contain hazardous substances dangerous to children.

We are proposing to allow the Department by regulation to exclude from household use products that are too dangerous for use around the household such as X–33 which we demonstrated here and the Jequirity beans.

Mr. SPRINGER. Authority to do what under that?

Mr. GOODRICH. To ban those for household sales.

Dr. GODDARD. Substances inherently too dangerous.

Mr. SPRINGER. That is for household sale?

Mr. GOODRICH. Yes.

Mr. SPRINGER. How do you propose to sell them?

Mr. GOODRICH. If they have industrial use such as X–33 they could be sold to that kind of person.

Mr. SPRINGER. Count 10. Have you anything else?

Mr. GOODRICH. That is all.

Mr. SPRINGER. That is the broad scope of the bill.

Mr. GOODRICH. I have summarized that all from not very much looking at the bill but I am pretty sure I have covered it all.

If not, I apologize.

Mr. SPRINGER. Let's take S. 3298. I want to know what you are doing with that?

Mr. GOODRICH. That is concerned with amendments to the Hazardous Substances Labeling Act. It provides for the same kind of provisions that I have discussed. To summarize them, to require that a toy treated with a pesticide chemical be subject to the Federal Hazardous Substances Act as it would be reworded, to apply to unlabeled containers, to allow the sale of some toys such as chemistry sets and some fireworks which can be adequately labeled to take care of the injuries when used by children; to exclude from interstate commerce toys that bear on container hazardous substances, to authorize us to exclude as banned substances, products that are too hazardous to have around the household, and finally this bill provides for a national commission to investigate the whole problem of safety including such things as lawnmowers, et cetera, and has a provision in it as passed by the Senate which says that State law cannot be inconsistent with this.

Mr. SPRINGER. What is the difference then between your part of S. 3298 and the same portion as I understand of 13886?

Is there a difference?

Mr. GOODRICH. The Senate adopted, I believe, three amendments, one the fireworks amendment. There was a problem there of whether fireworks would fit into this thing. We reviewed all of the State laws, found that in some States there were out-and-out bans on fireworks.

In your State, for example, I believe there is an out-and-out ban on fireworks. In others, in my State of Texas, there was an allowance of so-called class C's which have allowed some skyrockets and some roman candles and in Senator Magnuson's home State there was a so-called safe and sane fireworks law.

So, the issue came up of whether or not the law as we had recommended it would have banned fireworks, and a provision was written in to authorize, to make sure that we could authorize, the use of fireworks to the extent that labeling would take care of it.

Mr. SPRINGER. That is the difference, then?

Mr. GOODRICH. That is one of the differences. The other differences were the Commission and there was a clarifying amendment there, and clarification on banned hazardous substances, and also a clarification on toys to make sure that if it contained a hazardous substance it would be a substance reasonably accessible to the child.

Mr. SPRINGER. What has the Senate done on that bill?

Mr. GOODRICH. This went to two committees, to the Senate Committee on Interstate and Foreign Commerce which had jurisdiction over the amendments to the Hazardous Substances Labeling Act and they took out and adopted all of the amendments to that act with the modifications I have given you.

The other part to child safety goes to Labor and Public Welfare and they have not acted.

Mr. SPRINGER. They have not done anything.

Mr. GOODRICH. No.

Mr. SPRINGER. Therefore, the only thing thus far is S. 3298 which has passed the Senate.

Mr. GOODRICH. Except for our appearance here urging you to pass this.

Mr. SPRINGER. I want to get the legislative and parliamentary situation so that the subcommittee understands it.

S. 3298 was amended at the point with reference to fireworks, which you pointed out.

Mr. GOODRICH. Fireworks, the commission, clarifying provisions on banned hazardous substances and toys, and preemption.

Mr. SPRINGER. Now on 13886 has there been a bill introduced over there similar to this bill, or this bill.

Mr. GOODRICH. Yes.

Mr. SPRINGER. Who introduced it?

Mr. GOODRICH. Senator Hill.

Mr. SPRINGER. Has Senator Hill had a hearing on it?

Mr. GOODRICH. No, sir.

Mr. SPRINGER. Has he said he is going to have a hearing?

Dr. GODDARD. He has not scheduled one as yet.

Mr. SPRINGER. Have you talked to Senator Hill?

Dr. GODDARD. Yes, I have.

Mr. SPRINGER. What has he said?

Dr. GODDARD. He has said that he has a lot of hearings to be held and is pressed for time and he can't give a date.

Mr. SPRINGER. I want to be sure of the thing; without taking up all of the time of this committee, that we have an understanding of where we are with this legislation at this point.

There ought to be some indication from Senator Hill that he is going to do something or not do something. This committee is going to be pretty busy. We are going to face up to our responsibilities, but if we are going to turn out a piece of legislation and go to the floor with it and nothing is going to be done with it, we have learned many times in this committee, to our bitter experience, that we go into controversial things—and this is going to be an extremely controversial thing—and we get through with it and after we have knocked everybody's brains out and blood is all over the floor, we do something about it and the Senate doesn't do anything.

This committee ought to have some idea of the chances for enactment, although that doesn't excuse us from facing our responsibility and we are going to do it.

I am glad to know what has been done on the other side.

Dr. GODDARD. We expect action on the Senate side, sir.

Mr. GOODRICH. I would like to say that in all of our experience in which you, of course, have participated, in the passing of the food additives bill, the pesticide chemicals and the color additives, in all of those cases where this committee held comprehensive hearings, Senator Hill was willing to go ahead on the basis of the record here and recommend those bills although they were controversial.

Mr. SPRINGER. It may be just as well if this committee hears it, and we certainly went through the heart, stroke, and cancer bill and that was the worst bill ever sent here and we spent 3 months and finally came up with a heart, stroke, and cancer bill and they adopted it without changing a single point.

Thank you, Mr. Chairman.

Mr. JARMAN. Dr. Goddard, since S. 3298 has been referred to in this hearing this morning, would you care to comment on the national commission that is a part of that?

Dr. GODDARD. If I may, sir, I would like to read into the record a paragraph from a position paper on this.

As was brought out during the Senate hearing, a study of the subject matter covered by Title II of the bill, including the question of need for regulatory legislation in this field, would no doubt be appropriate.

We question, however, whether the character and scope of the proposed study are such as would warrant the establishment of a statutory Presidential Commission. It would appear more appropriate for this Department to undertake a study of hazardous household products with the cooperation of other agencies and report the results of the study to the President and the Congress.

Alternatively, if it develops that a study by a group independent of an executive department is desirable, such a study could be established by a mechanism designated by Executive Order. A study under either of these alternative approaches could, we think, be launched and concluded more expeditiously than one requiring the establishment, organization, and staffing of the Commission envisioned by the bill.

However, if your Committee should conclude that a statutory Commission of the kind proposed by Title II of the bill is desirable for this purpose, we would have no objection.

Mr. JARMAN. I might say that the committee is in receipt of a letter from Mrs. Peterson of the President's Committee on Consumer Interest in which she says in part:

> We do, of course, recognize the argument that such a study might be more efficiently conducted from within the Executive Branch in terms of speed and total cost.

The Senate bill, as I understand it, authorizes appropriations not to exceed $2 million to carry out the provisions of the commission.

Dr. GODDARD. That is correct.

Mr. JARMAN. That is not a part of the budget.

Dr. GODDARD. No.

Mr. JARMAN. Thank you.

Mr. Satterfield?

Mr. SATTERFIELD. Thank you, Mr. Chairman.

In answering Mr. Springer a few moments ago, is it not correct that what you were really saying is that in title I of House bill 13886, we are bringing in labeling legislation that is not necessarily confined to matters involving children?

Is this correct?

Dr. GODDARD. That is correct. It goes beyond the relationship to childrens' accidental poisoning.

Mr. SATTERFIELD. Is there any reason that you feel it essential that this particular title be considered a part of a bill dealing with children primarily rather than being treated separately?

Dr. GODDARD. Well, it does include aspirin and other products that are ingested by children. It would require two separate bills, otherwise.

Mr. SATTERFIELD. But the aspirin aspect and the children aspect is only incidental to the main thrust of title I; is it not?

Dr. GODDARD. No, I believe it is in fact one of the main justifications for the labeling, the aspirin problem and the whole problem of accidental ingestion of over-the-counter drugs by children.

Mr. SATTERFIELD. That might be justification but insofar as the thrust of that section is concerned it is certainly not the main thrust of it?

Mr. GOODRICH. There are three things here; first, to limit the number of children's aspirins; second, the provision of safety closures for those drugs for which the experience shows that they have been involved in a number of poisonings; and third, to require increased warnings on accidental ingestion.

The point that is more relevant to general drug safety than to children's safety, or at least as relevant, has to do with requiring changes in labeling which you find over on page 3, beginning down on line 24, which is relevant both to child safety and to general drug safety.

Mr. SATTERFIELD. Looking at section 502, and that is what you are talking about, is it not true that it would apply to a greater percentage of drugs not specifically designed for children?

Dr. GODDARD. It would apply to all drugs.

Mr. SATTERFIELD. Wouldn't a greater percentage of them be non-children's drugs?

Mr. GOODRICH. Certainly.

Dr. GODDARD. They would be nonchildren's drugs but I must point out that in the case of accidental poisoning involving children that any drug is a candidate for misuse and accidental ingestion.

Mr. SATTERFIELD. I agree, but I am disturbed by the figures. You mentioned there had been an increase from 72 to 140 deaths.

Dr. GODDARD. Aspirins and other salicylates.

Mr. SATTERFIELD. How many of those were due to aspirin alone?

Dr. GODDARD. I don't have the breakout for this which is one of the problems of not having detailed information. The national clearinghouse has not been able to provide us with the breakout of the cases, the deaths due to adult aspirin, children's aspirin, and other salicylates.

Mr. SATTERFIELD. In other words, we don't really know whether aspirin has caused any deaths?

Dr. GODDARD. Yes, we do. We have cases, a tabulation that we are supplying for the record (see p. 278), of children 2 to 5 years of age who ingested 120 or more grains of aspirin and in that series of cases there are four deaths specifically from aspirin.

This is aspirin of all types.

Mr. SATTERFIELD. All kinds of aspirin?

Dr. GODDARD. Yes.

Mr. SATTERFIELD. And out of how many ingestions?

Dr. GODDARD. This was a series of 22 cases.

Mr. SPRINGER. Would the gentleman yield?

Mr. SATTERFIELD. Yes.

Mr. SPRINGER. Would you indicate what other salicylates are involved?

I don't know what a salicylate is. That is the reason I asked that question.

Dr. DELTA. That is salicylic acid, and salicylates are the entire group that are used for pain or reduction of temperature. These are not drugs to cure a disease but to palliate a symptom such as fever or pain.

Mr. SPRINGER. What else besides aspirin?

Dr. DELTA. Salicylic acid is used externally like for athlete's foot and methylsalicylate is used externally, but both of these compounds when ingested accidentally by children are much more poisonous than aspirin, itself.

Mr. GOODRICH. Oil of wintergreen is an old rubbing compound.

Dr. DELTA. Methylsalicylate is oil of wintergreen. Salicylic acid is used externally for athlete's foot and the third is acetyl salicylic acid or aspirin.

Mr. SPRINGER. Thank you.

Mr. JARMAN. Mr. Mackay?

Mr. MACKAY. Thank you, Mr. Chairman.

Doctor Goddard, as you know, there was discussion after you left about the adequacy of the statistical data that had been furnished the committee.

I would be interested to know whether you feel that the data now being collected is in a form as complete as it should be for the reasonable interpretation of it.

Dr. GODDARD. We would like to have it in a form that would specify how many deaths are due to adult aspirin, children's aspirin and other salicylates but it is not available in this form.

Mr. MACKAY. Could you tell us a little bit about the national clearinghouse for poison control centers, whether this is voluntary or required by law?

Dr. GODDARD. This is a voluntary activity. It was established when I was chief of the accident prevention program in 1957, I believe. Its purpose was to coordinate poison control activities, and assist the local poison control centers by dissemination of information, to receive reports from local poison control centers located in all parts of the Nation, and to provide national statistics to highlight serious problems.

It has served those purposes. Its participation in these activities is voluntary but most of the local poison control centers do provide reports to the national clearinghouse and they do disseminate a bulletin to all hospitals where there are poison control centers and other groups who are interested.

Mr. MACKAY. Do you feel it would be possible to strengthen or improve that data?

Dr. GODDARD. Certainly, when there is this deficiency I feel that it not only would be possible but desirable.

Mr. MACKAY. The specific language in your testimony that some of the other witnesses took exception to was your statement that in 1964 there were 3,058 reported cases of accidental poisoning for children under 5 by cosmetics and it was pointed out that table 2 of the report discloses that there were 3,058 accidental ingestions among children but does not indicate a poisoning resulting from any such ingestion.

Dr. GODDARD. Mr. Mackay, I think that is hair splitting and I will classify it as such.

If you have a 3-year-old child who drinks a bottle of cologne or ingests a cosmetic, I don't know whether you are going to quibble over whether it is a poisoning or ingestion, but you are going to get that child to a doctor. He is handicapped by the fact that there is no list of ingredients or instructions for first aid. I don't think the relevant issue is whether these are ingestions or poisonings.

Practically, it is that the 3,000 patients, maybe more because these were the reported instances, were confronted with the problem.

I would be glad to make those people feel better and change my statement to say ingestions.

Mr. MACKAY. As laymen, we were trying to understand the meaning of the word "poisoning." In the laymen's mind this suggests a serious situation.

Dr. GODDARD. These are all potentially serious because we are up against not knowing what the ingredients are. This is one of the hardest things that the physician must make a decision on when confronted with the actual case in the emergency room.

Mr. MACKAY. If we could get language that would bridge the gap between the professional and layman, it would help us as legislators.

With regard to the issues that you discuss here as to whether the maximum number of children's aspirin in the container should be fixed by law or left to the regulation by the secretary, do you think that a group of scientists can agree on this figure?

Dr. GODDARD. I think that there can be agreement, yes.

I believe there is general agreement among scientists that the 1 grain per pound is considered to be a dose that one must be concerned about.

Mr. MACKAY. If this happens to be in an area in which there really can be agreement, doesn't the fact that it is stated in the law relax the industry somewhat from having to constantly worry about whether what they are doing is going to be changed?

Dr. GODDARD. It may relax them somewhat, but I don't really believe that is the scientific way to approach a problem of this type because we have to take into account actual experience and actual experience even after such limitation may indicate that a further 5-grain decrease in the total dosage would achieve greater gain. I think it is that that concerns us, having to come back here to justify a technical medical issue when there is need for a change that could be agreed upon by the scientific community.

Mr. MACKAY. I missed the last hearing and have not studied the testimony but the industry witnesses prior to the last hearing said it ought to be defined by law but when I would ask them at what point it ought to be defined, there was no testimony.

I don't know whether they really have any agreement as to what number should be fixed by law. I would like to ask if the staff, or if Mr. Goodrich knows, whether they have come up with a figure.

Dr. GODDARD. We mentioned it in our testimony today.

Mr. MACKAY. I mean the industry.

Dr. GODDARD. Three levels have been suggested in hearings before this committee—25, 35, and 40 is my recollection—as to the number of 1¼-grain tablets.

Mr. GOODRICH. Those are the figures we have mentioned on page 6.

Mr. MACKAY. Does it appear to you that aspirin is in a category by itself because of the large volume that is consumed?

Dr. GODDARD. In what respect, Mr. Mackay?

Mr. MACKAY. I mean that I would agree with you generally that you have to delegate power to scientific groups to handle many matters but there are no differences in what we call aspirin, are there?

Dr. GODDARD. On the fine points one could say yes, but generally, no. That doesn't make sense, but it relates to the way the tablet is compressed, the dosage forms, and all the other technicalities.

Are you saying: Do I think this is a special problem?

Mr. MACKAY. Yes, can you justify the rule of law here rather than the rule of regulation because of the nature of aspirin and the extent that it is used in our society?

Dr. GODDARD. Well, my personal feeling is that to fix dosages, the total number of grains, in this matter is sort of fixing it in concrete and not recognizing the kinds of changes that may occur.

We may see changes in packaging that would then make it easier to handle the problem.

Mr. MACKAY. I really was asking you that to hear your rebuttal to what the industry has been testifying.

Dr. GODDARD. I would prefer to see it done by the method of regulation after consultation with the scientists involved, the American Academy of Pediatrics, their study group on this matter and the members of the affected industry.

Mr. SPRINGER. Would the gentleman yield?

Mr. MACKAY. Yes, sir.

Mr. SPRINGER. What is your preliminary recommendation as to the number?

Dr. GODDARD. We said in our statement, sir, somewhere between 20 and 25 total tablets, 1¼-grain, seemed reasonable but we would want to consult with the Academy of Pediatrics.

Mr. SPRINGER. But that is your range?

Dr. GODDARD. Yes.

Mr. SPRINGER. I thank the gentleman.

Mr. MACKAY. My brother-in-law is with Richardson-Merrell, Inc., as a biochemist. I wish he were here to cross-examine you. He wrote me that he thought that the method used in 1955 which is described in a news release from the Food and Drug Administration in Drug Trade News, February 28, 1955, was a sensible way to thrash out this business of the number of aspirin in a bottle. He expressed hope that this could be done again. There has been criticism of the Department for asking Congress for this authority without any new discussions of this kind.

This has already been mentioned by the chairman. You seem to me to be saying that the trouble with this is that 5 percent of the trade is not acting in good faith with the rest of the industry.

Dr. GODDARD. Assuming those figures are correct, one would say then all right, the firms involved, the major producers could come back in and we could discuss this with them and they would agree after some debate to set the total limit at 20 to 25.

This means then that the purchasers in the marketplace who buy the trade name brands have that protection and those who don't buy the trade name brands do not.

I am hard put to find out what the real objection of the industry is in this instance, Mr. Mackay. If this is something that contributes to child safety, granting that it is not the total solution to the problem, and if it does get at the 5 percent who violated the good spirit of the industry in the past on the 50-tablet limitation, then I am hard put to understand why they are unwilling to work toward a solution where we would consult with them and use the opinion of scientists who are chiefly concerned with this, the pediatricians.

Just what is it they fear?

Mr. MACKAY. I might say in the letter I have here from Dr. Lee there is no shrill objection to what you are trying to do.

He said the 1955 meeting was good and thought it ought to be done again. Under the procedures of this bill it would be done again, wouldn't it?

Dr. GODDARD. In effect, I believe it would.

Mr. MACKAY. With reference to safety closures, we had some very interesting exhibits of the effort of the industry which seemed to me to be very energetic to solve this problem.

Dr. GODDARD. Yes.

Mr. MACKAY. As a practical matter, I wonder what your Department would do regarding safety closures. Would you approve safety closures for particular medicines or would you say, "These 20" and there are this many types it seems to me—"are approved"?

Dr. GODDARD. The thought behind the safety closure requirement would be that when there was a determination that a significant problem existed with a category of medication as to accident poisoning; and that the safety closure would assist in reducing the number of ingestions and thus the possible serious outcomes, that it would be

recommended and then required after notice in the Federal Register which affords the opportunity for comment.

Mr. MACKAY. Does this allow real latitude for competition?

Dr. GODDARD. Yes.

Mr. MACKAY. It doesn't really curtail the search for better safety closures, does it?

Dr. GODDARD. Not at all.

Mr. MACKAY. With reference to the commission idea which appeals to me, the National Commission on Hazardous Household Products, I received an interesting wire from the appliance industry saying they didn't like that "hazardous household products" name, they wanted it to be called the National Commission on Household Products Safety.

As I understood your position paper, the Department says it could do a better job or rather that you would prefer Department study rather than a commission.

Dr. GODDARD. We think it would be more expeditious if either the Department working with other agencies of Government studied the matter or a study group was set up through Executive order.

We would have no objection to a commission on either household safety or on hazardous household substances.

Mr. MACKAY. This is something that the Senate evidently thinks is a good idea. We are hunting for common ground. Your statement that you don't object to the commission is important.

Would it be a duplication of effort?

Dr. GODDARD. To my knowledge there is no such activity underway at that level.

The accident prevention program of the Public Health Service is attempting to gather the kinds of data that would illustrate hazards in and around the home but that would not in itself preclude or suggest that this would not be of value.

Mr. MACKAY. Finally, as I understand your testimony, you believe that H.R. 13886 ought to be passed as it now stands before this committee?

Dr. GODDARD. Yes, sir.

Mr. MACKAY. Do you find anything in S. 3298 that you do not feel should be enacted into law other than your comments on the commission?

Dr. GODDARD. No.

Mr. MACKAY. I have no further questions, Mr. Chairman.

Mr. JARMAN. Are there any further questions from the committee?

Dr. GODDARD. The amendments made by the Senate, Mr. Chairman, would be perfectly acceptable to us in this bill as well.

Mr. JARMAN. I understand.

Thank you, Dr. Goddard, you and your associates, for being with us to help conclude the hearings on these bills.

Dr. GODDARD. We thank you, Mr. Chairman.

Mr. JARMAN. The subcommittee stands adjourned.

(The following letters were subsequently submitted by the Department of Health, Education, and Welfare:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C. September 27, 1966.

Hon. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. JARMAN: As you know, several questions have been raised during the course of the hearings on H.R. 13886, the Child Safety Act, regarding the extent of illness and death as a result of the ingestion of childrens' aspirin.

As we pointed out in our testimony, it is clear from available data that children's aspirin was by far the most frequently implicated in cases of accidental ingestion of aspirin—the overwhelming majority of which required medical attention.

For your further consideration, we are enclosing some supplemental information which we have just received from the Division of Vital Statistics, Public Health Service. The listing gives the cause of death entries on the death certificates of the 125 children under 5 years of age whose deaths were attributed to accidental poisoning by aspirin and other salicylates in the U.S. during 1964. (See attachment A.)

Unfortunately, with only a few exceptions, the physician or medical examiner certifying cause of death did not specify whether or not children's aspirin was involved. Thus the new data do not improve our ability to determine the proportion of deaths caused by childrens' aspirin. The data do indicate, however, that some children did die in 1964 as a result of the accidental ingestion of chilrens' aspirin.

We continue to believe that the number of reported instances and the danger inherent in this situation warrant Congressional action to protect children from these risks by limiting the availability of children's aspirin in retail packages which now contain enough aspirin to kill or cause serious illness to a child of tender age.

Sincerely yours,

JAMES L. GODDARD, M.D.,
Commissioner of Food and Drugs.

ATTACHMENT A

EXACT ENTRY ON DEATH CERTIFICATE

1. Child took approx 40 aspirin.
2. Given salicylate over period of approx 16 hrs to reduce temperature due to upper resp. infection.
3. Child got into aspirin bottle, ate unknown quantity.
4. Child acc. took unknown quantity aspirin.
5. Salicylate intoxication.
6. Got hold of aspirin.
7. Overdose of aspirin—cold treatment.
8. Salicylism—adm. for upper resp. infection.
9. Overdose aspirin.
10. Aspirin intoxication.
11. Child ingested many aspirin.
12. Child took aspirin.
13. Aspirin—self ingested. Overdosage.
14. Therapeutic Overdose—aspirin.
15. Acc. ingestion aspirin.
16. Ingestion of oil of wintergreen.
17. Overdose salicylate.
18. Salicylate—given by mother.
19. Salicylate—child took in error.
20. Aspirin intox.
21. Salicylate—ingestion of overdose.
22. Ingest 200 gr. salicylate.
23. Child took aspirin.
24. Child took bottle of baby aspirin.
25. Salicylate intox.
26. Therapeutic adm. of aspirin 3–5 gr. asp in 12 hrs.
27. Salicylate poisoning.
28. Excessive aspirin given for treatment.

29. Child took unknown quantity.
30. Given aspirin for home treatment.
31. Ate aspirin by mistake.
32. Ingestion of oil of wintergreen.
33. Aspirin given for fever and infection.
34. Salicylate poisoning.
35. Salicylate intoxication—accidental overdose.
36. Ingestion 30–40 aspirin.
37. Overdose aspirin—unknown quantity.
38. Acetylsalicylic acid intoxication.
39. Salicylate poisoning.
40. Salycilate acid poisoning.
41. Salycilate intoxication—swallowed linament.
42. Upper respiratory infection and salicylism.
43. Salicylate poisoning—given by mother as prescribed.
44. Salicylate poisoning.
45. Mother accidentally gave too many aspirin.
46. Mother gave too many aspirin for fever.
47. Ate bottle of baby aspirin.
48. Ingestion of oil of wintergreen.
49. Salicylate poisoning—ingested plaster.
50. Ingestion of aspirin.
51. Aspirin intoxication.
52. Apparently ate large amount aspirin.
53. Accidental ingestion aspirin.
54. Salicylism.
55. Ingestion of aspirin.
56. Child crawled in chair and swallowed 150 grains asp.
57. Ingested unknown amount aspirin.
58. Salicylate intoxication.
59. Intoxication c̄ aspirin—(Liqui'-prin).
60. Salicylate poisoning.
61. Ingested aspirin.
62. Accidental ingestion—80 grains sodium salicylate.
63. Salicylate overdose—being treated for elevated temp.
64. Swallowed 20/40 grains aspirin.
65. Acute salicylate poisoning.
66. Aspirin intoxication.
67. Salicylate poisoning—played c̄ bottle of pills.
68. Salicylate poisoning.
69. Child ate aspirin.
70. Salicylate poisoning.
71. Alleged to have ingested methyl salicylate.
72. Acute methyl salicylate (oil of wintergreen).
73. Ingested large number 5 gr. aspirin.
74. Salicylism.
75. Intoxication methyl salicylate.
76. Salicylism.
77. Salicylate poisoning.
78. Took overdose aspirin.
79. Salicylate poisoning—overdose.
80. Drank—Oil of Wintergreen.
81. Swallowed unknown amt. aspirin.
82. Aspirin poisoning.
83. Accidental overdose of salicylate.
84. Given too much aspirin.
85. Ingested aspirin tablets (salicylate poisoning).
86. Ingested 12–16 5 grain ASA aspirin tablets.
87. Acute salicylism.
88. Ingested aspirin tablets.
89. Overdose of aspirin tablets.
90. Salicylate poisoning.
91. Ingested infant aspirin.
92. Ingested methyl salicylate.
93. Salicylate intoxication.
94. Salicylate intoxication.
95. Salicylate poisoning.

96. Salicylate poisoning.
97. Salicylate intoxication.
98. Ingestion of aspirin.
99. (Overdose of aspirin) Mother giving infant one baby aspirin every 2 hrs. for 5 days.
100. Aspirin poisoning.
101. Salicylate poisoning.
102. Salicylate intoxication.
103. Overdose of aspirin (intoxication).
104. Aspirin ingestion.
105. Salicylism.
106. Salicylate poisoning—ate 50 5 grain aspirin.
107. Salicylate intoxication.
108. Salicylic acid poisoning.
109. Aspirin (swallowed 12 to 15 aspirin tablets).
110. Aspirin intoxication.
111. Salicylism.
112. Swallowed undetermined number of aspirin.
113. Aspirin poisoning.
114. Aspirin intoxication.
115. Ingestion of aspirin (poisoning).
116. Salicylate intoxication.
117. Overdose of salicylate by mother and grandmother.
118. Aspirin poisoning.
119. Salicylate poisoning.
120. Salicylism (excessive aspirin ingestion).
121. Acetylsalicylic acid poisoning (ingested large quantity of aspirin).
122. Salicylism.
123. Ingested Sod. salicylate tablets (poisoning).
124. Aspirin poisoning (ingestion of unknown quantity).
125. Salicylate intoxication.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., August 29, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Enclosed for your information is a copy of our letter (attachment A) of this date to the Chairman of the Senate Commerce Committee on the status of fireworks under S. 3298 (the proposed Child Protection Act of 1966), which is a companion measure to title II of H.R. 13886 (Child Safety Act of 1966).

We should appreciate it if, in considering title II of H.R. 13886, your Committee would take account of the suggestions in the enclosed letter.

Sincerely,

RALPH K. HUITT,
Assistant Secretary.

ATTACHMENT A

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., August 29, 1966.

Hon. WARREN G. MAGNUSON,
Chairman, Committee on Commerce,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: At the suggestion of Mr. Pertschuk, Counsel to the Consumer Subcommittee, we are writing to you with respect to certain questions that have been raised as to the status of fireworks under § 3 of S. 3298, the proposed "Child Protection Act." (Fireworks, when intended, or packaged in form suitable for, use in the household or by children, would be within the coverage of the basic Act.)

1. COMMON FIREWORKS

Section 3 of the bill would amend the Federal Hazardous Labeling Act—which is to be renamed as the "Federal Hazardous Substances Act"—by excluding from interstate commerce any "banned hazardous substance", a term defined by two clauses in the bill. Clause (A) includes in the term "banned hazardous substance" "any toy, or other article intended for use by children, which is or

bears a hazardous substance, or which contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted * * * *Provided*, That the Secretary shall by regulation exempt from clause (A) of this paragraph articles, such as chemical sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved and which are intended for use by children who have attained sufficient maturity to read and heed the directions and warnings in the labeling of such article."

Representatives of the American Pyrotechnical Association have expressed concern lest these provisions would result in the ban, from interstate and foreign commerce, of all or some of the so-called "common fireworks" defined and listed in § 73.100(r) (49 CFR 73.100(r)) of the current regulations (under the heading "Class C Explosives; Definitions") issued by the Interstate Commerce Commission under the Transportation of Explosives Act (18 U.S.C. 834). A copy (exhibit A) of that list is enclosed herewith for your convenience.

As indicated by the Commissioner of Food and Drugs in the course of his testimony on S. 3298, the question whether such fireworks—which do not include items, such as "crackerballs," that are likely to be confused with candy or other food—can be adequately labeled for the protection of purchasers and users so as not to make necessary a Federal ban thereon when they are so labeled, has been reviewed by the Food and Drug Administration's technical experts concerned with this matter. On the basis of their advice and of present knowledge, we have, as also indicated in the Commissioner's testimony, concluded that we would have no objection to the continued sale of such fireworks with adequate labeling. (This is subject to a qualification with respect to the last item in § 73.100(r) of the ICC regulations, i.e., "Novelties consisting of two or more devices enumerated [in paragraph (r)] when approved by the [ICC's] Bureau of Explosives." We cannot, of course, foretell whether new novelties in this category devised in the future could be adequately labeled for the protection of the ultimate purchaser or user; ICC approval, which would be for the purpose of assuring safety in interstate transport, would, of course, not be conclusive on this point.)

Two things should be clearly understood. In the first place, we believe that States and localities should continue to be left free, so far as Federal law is concerned, to ban or restrict the sale of any such common firework even though Federal law and regulations be observed. There is a wide variance among the States in this connection, ranging all the way from complete prohibition to little, if any, restriction. Secondly, we would feel constrained to object, as unsound and inconsistent with the principles of the basic Act, to any amendment that would freeze into the Federal Act, by actual listing or by reference to the ICC list, an exemption of a particular list of fireworks, such as those in Class C, and thereby foreclose regulatory action that further knowledge or experience may require.

We have also reviewed the above-quoted clause (A), and proviso thereto, of the definition of "banned hazardous substance" to determine whether it needs amendment so as not to require us to ban Class C fireworks when we determine them to be adequately labeled for the protection of purchasers and users. While we believe that the clause and proviso, when read together, need not result in such a ban, we believe that amplification and clarification of the proviso would be desirable in this respect (coupled, incidentally, with some clarification with respect to children's articles other than fireworks). We therefore recommend that the proviso (page 6, lines 5–11, of S. 3298) be revised to read as follows:

"Provided, that the Secretary, [shall] by regulation, (*i*) *shall* exempt from clause (A) of this paragraph articles, such as chemical sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved , and which *bear labeling giving adequate directons and warnings for safe use and* are intended for use by children who have attained sufficient maturity , *and may reasonably be expected*, to read and heed [the] *such* directions and warnings [in the labeling of such article] , *and* (*ii*) *shall exempt from clause* (*A*), *and provide for the labeling of, common fireworks* (*including toy paper caps*) *to the extent that he determines that such articles can be adequately labeled for the protection of purchasers and users thereof.*" (Deleted matter is shown in brackets; new matter is italicized.)

2. AGRICULTURE AND WILDLIFE FIREWORKS

A witness appearing on S. 3298 has suggested that § 3 be amended by adding a subsection to exempt "from the requirements established by or pursuant to this Act fireworks used for agriculture crop protection and depredation control." (The reference to "this Act" could be read to refer to the basic HSL Act and thus exempt such fireworks even from the regular cautionary labeling requirements that apply.) As explained by the witness, fireworks are used to prevent or reduce animal and bird depredation of agricultural crops.

We are opposed to this amendment. Such fireworks are not intended for use by children and hence are not within the scope of the above-quoted clause (A) of the definition of "banned hazardous substance". Nor are we aware of any facts—and surely the proponent of the exempting amendment does not suggest that there are facts—that show that such fireworks satisfy the requirements of clause (B) of that definition, which would be applicable only to hazardous substances that are so dangerous that nothing less than a complete ban, rather than appropriate cautionary labeling, could adequately serve the objectives of the basic Act. This is a severe limitation and, as explained by the Commissioner of Food and Drugs in his testimony, is coupled with procedural safeguards, including judicial review.

Sincerely,

RALPH K. HUITT,
Assistant Secretary.

EXHIBIT A

73.100(r) OF INTERSTATE COMMERCE COMMISSION REGULATIONS

(r) Common fireworks are fireworks devices suitable for use by the public and designed primarily to produce visible effect by combustion. Some small devices designed to produce audible effects are also included in this class. The types, sizes and amount of pyrotechnic contents of these devices are limited as enumerated in this paragraph. No component, of any device listed in this paragraph, which produces or is intended to produce an audible effect shall contain pyrotechnic composition in excess of 2 grains in weight; nor shall such device or component, upon functioning, project or disperse any metal, glass or brittle plastic fragments. (Propelling or expelling charges consisting of a mixture of sulfur, charcoal, and saltpeter are not considered as designed to produce audible effects.) Any new device, not enumerated in this paragraph, must be approved by the Bureau of Explosives before being offered for transportation as Common Fireworks. Common fireworks must be in a finished state exclusive of mere ornamentation as supplied to the retail trade and must be so constructed and packed that loose pyrotechnic composition will not be present in packages in transportation. Fireworks, except articles defined in paragraphs (s) through (y) inclusive, of this section, other than common fireworks as defined in this paragraph, and those forbidden for transportation in § 73.51, are classed as Special Fireworks (see § 73.88(d)).

(1) Roman candles, not exceeding ten balls spaced uniformly in the tube, total pyrotechnic composition not to exceed twenty grams each in weight. The inside tube diameter shall not exceed ⅜ inch.

(2) Sky rockets with sticks, total pyrotechnic composition not to exceed twenty grams each in weight. The inside tube diameter shall not exceed ½ inch. The rocket sticks must be securely fastened to the tubes.

(3) Helicopter type rockets, total pyrotechnic composition not to exceed twenty grams each in weight. The inside tube diameter shall not exceed ½ inch.

(4) Cylindrical fountains, total pyrotehnic composition not to exceed seventy-five grams each in weight. The inside tube diameter shall not exceed ¾ inch.

(5) Cone fountains total pyrotechnic composition not to exceed fifty grams each in weight.

(6) Wheels, total pyrotechnic composition not to exceed sixty grams for each driver unit or two hundred and forty grams for each complete wheel. The inside tube diameter of driver units shall not exceed ½ inch.

(7) Illuminating torches and colored fire in any form, total pyrotechnic composition not to exceed one hundred grams each in weight.

(8) Dipped sticks, the pyrotechnic composition of which contains any chlorate or perchlorate shall not exceed 5 grams. Sparklers, the composition of which does not exceed 100 grams each and which contain no magnesium or

magnesium and a chlorate or perchlorate, are not subject to the regulations in Parts 71–78 and 197 of this chapter.

(9) Mines and shells of which the mortar is an integral part, total pyrotechnic composition not to exceed forty grams each in weight.

(10) Firecrackers and salutes with casings, the external dimensions of which do not exceed one and one-half inches in length or one-quarter inch in diameter, total pyrotechnic composition not to exceed two grains each in weight.

(11) Novelties consisting of two or more devices enumerated in this paragraph when approved by the Bureau of Explosives.

(The following material was submitted for the record:)

STATEMENT OF THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.

This statement, directed to title II of H.R. 13886, is submitted on behalf of the Chemical Specialties Manufacturers Association, a non-profit trade association representing some five hundred and thirty member companies engaged in the sale and distribution of chemical specialty products for household use. This association does not oppose, but in fact supports title II of this bill, as it supported the Federal Hazardous Substances Labeling Act when it was before the Congress in 1959 and 1960. Many products sold by members of this association are subject to this law and the regulations issued pursuant to it, thus our direct concern with title II.

The Food and Drug Administration, having made a reasonable case for additional authority to enforce this law, should be delegated these powers, but of course not without some reasonable limitation. Two amendments to this bill are necessary, we believe, to clarify section 202(a) and to properly establish the role of the Federal law and regulations in the total regulatory program.

Section 202(a) will define for the first time the term "banned hazardous substances." The authority conferred by this section upon the Secretary is the equivalent of an injunction issued by a court but without the preliminary safeguards of judicial consideration of the order. An injunction has always been viewed as an extraordinary form of relief and not to be granted except under most compelling conditions. The reference to toys or articles in clause A of this section appears to be satisfactory. Extraordinary power may be required to deal promptly with a hazard which may be presented by an article intended for use by children which might result in injury or illness to the child when used as a toy.

Clause B, however, confers the same extreme authority upon the Secretary with respect to any hazardous substance where the Secretary finds that the hazard involved in use is such that precautionary labeling would not be adequate to prevent injury. The committee will certainly be most cautious before conferring such unlimited authority upon the Secretary. While the administrative remedies provided in subsection 2 appear to be adequate, they may be available only after the fact and the finding that the Secretary is required to make is susceptible of a multitude of interpretations. For example, in the case of careless or intentional misuse of a product resulting in an injury, the Secretary might find that the existence of the injury justifies a finding that the product is a "banned hazardous substance" because the cautionary labeling did not prevent the injury. This result, of course, is not intended by the committee. Cautionary labeling cannot prevent injury. The user must heed the instructions and cautions.

The concept embodied in this subsection appears to be intended to be limited to the situation where a product is so hazardous that it should not be sold for household use even when the cautions on the label are observed. With this, the association has no quarrel. There may be a product which presents a hazard so severe or insidious, even when used in accordance with the label, that action may be justified.

The direct analogy to this situation appears in the Federal Insecticide, Fungicide, and Rodenticide Act. That Act, approved by the Congress in 1947 and amended several times since, requires a cautionary statement which is adequate *if compiled with* to prevent injury or illness. The Secretary of Agriculture has several times refused to register a product for household use on the basis that the caution statement is not adequate to prevent injury even if complied with. Examples are methyl parathion and thallium sulfate. The experience of 19 years with this Act has proven its effectiveness to deal with the situation contemplated by clause B of this section of the bill. Therefore, we recommend that

section 202(a) be amended by adding in line 19 on page 10 after the word "labeling" the words "on the container" and in line 19 on page 10, after the word "not" the words "if complied with." With these amendments, this section will be consistent with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act and will more clearly state the conditions under which the Secretary may assert the awesome power delegated to him by this section.

When the Federal Hazardous Substances Labeling Act was before the Congress in 1959 and 1960, the need for a Federal Act was conceded to be solely to establish uniform requirements for the labeling of consumer packages sold throughout the United States. Under the heading "Purpose of the Legislation," the Senate Commerce Committee report states in part:

In recent years legislation has been enacted in several States—Colorado, Connecticut, Illinois, Indiana, Kansas, Ohio, Texas, and Vermont—regulating the labeling of hazardous substances suitable or intended for household use, many of which are shipped in interstate commerce. It is desirable that labeling of these substances be regulated when shipped in interstate commerce and that the standards and requirements of such labels be uniform. Thus, Federal legislation on this subject is needed to require uniform labeling of hazardous substances for household use. * * * (Senate Report No. 1158, 86th Congress, 2d Session, p. 3.)

There is extremely little commerce involved in chemical products for household use solely on an intrastate basis. These containers all move in interstate commerce. Approximately 25 States have versions of the Federal Act and many States have special labeling laws dealing with different classes or categories of products. Although no State has yet insisted upon labeling entirely inconsistent with that required under the Federal Act, the possibility of such action is very real in the present state of the law.

As a result of the habit developed during prohibition of consuming methanol antifreeze, many States adopted special laws requiring specific labeling on this type of product. There are considerable inconsistencies in these requirements and today it is practically impossible to write a label for methanol antifreeze which would meet all State requirements. Companies must market this product knowing that it is not in full compliance with all State laws.

A hazard in a consumer product does not vary from State to State. The hazard is the same in Maine as it is in Florida as it is in California. Local conditions do not vary the type or degree of hazard. The great mobility of our population demands consistent labeling if it is to be effective. If one authority decides that the hazard of flammability should be denoted by the word "flammable" while another prefers "inflammable," the injustice is to the consumer.

Only the Federal Government has the funds and the capability to do the research and conduct the studies necessary to appraise the manufacturers' evaluation of the hazards. Therefore, to carry out the original intent of the Congress—to provide uniformity in the labeling of consumer products—and to assure a manufacturer that he can market a product in compliance with Federal law without running the risk of variation in some local ordinance, a preemption provision should be added to the Federal Act. For this purpose, we suggest language taken from S. 985 (the Hart Bill), now pending before this committee, and S. 3005, approved on June 22 by the Senate Commerce Committee. This proposed preemption section is attached as Amendment No. 2.

This association appreciates consideration of its views and assures the committee of its continued support for this law and amendments which will strengthen and clarify the law. The two amendments submitted herewith, we believe, will add strength and clarity to the statute and aid in its enforcement as well as to assist the industry in complying with its requirements.

AMENDMENT NO. 1 TO H.R. 13886, SUBMITTED BY THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.

SEC. 202. (a) Section 2 of such Act (15 U.S.C. 1261) is further amended by adding at the end thereof the following new paragraph:

(q)(1) The term "banned hazardous substance" means (A) any toy, or other article intended for use by children, which is or bears a hazardous substance, or which contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or (B) any hazardous substance intended or offered for household use, or so packaged as to be suitable for such use, which the Secretary by regulation classifies as a "banned hazardous substance" on the basis of a finding that the hazard involved in the

use of such substance in households is such that cautionary labeling *on the container* would not *if complied with* be an adequate safeguard against substantial personal injury or substantial illness occurring during or as a proximate result of any customary or reasonably foreseeable handling or use of such substance: *Provided*, That the Secretary shall by regulation exempt from clause (A) of this paragraph articles, such as chemical sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved and which are intended for use by children who have attained sufficient maturity to read and heed the directions and warnings in the labeling of such article.

AMENDMENT NO. 2 TO H.R. 13886, SUBMITTED BY THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.

SEC. 203. It is hereby expressly declared that it is the intent of the Congress to supersede any and all laws of the States and political subdivisions thereof insofar as they may now or hereafter provide for the labeling of a container of any hazardous substance covered by this Act which differs from the requirements of this Act or the regulations promulgated pursuant thereto. Any law, regulation, or ordinance purporting to establish such a labeling requirement shall be null and void.

STATEMENT OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

The National Association of Boards of Pharmacy urges the adoption of H.R. 13884, a proposed amendment to Section 702 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 372). The members of this organization (various state Boards of Pharmacy located throughout the United States and its possessions), are involved daily in the enforcement of state statutes concerned with pharmacy practice and the pharmaceutical industry.

We are all familiar with the technological and scientific advances that have been made in the field of pharmaceutical and medical science. The expansion of this industry, coupled with increased legislation, both federal and state, has necessitated a continuing education of those officials charged with the enforcement of pharmacy and drug statutes and regulations. This continuing education is, at least at the state and local level, in many instances often inadequate and financially impractical for the assigned responsibility.

The complexity of proper investigation and enforcement by government officials requires increased cooperation between state and federal authorities because of the multiplicity of laws and regulations at both the state and federal level. Such cooperation is impossible unless state and local individuals responsible for enforcement are familiar with both state and federal regulations. The state and the federal government, if isolated, cannot work effectively in the area of enforcement.

In 1965, the Public Administration Service submitted a report to the Commissioner of the Food and Drug Administration, Department of Health, Education and Welfare, on state and local food and drug programs. This report stresses the skills needed by the individuals responsible for the administration of food and drug law programs. The report affirms the necessity of greater cooperation between the states and the Food and Drug Administration and emphasizes the need for qualified investigators at the state and local level. Some of the recommendations set forth in this report concerning the area of enforcement could, in the opinion of the National Association of Boards of Pharmacy, move closer to reality through the mechanisms provided by passage of H.R. 13884.

The National Association of Boards of Pharmacy has always encouraged further cooperation between the Food and Drug Administration and state authorities. The problem lies not in the fact that there is a refusal to cooperate between these bodies, but in the fact that there could be greater cooperation and understanding of mutual problems and the delineation of duties in the enforcement of both state and federal law.

This failure to cooperate is in many instances the result of a lack of knowledge on the part of state and local investigators concerning both the federal and state regulations. The failure of the State Boards of Pharmacy and other state officials to provide for the continuing education of inspectors has not resulted by reason of their ignorance of the problems, nor their lack of desire to meet and solve it. Studies made by our Association reveal that the annual budget of most State Boards of Pharmacy is not sufficient enough to permit the estab-

lishment of extensive training programs, even though most make an effort to provide some type of training. Many Boards are required to meet their own expenses only through fees obtained in licensing procedures. As a rule, this leaves little or no funds available for training of personnel.

Many Boards employ pharmacists as inspectors. These inspectors, on the whole, have little education or experience in the law or enforcement of drug legislation. While there is definitely an advantage of having pharmacists as inspection personnel, their education in the laws of drug legislation should be enhanced. It is incumbent upon them in many instances to "train on the job" which often leaves much to be desired.

H.R. 13884 permits the Commissioner of FDA to assist states with the training of personnel in the drug field through the establishment of educational programs in appropriate existing institutions, thereby making possible a federal state cooperative system for the overall enforcement of drug regulation. It will also permit state authorities to assist the FDA in enforcing the Food, Drug and Cosmetic Act. These educational training facilities could be staffed by both state and federal officials, thus providing the expanded and intensified training activity necessary for inspection personnel. The information disseminated at such training programs would permit the establishment of improved administrative practices at the state level even though the program may be designed to primarily emphasize the enforcement of the Federal Act. Basic law enforcement procedures are inherent in the enforcement of both state and federal acts.

Adequate training, coupled with a coordinated system of enforcement between state and federal officials can result in greater protection of the public health. Hopefully, such a coordinated training effort could bring about a greater uniformity of enforcement of drug statutes and regulations throughout the United States, and result in a more efficient and economically controlled system of drug administration.

We, of course, recognize that this amendment is broadly written in that it provides the Secretary of H.E.W. with the authority to administer its provisions. Since our Association has been consulted in the past on matters affecting Federal-State Relations in the area of drug law enforcement, and since one of the definite purposes of this amendment is for greater cooperation between states and the FDA, we feel confident that this same liaison will continue to exist.

The NABP understands that there are areas of enforcement which must be retained in the hands of the various states. It realizes, however, that effective drug enforcement can come about only through coordinated effort of state and federal government. Such coordinated efforts require the training and financial aid which can be provided through HR 13884.

HR 13884 has been carefully reviewed by the Executive Committee, Committee on Legislation and the Bureau of Law Enforcement of the National Association of Boards of Pharmacy and it is their opinion that this legislation, if passed and properly implemented, can result in improved and more effective enforcement of regulations at all levels. It is the recommendation of the National Association of Boards of Pharmacy that HR 13884 be favorably considered by the Congress of the United States.

We would welcome any questions that the Committee might have concerning this statement.

STATEMENT OF DR. IRVING SUNSHINE, TECHNICAL DIRECTOR, ACADEMY OF MEDICINE OF CLEVELAND POISON INFORMATION CENTER

My name is Irving Sunshine and I reside in Cleveland, Ohio. I am presently Assistant Professor of Toxicology at Western Reserve University School of Medicine and Technical Director of the Academy of Medicine of Cleveland Poison Information Center.

Since receiving my Ph. D. degree in 1950 I have been actively engaged in all phases of Toxicology. In the last nine years I have not only directed the local Poison Information Center program but have been Chairman of the Education Committee of the American Association of Poison Control Centers and am President-Elect of that organization and of the National Council for Poison Prevention Week.

Most of us who are concerned with the safety of children will endorse the general principles of the Child Safety Act (H.R. 13886). Its specific amendments to the Federal Food, Drug and Cosmetic Act are worthy of some discussion since

chemical agents *do* make many children ill and in some instances cause their death.

The first amendment purports to protect children and minimize the harm that can come to them from the ingestion of baby aspirin. It is true that most children ingest baby aspirin but the number of deaths due to baby aspirin is *not* known. The best available data are those from the Bureau of Vital Statistics and those from the National Clearinghouse for Poison Control Centers. The former merely lists deaths due to "aspirin and salicylates" and gives no indication of the number of fatalities due to baby aspirin. I have tried to get detailed information on fatalities due to salicylates but most of the other medico-legal agencies to which I wrote also were unable to indicate which type of salicylate was involved in the deaths they investigated. From their available data no conclusion can be made as to how many deaths were due to baby aspirin. It would be most desirable to have detailed information on deaths due to "aspirin and salicylates" (as well as all other poisonings) so that the proposed protective measures include all the offending agents. Accidental ingestion of foreign substances is potentially harmful—a poisoning—but this is not always so for many different reasons. Too frequently those who quote the National Clearinghouse data equate accidental ingestion with poisoning. Table 5 of the 1965 National Clearinghouse report illustrates this point that not all ingestions have harmful effects, i.e. are poisonings. It gives the data on the days of hospitalization required for therapy following an accidental ingestion. About half of the cases reported to the Clearinghouse were treated and of these, 10%, 2,828, required one or more days of hospitalization. This last group represents those that were poisoned; the others were exposed to a hazard, but were not poisoned for one reason or another. Our local experience showed that approximately 90% of those who ingested salicylates had no symptoms and no ill effects.

Limiting the number of aspirin for children in a given package does not preclude the purchase of more than one package at a given time. Thus despite the Act, a significant number of tablets could still be available to youngsters. To stop a parent from purchasing more than one package at a time would require that aspirin be reclassified as a drug that could be purchased only by a doctor's prescription. This is not practical nor would most physicians encourage this practice. Neither will this limitation overcome the problem of therapeutic overdosage by the parent. This is also a factor in deaths due to salicylates but its extent cannot readily be determined from the available data.

As in the past, the decision on the number of tablets in a container ought to be made after consultation with representatives of interested parties—FDA, physicians, poison prevention centers and industry. This practice was very successful in 1955. The result of that consultation led to a voluntary limitation on the size and number of tablets in a container which had a safety closure and bore a warning label. The major manufacturers have adhered to that agreement since that time.

The second amendment concerns safety closures. These theoretically can deter a curious child from gaining ready access to a harmful substance. At this time existing closures are not optimal. It is difficult to find a practical and perfectly safe closure for all toxic substances, in their varied forms. The proposed Bill does not indicate who has the responsibility for developing this desired safety closure nor does it indicate how or who will determine its effectiveness. It would seem that a joint government-industry study designed to *develop* effective closures would be in order.

As to the labeling provisions, lay people are not equipped to treat victims of poisonings. A physician is required and the victim should be brought to medical attention promptly. Seldom will a 15 minute delay in therapy be catastrophic and medical advice is available to almost everyone within that time period. Thus, all that is essential and all that should be required on a label is a general warning statement and the advice to consult a physician. A common misconception is that an antidote would be life saving and therefore reference to it should be placed on the label. The number of true antidotes is very small and they should be used *only* by a physician or under his direction. The time wasted by the average person looking for the materials in so-called "antidotes" is greater than that required to get medical advice and is less valuable to the patient.

Since children also ingest adult medications, it would be desirable to properly label *all* drugs dispensed to the public.

[Telegram]

WASHINGTON, D.C., *September 16, 1966.*

Hon. JOHN JARMAN,
House Committee on Interstate and Foreign Commerce,
House Office Building,
Washington, D.C.:

Except for a conflicting appointment, I would present this message in person as a witness at your hearing on the Child Protection Act of 1966 to be held on September 19. As executive secretary of the Institute of Appliance Manufacturers, which for 35 years has represented many appliance producers before congressional committees and government agencies, we offer our cooperation with the objectives of title II of the Child Protection Act to assure continuing safety in American homes. We urgently request your cooperation in changing the name of the commission to be appointed in this respect to the National Commission on Household Product Safety. This action would be in line with that taken in the National Automotive Safety Act. Thank you for your favorable consideration.

PAULINE B. DUNCKEL,
Executive Secretary,
Institute of Appliance Manufacturers.

[Telegram]

NEW YORK, N.Y., *September 27, 1966.*

Hon. JOHN JARMAN,
Rayburn House Office Building,
Washington, D.C.:

Your committee's questioning during child safety bill hearings encourages our belief that you are aware of this bill's controversial and objectionable nature. Bottle contents of children's flavored aspirin can be limited with possible benefit; but imposing through this bill all-encompassing drug labeling authority is unnecessary, impractical, and, frankly, unsound. What may appear to be a simple provision for warning wording would, in effect, supersede all present drug labeling requirements evolved through years of legislaton and voluntary effort.

JOHN W. CULLIGAN,
President, Whitehall Laboratories.

AMERICAN MEDICAL ASSOCIATION,
Chicago, Ill., September 23, 1966.

Hon. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN JARMAN: I am writing to you to express the views of the American Medical Association on H.R. 13886 which relates to the packaging of children's aspirin.

As I am sure that you recognize, the American Medical Association as an organization, and the practicing physician as an individual, are vitally concerned with the preservation of life and health, and with the alleviation of pain, disease and debilitation in persons of all ages. While accidental poisoning is a tragic occurrence among adults, it is doubly tragic when it strikes infants or small children.

When Commisisoner of Food and Drugs, James L. Goddard, M.D., presented his statement on H.R. 13886 before the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, he stated that in 1965, 16,328 children under the age of 5 were reported poisoned from the accidental ingestion of aspirin and other salicylates, and that some of these children died. While there has not, to our knowledge, been a single reported death from the ingestion of children's aspirin, we are still in complete agreement that these accidental poisonings are a serious problem.

However, we believe that in spite of the desirable goals of this legislation, it is unrealistic to hope that the mere act of limiting the number of children's aspirin

in a bottle, or the requiring of some undefined safety closure, will effectively reduce the number of children poisoned each year.

The primary cause of the accidental poisoning of children must be traced to parental ignorance, carelessness or indifference. It is an unfortunate fact of life that such ignorance or negligence does not lend itself to convenient remedy through the legislative processes of the Congress. This is a responsibility which parents themselves must accept. It is a task which cannot be assumed solely by either the Congress, the community, or the medical profession.

Perhaps the only realistic approach to the problem is a positive all-out joint cooperative campaign by the Public Health Service, the medical profession, industry, community and educational leaders, so that parents and others may be aware that all substances in the home which might be hazardous must be made inaccessible to children. In this way, we can make real and significant progress in reducing the incidence of accidental poisoning among children and individuals of all ages.

Thank you for permitting us to submit our views on this legislation.

Sincerely,

F. J. L. BLASINGAME, M.D.,
Executive Vice President.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., September 23, 1966.

Hon. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare,
House Committee on Interstate and Foreign Commerce, Washington, D.C.

DEAR MR. CHAIRMAN: Representatives of the Pharmaceutical Manufacturers Association appeared before the Health Subcommittee of the House Interstate and Foreign Commerce Committee on August 15 to present the Association's views on Title I of H.R. 13886, 89th Congress. A supplemental statement was filed on September 16.

We have reviewed the transcript of the testimony delivered by the Commissioner of Food and Drugs before the Committee on September 19 as well as the statements and exhibits submitted by other parties. As a result of this review, we are even more firmly convinced that the Food and Drug Administration should not be granted authority to set standards for safety closures and to require use of such closures on all drug containers.

The Commissioner of Food and Drugs admitted in his statement that a satisfactory closure has not yet been developed. An arbitrary choice of a closure of unproven effectiveness by the agency would discourage the many research projects currently in progress and would result in an unjustified increase in the price of drugs.

We are also completely opposed to the granting to the Food and Drug Administration of any additional cautionary labeling authority. Our supplemental statement of September 16 sets forth the broad authority already enjoyed by FDA in this area. The Commissioner's statement reflects the failure of the agency to appreciate the significant differences between drug reactions and untoward effects of hazardous household substances and the impossibility of devising proper drug warning and first-aid information appropriate to the laity. Indeed, the Food and Drug Administration has historically taken the position that one of the major reasons why a drug may be required to be dispensed only upon prescription is that adequate directions for lay use (let alone misuse) cannot be written.

The Commissioner, in his statement of September 19, inadvertently pointed out that new labeling authority regarding effectiveness, contraindications, and warning information is not needed. He cited two examples (Phenacetin, Dipyrone) where drugs long considered safe required new warnings and stated that, under existing authority, policy statements were issued. No indication was given that the affected companies did not comply. Indeed, a company would have been faced with court action if it did not obey the mandate. More importantly, Dr. Goddard admitted the real goal sought by the added authority when he stated, "Moreover, most drugs that will require labeling changes of the type called for in Section 502(f), will also require new drug clearance for the new labeling. The Court of Appeals for the Tenth Circuit has held that labeling changes take the product out of its grandfather clause protection and subject it to reclearance from the standpoint of safety and effectiveness under its new labeling."

As pointed out in our supplemental memorandum of September 16, FDA is seeking to impose clearance authority on products which Congress specifically excluded from such requirements in the Kefauver-Harris Drug Amendments of 1962 without showing any need for such drastic action, and without affording affected parties an opportunity for a hearing.

We strenuously oppose the enactment of legislation granting the Food and Drug Administration additional authority over labeling and therefore request that Section 4(b) of H.R. 13886 be deleted.

Sincerely yours,

C. JOSEPH STETLER, *President.*

THE AMERICAN PUBLIC HEALTH ASSOCIATION, INC.,
Washington, D.C., July 1, 1966.

HON. JOHN JARMAN,
Chairman, Health and Welfare Subcommittee, House Committee on Interstate and Foreign Commerce, Rayburn Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: I am pleased to forward to you this expression of our Association's support of H.R. 13886, the Child Safety Act of 1966, introduced by Congressman Harley Staggers. The American Public Health Association, by the official action of its Governing Council in 1952, pointed out the serious proportions of the problem of accidents occurring in the home and urged specific action to curb them. Five years later we urged all States and Territories to adopt uniform laws on labelling hazardous chemicals. It is our belief that enactment of H.R. 13886 is the next logical step to afford a safer home environment for the children of this nation.

Quite admittedly no amount of precautionary effort can eliminate accidental deaths and injuries. None the less it would be little short of criminal not to make every reasonable effort to reduce to the minimum all possibility of danger. Safety campaigns including exhortations to keep dangerous materials out of the reach of children simply will not insure 100% cooperation. This doesn't mean we should cease or even diminish educational programs—the APHA certainly intends to continue its efforts. Nor does it mean that enactment of H.R. 13886 will produce a panacea. But it will be helpful. Limited numbers of flavored children's aspirin in a container, for example, will reduce possibility of tragedy.

Our efforts should be directed toward reducing the possibilities for accident. *It is the opinion of the APHA that enactment of H.R. 13886 will make a positive contribution to this end. We therefore request favorable action by your committee.*

Sincerely yours,

BERWYN F. MATTISON, M.D.,
Executive Director.

THE ASSOCIATION OF FOOD AND DRUG OFFICIALS OF THE UNITED STATES,
Topeka, Kans., June 29, 1966.

HON. HARLEY O. STAGGERS,
Chairman of the House Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

MR. CHAIRMAN: I have been instructed by the Executive Board of the Association of Food and Drug Officials of the United States to file with you a statement of the Association's support of H.R. 13884.

The Association of Food and Drug Officials of the United States has been in existence continuously since 1896. Its 70th Annual Conference was held last week in Kansas City. The Association's membership is composed of the officials—state, local and federal—charged with the enforcement of food and drug laws. Its current membership represents 47 of the states. Its purpose is to inform the public concerning the consumer protections of the laws, to advance scientific and administrative methods to improve food and drug law enforcement, and to foster cooperation and uniformity in the enforcement of the laws.

The Association had for many years advocated a nationwide study of state and local food and drug programs to complement the two studies of the Federal Food and Drug Administration by the two citizens' committees. Such a study was done, under a contract with FDA, by the Public Administration Service and reported in February, 1965. A committee, composed mostly of state food and drug officers, was appointed to consult with the Public Administration Service. The Commit-

tee on the Study of Food and Drug Programs met frequently with the staff of the Public Administration Service during the course of the study and preparation of the report. Section 2 of H.R. 13884 contains several provisions which would serve to implement recommendations of the Public Administration Service's report. The Association's committee and its executive board were in unanimous approval of the recommendations and support the adoption of the legislation to implement them.

Section 2 of H.R. 13884 would amend Section 702 of the Federal Food, Drug and Cosmetic Act by adding a subsection (f). This subsection would authorize the Secretary of Health, Education and Welfare to turn some of the enforcement of the federal act to state or local authorities. There are areas of enforcement of the federal act in which state or local personnel have as great or greater competence than federal personnel:

Frequently the state or local personnel are closer to the problems and people involved and can work more efficiently and effectively than federal officers.

Additionally, state laws often contain authority to proceed in the correction of violative conditions much more directly than is possible under the federal law. For example, state embargoes may stop the sale of violative articles immediately. Insanitary establishments may be closed summarily or by court orders which can be obtained in state courts within a few hours.

By the utilization of qualified state or local officers, having at their disposal the provisions of both federal and state laws, more efficient and more expeditious corrections of unsatisfactory conditions could be obtained.

By the farming out, so to speak, of some of the enforcement and administrative duties to state or local personnel, in areas where these have equal or greater ability to produce the desired results, the Federal Food and Drug Administration could obtain needed services at lower cost.

The portion of Section 2 which would become 702(f)(2) would simply give furtherance to the assistance and advisory services the Food and Drug Administration has offered the states in the past. It would permit the stationing of scientific or technical personnel in state or local agencies to guide new program development and enforcement procedures. It would aid in the more uniform interpretation and enforcement of corresponding provisions of the federal and state laws.

The portion of Section 2 of H.R. 13884 which would become 702(f)(3) is aimed at stepping up the training program which is presently being offered the states by the Food and Drug Administration. A greatly accelerated program in this area is vital. Better training of all food and drug law enforcement workers is an absolute essential to the progressively greater needs in this field. Most states do not have adequate facilities for proper training and generally they are underfinanced to a degree that they cannot pay travel and subsistence during periods of training. This subsection, if enacted into law, could serve to give the state and local authorities much greater ability to produce and thus reduce some of the demands now placed on the Food and Drug Administration.

Section 3 of H.R. 13884 would allow the Food and Drug Administration to obtain analytical work of a special nature, have special investigations and studies made, and pay for the obtaining of special information in many cases where it is more economical to go outside the agency than to tool up to do it internally. While Section 3 is of less direct interest to state and local officials than Section 2, it must be recognized that knowledge developed through any means by the Food and Drug Administration becomes common knowledge in the whole field where it may be equally applicable to state laws as to the federal law.

We regret that we had insufficient notice of the hearing on H.R. 13884 which began on June 24 to have a representative of the Association present. If your committee feels that any purpose would be served by our representation at any future time, we will make the necessary arrangements for an appearance.

We respectfully request that this statement be included in the records of your hearing.

EVAN WRIGHT, *Secretary-Treasurer.*

INDIANA STATE BOARD OF HEALTH,
Indianapolis, Ind., August 19, 1966.

Hon. LEE H. HAMILTON,
House of Representatives,
Washington, D.C.

DEAR MR. HAMILTON: We are writing to you in regard to H.R. 13886 introduced by Representative Staggers. This bill is to be known as the "Child Safety Act of 1966" and has considerable merit for its passage.

However, on June 24th the Chemical Specialties Manufacturing Association, Inc., presented an amendment which reads as follows:

"Sec. 203. It is hereby expressly declared that it is the intent of the Congress to supersede any and all laws of the States, and political subdivisions thereof, insofar as they may now, or may hereafter provide for the labeling of a container of any hazardous substance covered by this Act which differs from the requirements of this Act or the Regulations promulgated pursuant thereto. Any new, regulation, or ordinance purporting to establish such a labeling requirement shall be null and void."

Indiana pioneered in this field of labeling hazardous household products and you will note by a copy of our enclosed act, that Indiana's law preceded the Federal Hazardous Substances Labeling Act by two years.

In addition, the Indiana law requires the manufacturer, seller or distributor to file formulation data on each product. In this way Indiana is able to evaluate the hazards of a product with the manufacturer and also to serve as a poison information center for Indiana hospitals and physicians. The federal law and all other state laws require only labeling of a hazardous product.

Those manufacturers and their organizations that support the proposed amendment claim that one state or one city may require special warning statements on a label that, in effect, require the firm to label for the entire country. This may be true on occasion, but such rulings are not made without merit and may be based on formulation data which are furnished as required by the Indiana law. Often these rulings are later adopted by the various federal agencies.

Passage of this amendment would nullify much of the protection now available to Indiana citizens under the Indiana Hazardous Household Product Act. The evaluation of product formulations allows us to discuss potential hazards of certain chemicals or combinations of chemicals with the manufacturer and to come to an agreement as to proper labeling of his product. Since the federal law and all other state laws do not require the submission of formulation of potentially hazardous products, those regulatory agencies do not have this advantage unless the manufacturer volunteers the information. Therefore, in many cases, the labeling of a substance represents the appraisal of hazard by the manufacturer alone and the formulation has not been evaluated by any official agency.

Under the provisions of the amendment, we could still require manufacturers to submit formulations but if our evaluation would indicate labeling at variance with labeling accepted by federal authorities who had not had the benefit of the examination of the formula, we would be forced to accept labeling which was, in our opinion, contrary to the provisions of Indiana law. For this reason, we feel that it is important the proposed amendment be deleted from the bill.

It is respectfully requested that you review this important matter and take what action you deem proper for the best good of the people in Indiana. We would favor the passage of H.R. 13886 but not the amendment.

Sincerely,

A. C. OFFUTT, M.D.,
State Health Commissioner.

COMMERCE AND INDUSTRY ASSOCIATION OF NEW YORK, INC.,
New York, N.Y., July 22, 1966.

Re H.R. 13886.

HON. JOHN JARMAN,
Chairman, Public Health and Welfare Subcommittee,
House Committee on Interstate and Foreign Commerce,
House Office Building,
Washington, D.C.

DEAR SIR: This association, representing some 3,500 business firms located primarily in the metropolitan New York area, is deeply disturbed by two aspects of subject legislation.

Both aspects are related to what we conceive to be an unreasonable overextension of government regulation of legitimate business enterprise and a concept of regulations which heads in an undesirable precedent-setting direction.

While it is reasonable to require that printed matter describing the total contents of a package not be deceptive, it is a totally different thing for the government to specify the quantity of materials that may be contained in such a package. If carried to a logical conclusion, the provisions of this legislation would require repackaging not only all home remedy products but also a wide variety of food products which also are available to children in a housesold. It takes no great imagination to foresee a limitation on the number of prunes in a package, based on the excuse that a child, finding them tasty, might take a larger than healthy quantity with devastating results.

However, if in its wisdom the Public Health and Welfare Subcommittee deems it vital that the number of children's aspirin contained in a retail package be limited in some way, then we most urgently suggest that such quantity be specified in the law itself and not be left to administrative discretion which too often is dependent upon the personal viewpoint of a given administrator. This deficiency in the administrative process all too frequently in the past has led to sudden changes in regulatory requirements, resulting in unnecessary problems and great expense to the legitimate manufacturer in complying with changing directives.

Even more basic is the proposed suggested change with respect to labeling. Heretofore government has established standards and provided numerous sanctions which may be imposed on anyone who fails to meet his responsibility in living up to those standards. It is now proposed that, in place of standards, government will determine the manner and form of any statement carrying out those standards in labeling any drug product, including home remedies. Failure to conform in every respect to these agency regulations, even though the labeling may be clear beyond a doubt to any who read it, subjects the seller to all the penalties imposed in connection with misbranded merchandise.

We strongly urge amendment of this legislation to remove the objections above indicated and, further, that these views be incorporated in the record of the hearings you are conducting with respect to H.R. 13886 and similar measures.

Sincerely,

ARNOLD WITTE,
General Manager.

COLLEGE OF PHYSICIANS AND SURGEONS OF COLUMBIA UNIVERSITY,
INSTITUTE OF CANCER RESEARCH,
New York, N.Y., September 20, 1966.

HON. JOHN JARMAN,
Chairman, Subcommittee of Public Health and Welfare,
House Institute Foreign Commerce Committee,
Rayburn House Office Building,
Washington, D.C.

DEAR CONGRESSMAN JARMAN: Recently I had the occasion to read a copy of the bill H.R. 13886, the so-called "Child Safety Act of 1966" introduced by Mr. Staggers. Although I, as a physician, fully support precautions which prevent the abuse and misuse of drugs, one provision of the bill struck me as wholly impractical, if not outright hazardous. This section 502(f) deals with the instructions for first-aid treatment. After all, accidental ingestion of excessive amounts of a drug requires gastric lavage and often also the injection of antidotes. These procedures can only be done by properly trained personnel, preferably in the emergency room of a hospital. Valuable time may be lost by instructing the con-

sumer how to treat rather than how to obtain help. I would rather see the label be worded: "In case of overdose or accidental ingestion by children contact your physician, your pharmacist, or your local police force."

Furthermore, drugs which are issued on prescriptions are usually not sold in the original (manufacturer's) container. Since different drugs may require different antidotes an additional administrative burden is placed on the pharmacist and another potential source of errors is introduced in that the wrong directions may be placed on the container.

Sincerely,

HENRY O. HEINEMANN, M.D.,
Assistant Professor of Medicine.

UNIVERSITY OF UTAH MEDICAL CENTER,
DEPARTMENT OF PEDIATRICS,
Salt Lake City, Utah, August 9, 1966.

Re H.R. 13886.

Mr. W. E. WILLIAMSON,
Clerk, House Committee on Interstate and Foreign Commerce, Rayburn House Office Building, Washington, D.C.

DEAR MR. WILLIAMSON: I should have welcomed the opportunity to present testimony regarding the bill specified above before the Subcommittee on Public Health and Welfare, but my awareness of the impending hearings came too late to allow this. Consequently, I am submitting the following comments and recommendations in hope that they will be considered in the deliberations of the Subcommittee.

In addition to the academic appointment specified below, I am Director of the Poison Control Center of this institution, a member of the Household and Economic Chemicals Panel of the American Medical Association Registry on Adverse Reactions and a consultant to the National Clearinghouse for Poison Control Centers of the Public Health Service. I have researched and written extensively on problems of poisoning in general and aspirin poisoning in particular.

Of great concern to me is the implication that children's (1¼-grain) aspirin tablets are the only or the most significant childhood poisoning threat. As a result, efforts have been directed toward such preparations, but not toward the adult (5 grain) aspirin tablets. Such as approach indicates a lack of cognizance of the true facts. While flavored children's preparations of aspirin are involved most frequently in accidental encounters invloving children, it is the adult preparation which causes the majority of serious cases of poisoning and of childhood poisoning death. Apparently, the fact that the children's preparation contains one-fourth as much aspirin as the adult preparation, plus the fact that the number of pills available per bottle is fewer, more than overcomes the problems of greater availability in homes having young children and the enticement brought about by the addition of flavoring. Dr. James Goddard's inferences to the contrary are in error, as would clearly be indicated by perusal of the records of Poison Control Centers or of those mortality statistics for which information as to the type of aspirin invloved is provided.

The foregoing is not meant to de-emphasize the importance of children's aspirin as a cause of childhood poisoning but rather to suggest that any attention directed toward them should be directed also toward the adult preparations. Any efforts which increase the cost of children's aspirin preparations is likely to aggravate the problem of severe aspirin poisoning by leading to more extensive use of adult preparations. Suggestions that the number of pills of children's aspirin allowable per bottle be limited (as requested also in the McGovern Aspirin Amendment to a Senate bill) has merit only if this danger is removed. Unfortunately, it would not be practical to similarly limit the number of pills available in a single package of adult aspirin, for the reason that packages would have to contain less than 5 or 6 tablets in order to be below the potentially toxic dose for a small child. Safety closures have rather limited value, not only because none has proven to be "child-proof", but also because approximately half of the cases of accidental aspirin poisoning involve bottles from which the tops had previously been removed by the parents. What utility there may be in safety closures should, in any event, apply to the adult preparations as well. A major disadvantage of legislative requirements for a safety closure is that

specifications as to acceptability must be developed, and this is likely to stifle progress and incentive in regard to improvements of design of safety closures. A far more effective approach, in my opinion, would be to require "unit" packaging of not only aspirin, but perhaps many other common offenders as well. This invloves the sealing of individual pills in foil or cellophane packets which must be individually opened in order to obtain the pill. The prevention of childhood poisoning comes about by virtue of the fact that the child is delayed in his efforts to obtain the pills, usually far beyond the duration of his attention span, so that the likelihood that a toxic dose would be ingested is very small.

Whatever approach is selected, I put forth the plea that potentially equally effective steps be taken in regard to adult aspirin. I personally do not believe that the best answer at this point is necessarily in the form of legislation of any type. If the pharmaceutical industry knew that the alternative was legislation of one of the aforementioned types if they do not succeed in solving the problem themselves, it seems to me that they would voluntarily make greater efforts to market safe products than could ever reasonably be required by legislation. Whatever steps are taken, let us not "throw out the baby with the bath water" by creating more problems than we prevent or by enacting legislation which stifles the initiative to continue to improve the safety of products which are made available to the American home.

Another point of concern in the proposed legislation has to do with the requirement for inclusion of poisoning treatment instructions on the label. Medically speaking, such labeling is not only doomed to failure insofar as efficacy is concerned, but is contrary to good medical practice. One cannot safely generalize about the treatment of any condition, much less acute poisoning. Furthermore, there are very few truly effective treatments for acute poisoning (contrary to popular belief), so that the best treatment depends upon the circumstances. Many factors must be taken into account in arriving at a satisfactory decision regarding treatment, including age and condition of the patient, the quantity of the material ingested, the length of time since ingestion, the presence or absence of other toxins or medical conditions, etc. The only advice for the tretment of poisoning which would be reasonable to include in labeling would be the instruction to call a physician or Poison Center. Anything else is likely not only to be ineffective, but also to create a false sense of security which might lead to delay in institution of more effective treatment. In the case of aspirin poisoning, for example, there is no effective treatment which could be administered in the home. The only procedure which would have any likelihood whatever of improving the situation would be to prevent absorption by inducing vomiting. However, this may be ineffective if too much time has elapsed since ingestion, or it may be exactly the wrong thing to do if the patient happens to be obtunded or in impending convulsions. Furthermore, the likelihood that vomiting can be induced in the home is extremely small, and attempts to do so may simply result in a delay of definitive medical care. This particular provision of the proposed legislation is extremely ill-advised.

I hope that the above comments will be considered by your Subcommittee in their deliberations regarding the subject bill. I regret not having the opportunity to elaborate further upon these and other points with respect to the proposed legislation, but trust that reason and careful consideration of all facets will prevail.

Respectfully submitted.

ALAN K. DONE, M.D.,
Associate Professor of Pediatrics.

UNIVERSITY OF UTAH MEDICAL CENTER,
DEPARTMENT OF PEDIATRICS,
Salt Lake City, Utah, September 8, 1966.

Re H.R. 13886.

Mr. W. E. WILLIAMSON,
Clerk, House Committee on Interstate and Foreign Commerce,
Rayburn House Office Building,
Washington, D.C.

DEAR MR. WILLIAMSON: This is an addendum to my letter of August 9 concerning the deliberations of the Subcommittee on Public Health and Welfare in regard to H.R. 13886.

It has come to my attention that there is some uncertainty with regard to the numbers of children's (1¼ grain) aspirin tablets which could safely be allowed

per package if legislation is adopted which limits the packaging of such tablets. There is a considerable backlog of information upon which we can base such an estimate, both from extensive past experiences with the intentional induction of mild aspirin poisoning in the treatment of rheumatic fever patients and from experiences with accidental and suicidal poisoning and experimental studies of the effects of aspirin. It is reasonably safe to say that fatality is unlikely with a single dose of less than about one grain per pound of body weight. The lethal dose is probably considerably more, but this dose would be expected to be tolerated, albeit with symptoms of non-fatal poisoning, by people who do not have predisposing problems. In relation to the average two-year-old child (the age at which accidental poisoning is most common) this would be about 22 1¼-grain tablets. Considering that the aforementioned figure incorporates some margin of safety, it is probably safe to say that 25 such tablets would be reasonable.

It should be understood that no limitation will remove all possibility of a fatal reaction. Hypersensitivity reactions may occur with a single tablet, and the amount which would be tolerable may be reduced significantly in the presence of dehydration and other illness. Moreover, such restrictions will not prevent the not uncommon occurrence of an older child's feeding dangerous quantities of aspirin to a baby. Restricting the number of tablets available cannot reasonably be expected to circumvent any of these problems. Thus, I would suggest the choice of a 25-tablet restriction as a reasonable compromise. A lower number would obviously provide greater assurance of absolute safety, but would probably reach the point of diminishing returns where one might expect to discourage the manufacture or purchase of these low-dosage preparations of aspirin and, thereby, to encourage dissemination of the more dangerous adult preparations.

The foregoing should not be construed as favoring the type of legislation described. I continue to have the reservations stated earlier, but wished to offer what help I could in making such measures reasonable if they are adopted.

Respectfully submitted.

ALAN K. DONE, M.D.,
Associate Professor of Pediatrics,
Director of Poison Information and Therapy Center.

MANUFACTURING CHEMISTS' ASSOCIATION, INC.,
Washington, D.C., August 18, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is being sent to you on behalf of the Manufacturing Chemists Association, a non-profit trade association including 189 U.S. companies, large and small, which together account for more than 90 percent of the country's productive capacity for chemicals.

The Association has reviewed H.R. 13886, the "Child Safety Act of 1966", introduced by you. We endorse the objectives of this bill, but recommend a modification of clause (B) of the definition of the term "banned hazardous substance", contained in Section 202(a), with respect to a substance intended or offered for household use, or so packaged as to be suitable for such use.

As the clause now reads, the Secretary might find, for example, in the case of careless or intentional misuse of a product resulting in an injury, that the mere occurrence of the injury would justify classifying a product as a "banned hazardous substance" because the "cautionary labeling" did not prevent the injury. We do not believe this result is intended. The instructions on the container obviously must be heeded, because the labeling by itself cannot prevent an injury. We stongly recommend, therefore, insertion of the words "if complied with" following "would not" in line 19, page 10 of the bill.

In addition, we urge the inclusion in the bill of a new section which would provide uniformity in labeling requirements through Federal preemption of this legislative area. Such a provision would eliminate the inconsistencies in label requirements among the States. In some cases, it is practically impossible to write a label which would meet the requirements of all of the States. With regard to such a preemption provision, it is suggested that it be modeled after the language of section 12 of S. 985, the "Fair Packaging and Labeling Act", now before your committee.

We appreciate this opportunity to express our views for your consideration, and request that they be made a part of the printed record of the Committee's hearings.

Sincerely,

G. H. DECKER, *President.*

INSTITUTE OF MAKERS OF EXPLOSIVES,
New York, N.Y., August 31, 1966.

Hon. JOHN JARMAN,
Chairman, House Commerce Subcommittee on Public Health and Welfare, Rayburn House Office Building, Washington, D.C.

DEAR REPRESENTATIVE JARMAN: Our attention has been directed to a statement of Melvin Block, an attorney in Brooklyn, New York, which was filed with your subcommittee on August 29 in the course of hearings on the Child Safety Act (H.R. 13886). For your information, the Institute of Makers of Explosives, an industry trade association now representing thirteen companies, has been in existence over 50 years. One of IME's most important continuing activities has been the education of the juvenile public so that children will recognize blasting caps and realize they are not something to be played with. The Institute also engages in an additional campaign with users of blasting caps, urging them to keep blasting caps under strictest security and surveillance to assure that they do not get into the hands of inexperienced people.

Each Institute member follows up on these campaigns. Despite Mr. Block's statements, the record shows that our safety education efforts have been successful. For example, in 1958, 139 children under age 17 suffered injuries from uninformed play with blasting caps; in every year since there has been a substantial reduction in such accidents. In 1965, the number of recorded blasting cap mishaps involving such children was down to 56. Through the first six months of 1966, the total reported is 8.

The Institute's education program annually reaches every elementary and secondary public, private, and parochial school in the nation. An average of more than 7500 schools have responded annually during the past five years to our direct mail contact requesting supplies of our blasting cap safety posters for classroom display and discussion.

We estimate that 72,000,000 students in nearly 120,000 schools are reached in this manner. In addition, the Boy Scouts of America annually cooperate in our distribution of similar material. This particular effort places blasting cap safety information in the hands of youth in that particular age bracket which tends to experience a somewhat higher degree of "exposure" to lost, strayed, or stolen blasting caps which youngsters might come across in their play near those locations where blasting work may be in progress.

You are probably familiar with our series of one minute public service television film spots in which such widely recognied and highly respected personalities as Mickey Mantle, Chuck Connors with Flipper the Dolphin, Major "Gus" Grissom, or Willie Mays inform TV viewers what blasting caps look like, how they're intended to be used, and of the hazards they present when handled by inexperienced, uninstructed persons. IME regularly furnishes prints of these public service films to nearly every licensed television station in the country. Our records indicate frequent use by the majority of the stations of these Don't Touch Blasting Caps! warnings.

A 26 minute film, Blasting Cap—Danger!, produced especially for juvenile audiences, has been circulated for over twenty years. Nearly 250 prints of its current version are distributed by 42 State Health Departments, 9 regional offices of the U.S. Dept. of Health, Education and Welfare, 12 Bureau of Mines offices, and 28 Army Ordnance Units (among a total of 155 outlets) for school and youth group showings.

IME has the wholehearted cooperation of the U.S. Army Ordnance through the Explosives Disposal Teams working in every Army Area. These teams are in frequent contact with local law enforcement agencies and through such contacts gain supplemental public distribution for our blasting cap safety education materials.

Mr. Block, in his statement, criticized the adequacy of the warning on the cap itself. Most blasting caps are less than 2¼ inches long, and approximtaely ¼ inch in diameter. For safety reasons caps are made from non-sparking copper or aluminum. A ferrous metal also would present serious problems of rust under

conditions of storage or exposure to weather in field use. Each blasting cap is marked: "Explosive—Blasting Cap—Dangerous."

Because of the cap's size, additional wording would, we believe, reduce the effectiveness of the above warning. All of the wording suggested in Mr. Block's statement is copied from this Institute's educational posters which have been widely circulated throughout the nation for over two decades. The containers in which caps are packed for shipment are labeled in accordance with regulations issued by the Interstate Commerce Commission.

We also wish to point out that no blasting cap explodes by itself. To explore, a blasting cap must be subjected to the relatively high heat of flame or severe friction, to a shock of considerable magnitude such as a hammers' blow, or to electric current.

The Insttitue of Makers of Explosives and its members have always had the greatest concern and active interest in the prevention of accidents arising from the use of their products. We sincerely believe our efforts have been effective, although there may still be unfortunate mishaps stemming from a child's uniformed play with these products. IME is continuing and will continue its efforts to reduce the number of blasting cap accidents to zero.

If we can furnish additional information, please call on us. We would welcome the opportunity to outline in greater detail the blasting cap safety education program conducted by this Institute.

Sincerely,

HARRY HAMPTON, *Secretary.*

NEW JERSEY FIREWORKS MANUFACTURING CO., INC.,
Elkton, Md., August 11, 1966.

Hon. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare,
Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is with reference H.R. 13886, which deals with articles considered to be hazardous, and which is now before your subcommittee.

As manufacturer of a complete line of commercial fireworks, covering over 100 items, we are concerned that this legislation conceivably could ban all types of fireworks.

Approximately 25 States permit the sale and use of some types of fireworks which are relatively safe and suitable for public use.

We request that an amendment be added to H.R. 13886, on page 11, after line 4, as follows:

"Commercial fireworks devices suitable for use by the public, classified and defined as 'Class C—Common Fireworks' by the Interstate Commerce Commission to be exempt from this Act".

Our company has two plants—in Vineland, New Jersey and Elkton, Maryland—each of which employs approximately 100 employees on a year-round basis.

Needless to say, if H.R. 13886, is enacted in its present form, we would be legislated out of business. We would be forced to lay off our employees, and our Plant equipment and capitol investment could become worthless.

As a matter of information, there are several other fireworks companies in the Elkton, Maryland area which would face the same fate. In addition, fireworks factories would be affected in the following areas:

Fort Worth, Tex.
Dayton, Ohio
Loveland, Ohio
Dunbar, Pa.
River Grove, Ill.

There are many small factories, employing from 1 to 25 people, they are too numerous to mention.

Mr. Chairman, we do not object to, but welcome the labeling provision. In fact, all fireworks are labeled in accordance with Food and Drug Administration regulations; however; for the above mentioned reasons we respectfully request that your subcommitte give careful consideration to our amendment.

Thank you for your cooperation in this matter:

Very truly yours,

A. P. FABRIZI.

E. I. DU PONT DE NEMOURS & CO., INC.,
Wilmington, Del., August 1, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House Office Building,
Washington, D.C.

DEAR CONGRESSMAN STAGGERS: This letter is in regard to H.R. 13886, The Child Safety Act of 1966, which is currently pending before your Committee.

Six years ago, when Congress enacted the Federal Hazardous Substances Labeling Act as a logical and modern development of the area first touched under the Federal Caustic Poison Act of 1927 (44 Stat. 1406), the House Committee on Interstate and Foreign Commerce stated that the purpose of the act was "to provide nationally uniform requirements for adequate cautionary labeling" of hazardous substances packaged in containers intended or suitable for household use. (House Report No. 1861, 86th Cong., 2d Sess., accompanying S. 1283, 86th Cong., p. 1, 1960 U.S. Code Cong. & Adm. News, p. 2833). "The labeling requirements", continued the Report, "should also provide a pattern which States may follow in enacting similar legislation." (*ibid*). Over and over again, House Report 1861 acknowledged that the adoption by the States of "diverse labeling requirements" would lead "to a multiplicity of requirements" and create "unnecessary confusion in labeling to the detriment of the public", whereas "nationwide uniformity in the labeling of potentially hazardous chemicals would be advantageous to everybody." (*ibid*, p. 2835).

In our judgment, labeling practices have improved substantially during the past six years. Our experience teaches, however, that it is doubtful whether substantial nationwide uniformity will ever be achieved in the labeling of household containers so long as each state and municipality has the power to impose labeling requirements which depart from federal standards. Moreover, the state or municipality which departs from the federal standard by imposing a different or more restrictive labeling standard sets the standard for all, since suppliers cannot economically or effectively adopt different labels tailored to each jurisdiction.

To our knowledge, there are six (6) different groups of state and local laws which impose labeling requirements likely to vary from the federal standards currently imposed on household products by the Food and Drug Administration. These classifications or groups may be described as follows:

(1) Methyl alcohol (methanol) and "wood alcohol" laws. There are over fifty (50) state and local laws and regulations affecting the sale of and prescribing labeling for methyl alcohol and products containing methyl alcohol. Varying label requirements are inevitable in this situation (Example 1, Attachment).

(2) States and municipalities have often adopted their own hazardous household substances labeling laws or regulations. While generally similar to the federal law and regulations, this is not necessarily, or even likely, to be so in specific jurisdiction (Example 2, Attachment).

(3) The New York City Fire Department has adopted flammability and labeling standards which depart in significant ways from the federal standards (Example 3, Attachment). Since no supplier who sells nationally can afford to ignore the New York City market, the standards adopted by this one municipality have a significant impact.

(4) The former model fire code of the National Fire Protection Association has been adopted by twenty-five hundred (2,500) municipalities and four (4) or five (5) states. The Association is now sponsoring a proposed revision of its labeling standards to conform to its revised basic classification of flammable liquid. Among other things, the revision changes the methods set forth in the former code for determining flammability. This will create a conflict with the test methods currently specified by the Food and Drug Administration and the states and municipalities following the former model code. At the least, this will cause needless confusion and unnecessary expense. At the worst, the decision as to whether products will be labeled, for example, to be "not flammable" or "flammable" will turn on the test method used (Example 4, Attachment).

(5) Some states adopted caustic poison acts modeled on the Federal Caustic Poison Act of 1927, *supra*, but broadened their acts to encompass more than the twelve (12) substances covered by the federal law. Typically, the states would specify that the act was to apply to any other substance "substantially as caustic" as the named substances. The regulations under the Federal Hazardous Substances Labeling Act retain the label word "poison" in lieu of any signal word for products containing specified minimum percentages of the substances

formerly covered by the Caustic Poison Act (21 CFR § 191.109). However, other labeling changes were required. Unfortunately, not all states have put through similar changes to their caustic poison acts (Example 5, Attachment).

(6) "Poisonous pharmaceutical" laws. Here, the state or municipality attempts to regulate the sale or dispensation of poisonous, toxic, or potentially poisonous or toxic products which are commonly sold by retail drug stores but which are not prescription drugs. Typically, the law or regulation will specify a particular labeling which differs from and exceeds the federal standard (Example 6, Attachment).

For all of the above reasons, we strongly support the pre-emption amendment which has been proposed by the Chemical Specialities Manufacturers Association in its statement submitted June 24, 1966. It is especially important that the pre-emption clause not be limited to cases of express conflict between federal and state or local laws and regulations. The pre-emption clause in favor of the federal standard should also apply where the Food and Drug Administration has the power to act but by action or inaction concludes that no hazard is present and does not prescribe labeling. State and local regulators should not be permitted to impose a higher or different standard in these situations.

Very truly yours,

J. O. GRAVES,
Director of Marketing,
Consumer Products Division.

ATTACHMENT TO E. I. DU PONT CO. STATEMENT ON H.R. 13886

EXAMPLES OF FEDERAL AND STATE OR LOCAL CONFLICT IN LABELING

Example 1. We know of no substance which is the subject of regulation in more jurisdictions than is methyl alcohol. As with all harmful substances, the likelihood of harm varies with the amount of methyl alcohol to which the human organism is exposed. Thus, a product which is 98% methyl alcohol is much more likely to be harmful than one which is 2% methyl alcohol, all other things being equal. Under federal standards, a mixture containing four per cent (4%) or more by weight of methyl alcohol must be labeled with, among other things, the words "poison" and "danger" and the skull and crossbones symbol (21 CFR § 191.7 (a)(5), (b)(2). However, many state and local laws prescribe different threshold levels. According to the laws of the State of California, for example, any preparation containing more than one per cent (1%) or more methyl alcohol must bear the word "poison" and the skull and crossbones symbol (Deering's California Codes, B. & P.C.A. § 4160, Schedule B(1), § 4161, § 4168). In Massachusetts, on the other hand, the signal word "poison" must be used if a drug or medicine contains *any* methyl alcohol (Ann. Laws of Mass., c. 94 § 303C). Therefore, a product containing one half of one per cent (½%) methyl alcohol must have the word "poison" if it is to be sold in Massachusetts, but the threshold for such labeling is one per cent (1%) in California and four per cent (4%) under federal law.

Example 2. (a) Under federal standards, products containing five per cent (5%) benzene (benzol) by weight must be labeled with the words "danger", "poison", and "vapor harmful", and the skull and crossbones symbol. Additional labeling is prescribed for products containing ten per cent (10%) or more of benzene. (21 CFR § 191.7(a)(4), (b)(3)(i)). Under Massachusetts law, however, a product which contains *any* amount of benzene (benzol) must be labeled "danger", "poison", and "vapor harmful", but the skull and crossbones symbol is never required in connection with benzene (Mass. Dept. of Labor and Industries, Div. of Ind. Safety and Dept. of Public Health, Industrial Bulletin No. 11, App. B, p. 7 (1957)).

(b) Under federal standards, preparations containing ten per cent (10%) toluene by weight must be labeled with the signal word "danger" and rather elaborate additional wording must be used, but the skull and crossbones symbol is not required (21 CFR § 191.7 (a)(4), (b)(3)(ii)). Recently, a proposed California law which died in the Assembly would have required the skull and crossbones symbol on any glue or cement containing toluene (Assembly Bill A. 2162, cf. Deering's California Codes, B. & P.C.A. § 4160 Schedule D(a), § 4168).

(c) Under federal standards, a substance is toxic if a single oral dose of more than 50 milligrams but not more than 5 grams per kilogram of body weight kills 50% or more of a given test group of adult white rats. (21 CFR § 191.1 (f) (1)). Under Indiana state administrative standards, however, a substance is toxic if a single oral dose of up to 10 grams per kilogram of body weight kills 50% of a similar test group. The result is that a substance which does not amount to a lethal oral dose in 50% of the test animals unless 8 grams per kilogram of body weight is administered is considered toxic in Indiana but is not considered toxic anywhere else. Thus, many brake fluid labels must bear the legend, "Contains alkyl poly glycol ethers. Do not take internally", or something similar, if the product is offered for sale in Indiana. As a practical matter, the Indiana labeling standard has become the national standard, because of the practical and economic impossibility of adopting a special label just for Indiana (sample label (fig. 1) attached).

Example 3. Under federal standards, products which have flash points of above 20° F. to and include 80° F. when tested by a prescribed method are considered to be flammable and must bear the front panel statement "Warning—Flammable" (21 CFR § 191.1 (j) (2)). Products which flash at above 80° F. need not be labeled as flammable. Under New York City Fire Department regulations, products which have flash points of up to 100° F. to 300° F. are said to be combustible (Chap. 19, Administrative Code, City of New York, § C19–2.0, Subdivisions 11 and 22). The signal word "caution" must be used in labeling both classes of products. The result is that household products which flash at 80° F., for example, must bear a front panel notice reading "Warning—Flammable" because of federal requirements, and a back or side panel notice stating Caution—Flammable Mixture" because of New York City's peculiarities. Household products which flash at 120° F., for example, need not bear any front panel warning as to flammability, but must carry the notice "Caution—Combustible Mixture" if they are to be sold in New York City (sample label (fig. 2) attached).

Example 4. Current federal flammability standards are based on the determination of flash points by the Tagliabue *open* cup tester (21 CFR § 191.13). The National Fire Protection Association is currently sponsoring a different method of determining flash points (and thus a different standard for classifying flammable liquids) utilizing the Tagliabue *closed* cup tester (N.F.P.A. Publication No. 321). The Association also requires the determination of boiling points as a guide to classification. One result would be that a number of products, including gasoline, would be classified as "flammable" under Association standards, while continuing to be classified as "extremely flammable" under federal standards (FDA Publication No. 17, Feb., 1963).

Example 5. Sulfamic acid is corrosive under federal standards, but is not among the twelve (12) substances formerly covered by the Federal Caustic Poison Act and now given special treatment under the Federal Hazardous Substances Labeling Act requiring the word "poison" on the label. However, it is used in household bowl cleaners and is substantially as corrosive to the eyes as acetic acid—one of the special twelve (21 CFR § 191.109(g)). Thus, it is a "caustic acid" under the laws of some states, such as New Jersey (Title 24, Subtitle 1, Chap. 8, N.J. Stat. Ann.). Therefore, under federal law household products containing sulfamic acid are labeled in accordance with the standards for "corrosive" substances, whereas under New Jersey law the word "poison", among other things, must appear on the label of products containing sulfamic acid.

Example 6. Soldering fluxes for home use are likely to contain more than 5 percent (5%) of zinc compounds soluble in water, such as zinc chloride. Under federal law, these products would be labeled with the signal word "danger" and with a warning concerning the hazards of ingestion and skin and eye contact (Notices of Judgment Under the Federal Hazardous Substances Labeling Act, Nos. 12–17, dated August 12, 1963). Under California pharmacy laws, however, such products must be labeled with the word "poison" (Pharmacy Laws of California and Administrative Rules of the Board of Pharmacy, January 1, 1962, p. 59).

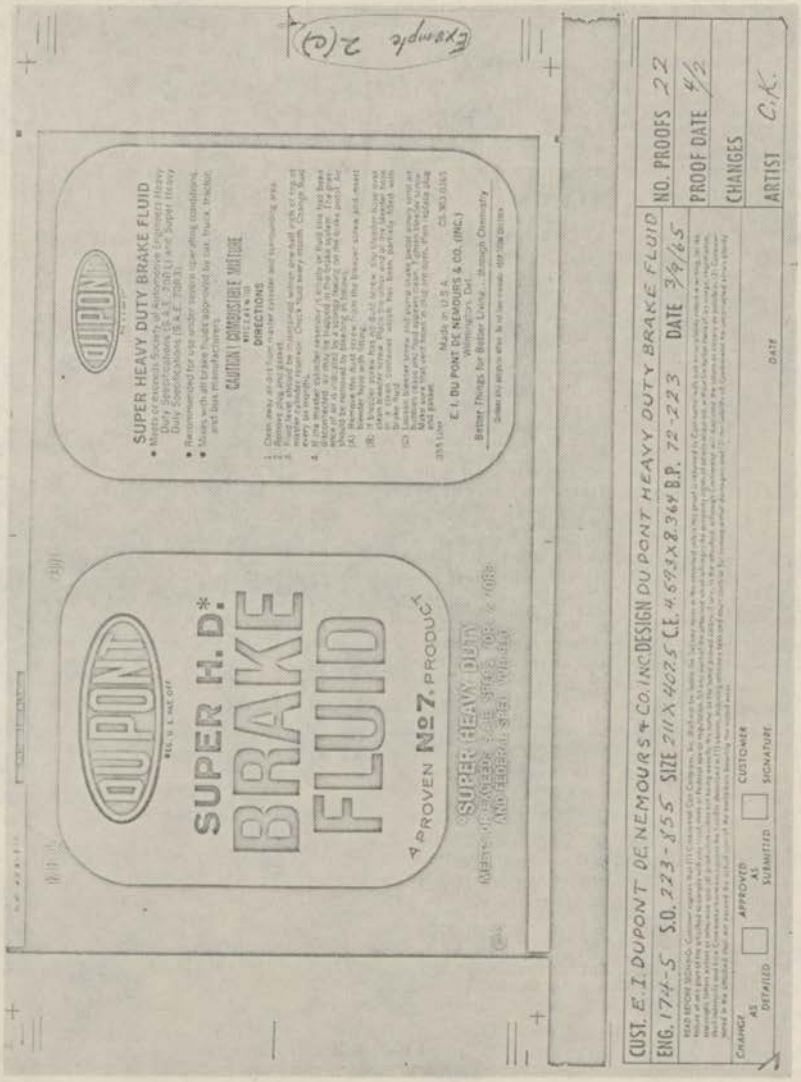
DUPONT
SUPER H.D.*
BRAKE
FLUID
PROVEN No 7. PRODUCT
SUPER HEAVY DUTY BRAKE FLUID
DIRECTIONS
CAUTION! COMBUSTIBLE MIXTURE
E.I. DU PONT DE NEMOURS & CO. (INC.)
Wilmington, Del.
Better Things for Better Living ... through Chemistry
Example 2(a)
CUST. E. I. DUPONT DE NEMOURS & CO. INC. DESIGN DU PONT HEAVY DUTY BRAKE FLUID
ENG. 174-5 S.O. 223-455 SIZE 7¼ X 4.625 CL. 4.693 X 8.364 B.P. 72-223 DATE 3/4/65
NO. PROOFS 22
PROOF DATE 4/2
CHANGES
ARTIST C.K.
CHANGES AS OBTAINED
APPROVED AS SUBMITTED
CUSTOMER
SIGNATURE
DATE

FIGURE 1

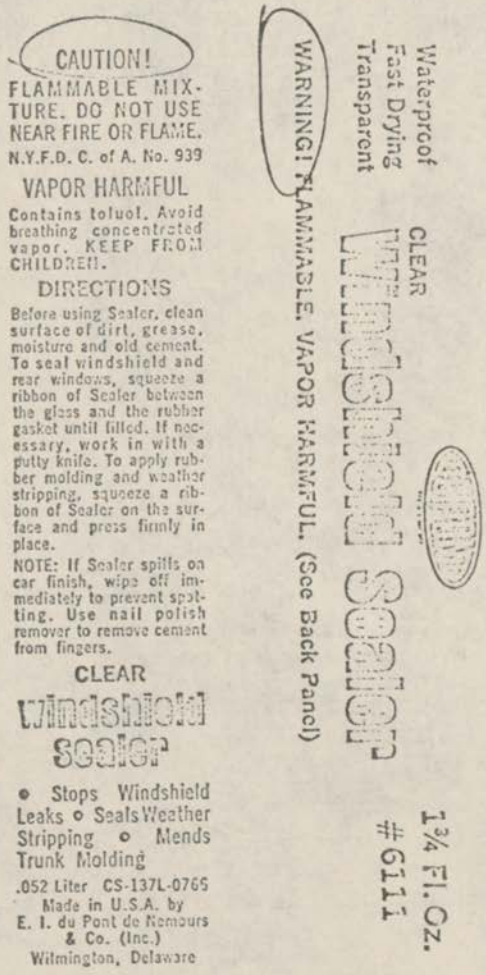
CAUTION!
FLAMMABLE MIXTURE. DO NOT USE NEAR FIRE OR FLAME.
N.Y.F.D. C. of A. No. 939
VAPOR HARMFUL
Contains toluol. Avoid breathing concentrated vapor. KEEP FROM CHILDREN.
DIRECTIONS
Before using Sealer, clean surface of dirt, grease, moisture and old cement. To seal windshield and rear windows, squeeze a ribbon of Sealer between the glass and the rubber gasket until filled. If necessary, work in with a putty knife. To apply rubber molding and weather stripping, squeeze a ribbon of Sealer on the surface and press firmly in place.
NOTE: If Sealer spills on car finish, wipe off immediately to prevent spotting. Use nail polish remover to remove cement from fingers.
CLEAR
windshield sealer
• Stops Windshield Leaks • Seals Weather Stripping • Mends Trunk Molding
.052 Liter CS-137L-0765
Made in U.S.A. by
E. I. du Pont de Nemours & Co. (Inc.)
Wilmington, Delaware
WARNING! FLAMMABLE. VAPOR HARMFUL. (See Back Panel)
Waterproof
Fast Drying
Transparent
CLEAR
windshield sealer
1¾ Fl. Oz.
#6111

FIGURE 2

UNION CARBIDE CORP.,
New York, N.Y., July 6, 1966.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR CONGRESSMAN STAGGERS: We are writing regarding your bill, H.R. 13886, the Child Safety Act of 1966, and more particularly with respect to Title II which would amend the Federal Hazardous Substances Labeling Act in certain respects.

We supported the enactment of the Federal Labeling Act in 1960 with hope that it would mean national uniformity for the legal requirements for warning labels on Prestone antifreeze which we make and package at our South Charleston plant, and on other household products which we make and sell. We also supported it because we were in complete accord with all of its objectives, as evidenced by the fact that we had been using strong label warnings on Prestone and on our other products since the 1930's, before there were any statutory requirements, Federal or State.

We now favor and support the enactment of your bill, H.R. 13886, which will broaden the scope of the Federal Labeling Act to include unpackaged substances and will in other ways improve that law in the light of the experience of government and industry since 1960.

We also strongly favor and support the preemption amendment which has been proposed by the Chemical Specialties Manufacturers Association in its statement submitted to your committee on June 24.

This proposed amendment is needed to accomplish a major purpose of the Federal Labeling Act and the express intent of the Congress in passing it. These were to establish *uniform* standards for warning labels on household products.

The original intent of Congress was clearly stated in Senate Report 1158, 86th Congress, 2d session, at page 3 as follows: "It is desirable that * * * the standards and requirements * * * be *uniform*. Thus, *Federal legislation* on this subject *is needed to require uniform labeling* of hazardous substances for household use." There was no House Report.

The Senate Report cited certain broad state legislation. Subsequently there has been even more broad state legislative activity.

There are also on the books a substantial mass of aged and obsolete, varying and conflicting labeling requirements for specific products.

One striking example is the mass of state statutes and city ordinances relating to the labeling of products containing methanol (wood alcohol). These laws date back to prohibition days. Our company can testify to the practical impossibility of preparing a single warning label which complies with all of their inconsistent requirements on wording and on type size and on the placement of the warning on the label. The requirements under the Federal Act should be the sole uniform requirements for products containing methanol which move in interstate commerce.

There are other striking instances of the need for uniformity and for a preemption provision in the Federal Act. One city, under an ordinance which dates back some 50 years, enforces its own special rules for the type size and the position of the warning on flammable products which are, of course, numerous and important. Since as a practical matter manufacturers cannot keep special stocks of products, specially labelled for sale there, this one city largely governs the labeling of all flammable products which move in interstate commerce. And states can and do require warnings on the basis of the opinion of a state toxicologist or doctor whose views happen to vary from the consensus of the staff of doctors and toxicologists in the Food and Drug Administration and the United States Public Health Service. Again, one State toxicologist or doctor can, and sometimes does, govern the warnings on a specific product for the country as a whole.

This is not a case where there are reasons why Congress should not preempt the subject matter in the interests of uniformity and of simplifying and facilitating the sale of goods in interstate commerce.

First, it is not a case where the "evil" to be remedied varies from state to state or from city to city. The hazards of a particular product are the same in all states and cities and the warnings and their typography and type size and their position on the label can be the same and still fully protect the public everywhere. (In fact, the warnings should be the same, given the tendency of people to move from state to state.)

And, second, as we have noted, this is not a case where a state law or a city ordinance has no extra-territorial effect. On the contrary, the necessities of

competitive marketing make it all but impossible for people like us to carry separate stocks of products in differently labeled containers for sale in special states or cities. As matters stand, individual states and cities can and do, to all intents and purposes, "preempt" the power to regulate interstate commerce which the Federal Government should exercise.

It is for these reasons and because of our own practical experience over the years that we especially urge that your committee recommend to the Congress the enactment of Proposed Amendment No. 2 to H.R. 13886 as submitted by the Chemical Specialties Manufacturers Association with its statement of June 24.

Very truly yours,

J. R. JOHNSTONE,
Vice President.

OLIN MATHIESON CHEMICAL CORP.,
CHEMICALS DIVISION,
New York, N.Y., August 25, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR CONGRESSMAN STAGGERS: Reference is made to bill, H.R. 13886, the Child Safety Act of 1966.

Our company fully supports the position of the Chemical Specialties Manufacturer's Association, Inc., given before the house committee of Interstate and Foreign Commerce on June 24, 1966 and also supports the letter of August 18, 1966 to you from G. H. Decker, of the Manufacturing Chemists' Association, Inc.

Special reference is made concerning the preemption amendment which has been proposed by CSMA. We are of the opinion that this amendment, if enacted, would further promote uniform standards for warning labels on household chemicals. You may appreciate that a nation-wide producer of household products is desirous of having labels that are acceptable by the Federal Government also fully accepted in all States and local Municipalities. Unfortunately this is not now necessarily the case. For example, a fire department in a major city requires warning statements in extra large type size for combustible and flammable products that vary from the consensus of technical opinion concerning combustible and flammable classifications.

We are of the opinion that the label should adequately reflect the hazards of the chemical, presented in a clear, concise manner that may be easily read and understood by the consumer. We do not believe in over-labeling products, by that we mean, to label a product "Combustible," "Flammable," "Danger," "Poison," when indeed this warning does not reflect the hazard of the product. The requirement to use such terminology by a few well meaning but uninformed local officials places us, we feel, in a position analogous to crying "wolf" when in fact there is no wolf. For example, a product may be only slightly toxic and instead of "Poison," an adequate statement would be, "Caution: May be harmful if swallowed."

Further we feel that over-labeling only tends to mislead the consumer and also results in a consumer disregarding precautionary labeling which we feel is contrary to the original goals of the Federal Hazardous Substance Labeling Act.

For the reasons stated above, we urge that your committee recommend to Congress the enactment of proposed amendment #2 of H.R. 13886 as submitted by the Chemical Specialties Manufacturers' Association with their statement of June 24, 1966.

Very truly yours,

RICHARD F. PHILPITT,
Manager, Legislative and Regulatory Affairs.

CHESEBROUGH-PONDS, INC.,
New York, N.Y., September 19, 1966.

Hon. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare,
Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN JARMAN: We would like to take this opportunity to comment to your committee regarding H.R. 13886—"Child Safety Act of 1966". We

are especially gratified that the committee has indicated its willingness to hear witnesses representing industry and to receive written industry comment on a bill that is, at least in part, highly controversial, unrelated to the bill's title and not in the best interests of the public.

The bill, in section 4(b), provides for the amendment of section 502(f) of the Food, Drugs & Cosmetic Act. Section 502(f)(3) involves a major change in the current rules governing drug labelling and is totally irrelevant to any question of child safety.

The section provides that the FDA shall have general authority to specify what claims may be made for a drug, treating for this purpose all drugs, whether new or old, proprietary or ethical, the same. Under such a section, if the scientific and regulatory personnel at the FDA disagreed with the scientific personnel in industry as to whether a given product were useful for a particular condition the FDA could prohibit any claim or reference to that condition, thus assuring the drug would not be used in treating any patient. This regulation could be put in force without hearings and without any effective recourse to the courts by industry. The consumer could be deprived of products which would be of help to him.

Passage of this bill would mean the end of drug and cosmetic marketing as we currently know it and the substitution of what would be, in effect, Federal licensing and control. We cannot urge your committee too strongly to strike out 502(f)(3) in its entirety.

Section 4(c) provides for a new section 602(f) of the Food, Drug & Cosmetic Act. This section in effect permits FDA to require cautions, warnings, antidotes, etc. on the label of a cosmetic if it might cause some reaction, however minor, through ingestion, topical applications, etc. In view of the excellent record of the cosmetic industry over the years in the area of safety, we believe the need for this legislation should be carefully weighed.

If the bill only required a pertinent, concise warning directed at ingestion by children in cases where substantial injury was possible, we could not object. However, the bill will be interpreted as requiring virtually every cosmetic label to warn and caution the purchaser, even though no substantial injury could possibly occur from misuse. Furthermore, the consumer will receive a package cluttered with wording which detracts from its cosmetic appearance.

We believe that the Congress as well as the Food & Drug Administration must concern itself with the continued proliferation of caution and warning labels lest respect diminish for them. If the householder sees the same warning on cologne as on turpentine or on cold cream as on silver polish, soon the caution will mean nothing. This would indeed be a disservice to the consumer who will become hopelessly confused as to where a real hazard lies.

We think a possible solution to the problem may lie in the promulgation by the FDA of realistic caution statements for cosmetics to cover those isolated examples where some substantial hazard may be present. We believe the proprietary drug industry has conscientously followed FDA suggestions as to label warnings and the cosmetic industry would undoubtedly do the same. We would think no new statutory authority would be required.

Since a number of "cosmetics" are also "drugs," such as underarm products, cleansers and medicated makeups, they would be subject to the proposed modification of section 502(f)(2). We urge for this reason that the current law remain unchanged. The FDA has never hesitated, where circumstances demanded, to require under current law appropriate cautions for drugs and this has served the consumer well over past years.

Under current law, however, these powers are definitely specified and not left on an open-end basis subject to the regularor's judgment and opinion.

We believe that the consumer's interest should be protected without infringing on the manufacturer's rights or putting the manufacturer on virtually an FDA licensing basis. The FDA has sufficient powers now which, if effectively enforced, enable it to properly protect the public.

We would appreciate your recording our comments in the minutes of your Committee.

Very truly yours,

ALBERT B. RICHARDSON.
Vice President.

THE S. E. MASSENGILL CO.,
Bristol, Tenn., September 9, 1966.

Representative JOHN JARMAN,
Chairman, House Interstate Health Subcommittee,
House Office Building, Washington, D.C.

DEAR CONGRESSMAN JARMAN: As a member of the pharmaceutical industry which will be affected by the Child Safety Act, H.R. 13886, we would like to place on record our objection to the portion of the bill giving the Food and Drug Administration open-end authority to require the use of safety closures on any drug selected by the government and also decide which safety closures meet F.D.A.'s standards.

We are very much in agreement with the objectives of the proposal; but, as I am sure you have been informed, this section of the bill is so broad that it covers every form of container and product whether for prescription or over-the-counter drug products. This could be a most difficult, if not impossible, requirement to fulfill since no safety closure really satisfactory for all such uses has been developed. The wording of the law should relate itself to specific inclusion of the current or not too distant state of safety closures.

Any assistance you can give the industry in this manner will be very much appreciated. Undoubtedly, when a completely adequate safety closure is available, many of us will be competing to be the first to use them.

Sincerely yours,

FRANK W. DEFRIECE, Jr., *President.*

FMC CORP.,
New York, N.Y., September 12, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR CONGRESSMAN STAGGERS: FMC Corporation is a producer of bulk chemicals. In this activity, it is frequently a supplier of chemicals produced for other manufacturers whose products are intended for household use.

Due to the fact that all of the customers supplied by this Corporation do not possess the necessary financial ability to maintain their own technical and research staffs, the Technical Service Department of this corporation is frequently called upon to give technical guidance and advice to its customers in the formulation and manufacture of their products and the labeling thereof.

In view of this situation, we have an interest regarding your bill H.R. 13886, the Child Safety Act of 1966. We are particularly interested in the pre-emption amendment proposed by the Chemical Specialties Manufacturers Association as reflected by Amendment No. 2 which such Association suggests be added to your bill. We understand that the Department of Health, Education, and Welfare has also endorsed the adoption of this Amendment No. 2 to achieve uniformity in cautionary labeling of hazardous substances.

As a manufacturer doing business in chemicals on a nationwide scale, it is natural that we be contacted by a multiplicity of customers from all cities and states of the nation when such customers desire technical advice and assistance in the formulation of their products.

Where such customers are governed by state or local laws prescribing labeling requirements that vary from state to state or city to city, it becomes a practically impossible task to give adequate advice for the cautionary labeling that such customers must place upon their products. Consequently a pre-emption provision which will serve to establish certain uniform and basic requirements in such labeling will do much to clarify the present confused situation.

A further reason for the adoption of a preemption provision in this particular situation is also worth noting. Over the span of the past 10 years, the various States have gradually adopted the Uniform Commercial Code which establishes certain basic uniform provisions governing the sales of goods in commerce. This Code has now been adopted by 47 States.

The Code contains a specific provision that unless excluded or modified, a sale of goods implies that they are merchantable and, in this respect, they must be at least such as are adequately contained, packaged and labeled as the sales

agreement may require. This warranty applies where the nature of the goods requires a certain type of labeling.

It follows, therefore, that if state or local law varies from region to region with each geographical area prescribing a different type of content for the cautionary statements to be placed on labeling, it becomes an almost impossible task for a producer or hazardous household chemicals to comply with; yet the failure to so comply places such producer in the position of being in breach of the implied warranty of merchantability now prescribed by the Uniform Commercial Code.

A pre-emption provision which will establish a national yardstick in this respect for hazardous household substances should do much to help cure this situation and enable a producer of such household products to know that his labeling is not only in accord with the Federal requirements but likewise complies with the implied warranties set up by the numerous states that have adopted the Uniform Commercial Code. In turn, this will be of considerable assistance to companies such as ours when called up to give technical advice and assistance in labeling to those producers among our customers who make a request for such assistance.

For the reasons set forth above, we recommend to the Congress that the House approve S3298 which contains the pre-emption amendment as submitted by the Chemical Specialties Manufacturers Association and as approved by the Manufacturing Chemists Association and the Department of Health, Education and Welfare.

Very truly yours,

D. C. OSKIN,
Vice President, Marketing.

THE BELL CO., INC.,
Chicago, Ill., August 15, 1966.

HON. HARLEY O. STAGGERS,
House Office Building,
Washington, D.C.

DEAR CONGRESSMAN STAGGERS: I am writing to you in connection with the Child Safety Act of 1966, H.R. 13886 and the three amendments which have been submitted by the Chemical Specialities Manufacturers Association.

We are members of CSMA and endorse the submission of the three amendments to H.R. 13886.

Our company manufactures automotive chemical products and also household chemical products, all of which are subject to the Federal Hazardous Substances Labeling Act and therefore will be affected by H.R. 13886.

We would particularly urge the adoption of Amendment No. 2 which provides that the Federal labeling laws would supersede all State, county, and municipal labeling laws which are now in effect. In many cases these laws have different labeling requirements for the same hazard and for the same product, and hence present a chaotic condition such that it is virtually impossible for manufacturers to comply with all of the conflicting requirements.

However, I feel that the most important contribution which such a Federal law would make would be to provide uniform labeling throughout the nation and thus make it possible for the public to recognize hazardous products labeling because of its uniformity. Presently, it is very confusing for the consuming public to recognize hazardous products labeling, because of the diverse requirements which have been established by various governmental bodies.

It seems to me that a Federal law which prescribes hazardous products labeling would make it possible for the public to learn the markings and words which accompany hazardous products in the same way the public has learned that a red light in a traffic signal means "stop."

I respectfully urge you and your committee to adopt Amendment Number Two as submitted by the Chemical Specialties Manufacturers Association in the interest of protecting the public by making it easier for them to recognize hazardous products labeling.

Very truly yours,

C. E. ALLDERDICE, Jr., *President.*

WEST CHEMICAL PRODUCTS, INC.,
Long Island City, N.Y., July 15, 1966.

Hon. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House Office Building,
Washington, D.C.

DEAR CONGRESSMAN: We are interested in your bill, H.R. 13886, The Child Safety Act of 1966 and Title 2 of it which would amend the Federal Hazardous Substances Act in certain respects.

We are especially interested in the preemption amendment which has been proposed by the Chemical Specialties Manufacturers Association in a statement submitted to your committee on June 24.

This company has, in every case, supported all reasonable safety regulations and is in accord with the principle that standards and requirements should be uniform throughout the nation. In effect, we are in accord with the original intention of Congress as was clearly stated in Senate Report 1158, of the 86th Congress, 2nd session, as follows: "It is desirable that * * * the standards and requirements * * * be uniform. Thus, federal legislation on this subject is needed to require uniform labeling of hazardous substances for household use."

We desire to comply with every rule and regulation of the Federal Government and every one of the many states of this country. Under the present circumstances, this is practically impossible due to the varying conflicting state and city requirements which are in existence throughout the country.

We urge that these amendments be adapted into law so that we can have a single guideline which will apply throughout the country instead of patchwork, a part of which is aged and obsolete.

Very truly yours,

A. LIEBERMAN,
Assistant Secretary.

THE W. T. RAWLEIGH CO.,
Freeport, Ill., July 5, 1966.

Re H.R. 13886, Child Safety Act.

Hon. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare,
House Office Building,
Washington, D.C.

DEAR CONGRESSMAN JARMAN: We understand that subject bill, introduced by Rep. Harley O. Staggers, has three major points of interest for companies such as ours:

1. Quantity limitation on Aspirin and Aspirin-containing Products intended for use by children.
2. Safety Closures.
3. Basic changes in O–T–C labeling.

With reference to changes in O–T–C labeling, we understand that H.R. 13886 includes in identical form, a provision of H.R. 13885, which bill relates to several aspects of drug regulation. We are informed that H.R. 13886, accordingly, takes one of these aspects entitled "Drug Labeling Regulation" incorporating it into the so-called "Child Safety Act of 1966". As we understand, such excerpted portion would apply to all drugs and with respect to them the use by children would be just incidental.

We also understand the excerpted portion would amend Section 502(f)(2) very drastically. Under this bill, as we understand, the directions and warnings would be shaped by F.D.A. Regulations. The bill would amend Section 502(f) to require warnings "against a substantial and reasonably foreseeable risk of causing accidental injury . . ., including instructions for first aid treatment when necessary or appropriate."

We submit that the importance of the amendment is basic. It appears that it would completely change the concept and application of the existing law with respect to over-the-counter drugs. It appears that it would amend existing law so substantially and so completely as to swallow up and replace practically all other labeling requirements pertaining to these drugs, putting them, insofar as labeling is concerned, under a system of virtual licensing. We believe the bill

is highly objectionable in constituting a vast extension of Federal Regulation and wish to express our opposition.

Respectfully submitted.

J. A. RESH, *Secretary.*

NEW YORK, N.Y., *September 9, 1966.*

Hon. JOHN JARMAN,
Chairman, Subcommittee of Public Health and Welfare,
House Institute Foreign Commerce Committee,
Rayburn House Office Building,
Washington, D.C.

DEAR CONGRESSMAN JARMAN: Reference is here made to H.R. 13886 "Child Safety Act of 1966." As a practitioner of medicine in New York City and as an associate in medicine at Columbia University, may I express my views regarding section 502(f) of such Act (21 U.S.C. 352f) and the proposed amendment in which, if I may paraphrase, it is suggested that a drug be considered mis-labeled unless information as to the appropriate antidote to be administered in case of its accidental use or over-use be included on such label.

It seems to me that this is, in effect, expecting the public to be able to practice medicine, which, believe me sir, they do very poorly indeed. Would it not be more to the point to label such drugs as follows:

"Keep this and all other medicines out of the reach of children. If accidentally ingested, Do Not Delay. Call your physician or go to the nearest hospital at once."

Children often take accidental overdoses of many drugs wherein delay while a family administers first aid could be fatal.

Respectfully submitted.

GEORGE H. MCCORMACK, Jr., M.D.

MAPLEWOOD, N.J., *August 10, 1966.*

Hon. HARLEY O. STAGGERS,
Member of Congress,
Rayburn House Office Building,
Washington, D.C.

DEAR MR. STAGGERS: Your correspondence of August 4 and August 5, notifying me of the scheduled continuation of public hearings by the Subcommittee on Public Health and Welfare on the Child Safety Act of 1966, is greatly appreciated. The fact that my letter of July 7, addressed to my Representative in Congress, the Honorable Paul J. Krebs, resulted in gaining your attention, and the receipt of an invitation to appear before this subcommittee as a witness confirms the basic tenets of the democratic processes of our Government.

Since I will be unable to appear before this subcommittee, I present the following opinions and viewpoints for the consideration of the members of that group.

Firstly, the title of the bill is misleading. Everyone is in favor of "Child Safety" but this proposed legislature goes well beyond that. It would drastically change the concept and application of existing laws as it applies to over-the-counter drugs, which, for the most part, have no relationship to Child Safety. In addition, the bill basically affects toilet goods, cosmetics, prescription drugs, "hazardous substances" and other products. The title of this act more correctly should be posted as a "labeling law."

This point was made by James L. Goddard, M.D., Commissioner of Food and Drugs, in his testimony before the subcommittee on June 24, 1966. Even Dr. Goddard noted that present warnings "have little effect on children who cannot read and understand, and some parents did not read or heed the warning". Then, the Commissioner went on to propose more warnings and instructions on labels as a preventive against accidental poisoning and hazards to health.

Secondly, the proposed law is much too vague and broad in its extent to be practical. It touches upon so many products that have no bearing on the title and would result in a virtual system of licensing of proprietary drugs. In effect, standards would be arbitrarily established by a governmental agency and the individuals appointed to that agency. For example, no definition of a "safety closure" is presented by the bill. Yet, the Secretary would be embodied with the "authority to require safety closures for containers of drugs frequently involved

in poisonings. This should apply both to over-the-counter drugs and to drugs dispensed on prescription", according to Dr. Goddard's testimony.

To the best knowledge available, there exists no known safety closure that is foolproof. So-called "safety closures" are presently used on aspirin and antipyretic substances. Periodically, modifications could be adopted in order to improve their safety factor. Each improvement might impress the "Secretary" to the point where that individual would insist that industry package their products with that device only to have it supplanted by the next improvement. The resultant costs for sequential modifications would or could be immense. Therefore, to make the proposed legislation practical, Congress must define and designate a "safety closure".

Thirdly, the law is not necessary. In presenting this proposed regulation, the contributions of the industry have been totally ignored. At this time, the drug industry has voluntarily and universally restricted the quantity of pediatric aspirin per tablet to 1¼ grains and, again, of its own volition, limited the quantity per package to 50 tablets . . . a total availability of active ingredient roughly equivalent to 12 adult tablets. Flavoring has been maintained at the insistence of pediatricians who know, professionally, of the need for palatability in this vitally needed medication.

Additionally, on this point, one must consider the impossibility of total protection against accidental poisoning. Certainly, additional cautions and directions will serve no purpose toward preventing toddlers and very young children from ingesting noxious substances. The occasional accidental swallowing of lye and household ammonia clearly proves that label directions and the taste have little to contribute in the prevention of these events.

Lastly, the law as proposed in H.R. 13886 is governmental intrusion into business without due cause. Statistics quoted by Dr. Goddard in his testimony of June 24 grimly point out the 125 deaths of children due to salicylate poisonings in 1964 and the death of 67 children due to poisonings other than aspirin. These figures must be weighed against the millions of packages of drugs distributed during that year. While deplorable that any child should meet an untimely end, Congress must realize that total protection in impossible. These unfortunate deaths should clearly point out that labeling is not a preventive of accidental poisonings, nor can any substance be restricted in quality to a point where no deaths can occur if that substance is digested erroneously.

In weighing this bill, the committee and members of Congress must place reason and practicability above the emotions engendered by the title "Child "Safety Act". They must also give serious consideration to the result of this bill which would establish a virtual Czar over products, over labeling and over packaging—all of which will be subject to a veritable licensing by the Government, with the manufacturer being vulnerable to undue costs and unreasonable penalties.

The presentation of these viewpoints is based upon twenty years of business experience within the pharmaceutical industry—an industry which has a proud record of self-policing and public welfare interest. I am currently employed by a company with no interest in analgesics, so the comments I have expressed are objective in viewpoint. I present these sentiments not as a company representative but, rather, as a vitally concerned individual who feels that this proposed regulation would be a grave and grievous disservice to the public and an onerous imposition on manufacturers.

Very truly yours,

GEORGE B. ROONEY.

ARLINGTON, VA., *August 16, 1966.*

Hon. JOHN JARMAN,
U.S. House of Representatives,
Rayburn House Office Building,
Washington, D.C.

DEAR CONGRESSMAN JARMAN: I am writing to you regarding H.R. 13886 "Child Safety Act of 1966," which has not been generally brought to the attention of the medical profession, especially the Pediatric field.

First, I would like to call your attention to a quotation from a book entitled "Current Pediatric Therapy" 1966–67 issue, by Drs. Sydney S. Gellis and Benjamin M. Kagan. On page 792 in this book, two contributors to the book, Drs. George H. W. Lucas and Robert J. Imrie write:

"Chemical poisoning is preventable if ordinary safety precautions are used in the handling, use and storage of drugs and toxic household preparations. Much has been said about the proper labeling of toxic substances by their manufacturers. This might help. The family physician, however, is the most important member of the team fighting accidental chemical poisoning. He alone knows the background, the customs, the traditions and the attitudes of his patients; he visits them frequently in their own homes and can see at a glance any potential hazards. This is a golden opportunity for him to educate the parent to be accident and safety conscious. He can make concrete suggestions for storage and handling of all potentially toxic substances; i.e. keep all drugs, poisonous substances and household chemicals in a locked cupboard, out of the reach of children; never transfer poisonous products from their original containers to pop bottles, coffee tins or drinking glasses. If flavored or brightly colored medications have been prescribed for children, always refer to these as medicine and never as candy."

I, too, have found as a practicing Pediatrican for the past 19 years in Arlington, Virginia, that the children's parents are the ones at fault. The containers in which the aspirin is packaged, both liquid and the pill, seem adequate to me. The present labeling likewise seems adequate, and to include a lot of first aid treatments, side effects, contraindications and effectiveness would only confuse the public in the use of this very wonderful drug.

As for the rest of the various amendments under title II, I would suggest that hazardous substances include a label stating the particular product or drug is dangerous to children and have the printing large enough to be clearly seen on the label.

Sincerely yours,

ARCHIBALD R. MACPHERSON, M.D.

ARLINGTON SAFETY COUNCIL, INC.,
Arlington, Va., August 27, 1966.

Hon. WARREN MAGNUSON,
Chairman, Commerce Committee,
U.S. Senate, Washington, D.C.

DEAR SENATOR MAGNUSON: Your secretary kindly sent me a copy of S. 3298 which I requested yesterday after reading committee plans to conduct hearings in the press.

I have read this bill with great respect and interest. I am wondering if your committee's examinations might not include the childhood hazards of suffocation in plastic bags, such as used in the drycleaning trade, and entrapment and suffocation in idle household refrigerators.

If these two distressing hazards could be brought under the cognizance of the "Child Protection Act of 1966," long needed safety improvement in these fields would undoubtedly be realized.

I respectfully inclose some material related to the hazard of child-refrigerator entrapment and suffocation.

With expression of my profound respect and appreciation,

Sincerely,

GAYLORD B. KIDWELL.

ARLINGTON, VA., *August 22, 1966.*

To: General Federation of Women's Clubs (Mrs. Chittenden, D/Legis) American Academy of Pediatrics, (Dr. Southard, Chrm. Acc. Prev. Comm.).

It is a privilege to enclose copies of correspondence between the Honorable Joel T. Broyhill and the Honorable Harley O. Staggers related to future hearings on child-refrigerator entrapment legislation.

May I again express my appreciation for your long interest and support and offer these observations as background to the current problem?

The backbone to the proposal to amend PL 930 stems from reports of the child behavior studies of 1957 and 1961. Besides your own esteemed organizations, the Federal Trade Commission, the Federal Safety Council D/Labor, the D/Health, Education, and Welfare, the National Safety Council, and others, are on record as viewing these tests to show unsatisfactory child safety benefits in the "push-open door" standards.

Infrequent, but unqualified reference to the fact that no deaths are known to have occurred in "push-open" door boxes seems very insignificant when the percentage of these boxes in the national inventory is still small, and none have reached an age for discard, or even devotion to "second use" by low-income families where many deaths have occurred.

As you know the industry representatives abstained from participation in the 1963 "progress report" committee hearings, as did the National Safety Council. It seems this deeply affected group might have given the committee and the public much useful information.

However, penetration of doubt in the adequacy of "push-open doors" by some manufacturers may be identified by the withdrawal of nationally advertised child safety claims for these doors, the inclusion of a tag with new deliveries warning that precaution should be taken with units when idle and exposed to possible entry by playing children, and the recent initiation of an independent and comprehensive test of all air-tight cabinet appliances, including a review of the refrigerator hazard. This is a test volunteered by one company to assist Congressman Broyhill in his consideration of need for further legislation, and to firm up the company policy around this safety problem.

Hope for future child protection from entrapment must depend on the public's acceptance and use of the safeguards urged in guides by the Federal Safety Council and the US Public Health Service. While these commendable safeguards are the best found after a decade of search, they are still too difficult and cumbersome to employ to impose on housewives and mothers upon whom the burden of child protection mainly falls.

The long delay in adequate remedy to this unnecessary childhood hazard is probably due largely to fragmented and loosely coordinated federal safety programming, and apathy on the part of the industry. Both of these conditions seem headed for drastic correction—at least in the automotive industry—through public support to recent dynamic congressional actions.

Sincerely

GAYLORD B. KIDWELL.

STATEMENT OF THE GENERAL FEDERATION OF WOMEN'S CLUBS

SAFETY LATCHES ON REFRIGERATORS

The General Federation of Women's Clubs has been concerned for a long time over the tragic and needless deaths which occurred when young children, while playing in abandoned and out-of-service refrigerators and freezers, became trapped in them and suffocated because they could not get out once the door was shut.

Last year the death toll from this cause was the highest ever recorded, despite the fact that we have been aware for many years of this particular hazard to the safety of our children and also despite the fact that 36 states have made it illegal to discard a refrigerator in a hazardous condition.

The General Federation of Women's Clubs feels that the "Protection of Children" is of utmost importance and at its annual Convention in June of this year, adopted the following resolution:

Whereas The safety of children is continually menaced by faulty appliances, refrigerators, ice boxes, and plastic bags and accessability to dangerous drugs, cleaning agents, and other hazardous materials; Therefore,

Resolved, That the General Federation of Women's Clubs call upon its member clubs to initiate and promote actively programs for safety through inspection, education and legislation.

Mrs. Frederic J. Knorr, General Federation of Women's Clubs' Safety Chairman, has recently undertaken the project of distributing a quantity of "toggle and plate" safety devices to all the Safety Chairmen in the various states. These devices will be used as visual aids in safety conferences and demonstrations. These toggle bolts were supplied as a public service by the Star Expansion Industries Corporation of Mountainville, New York, through Colonel Gaylord B. Kidwell, USA (Ret) of Arlington, Virginia. Colonel Kidwell, as the Committee is aware, has waged a long and commendable campaign in a private capacity to improve child protection from this danger.

Copies of the new safety guide, furnished by the Federal Safety Council in the Department of Labor, have also been sent to our state chairmen.

The General Federation of Women's Clubs applauds the improved protection that may be afforded by the standards under Public Law 930, but it feels that the

child behavior studies with children under simulated refrigerator entrapment in 1957, and again in 1962, indicate that more improvement should be sought in future manufacture.

The law now requires that newly manufactured refrigerators shipped in interstate commerce must be equipped with safety devices so that a child who is entrapped may be able to open the door. This law does not, of course, offer protection to children so far as the old out-of-service refrigerators are concerned. It is up to each of us to publicize this potential death trap and educate the American public on how a very simple precaution can save the lives of children. The saving from tragic death of even one child would be more than worth any efforts we might make. The General Federation of Women's Clubs will certainly do its utmost in this direction and our concern over this problem will not be lessened until it has been solved.

COMMITTEE ON ACCIDENT PREVENTION,
AMERICAN ACADEMY OF PEDIATRICS,
February 4, 1966.

To: The Committee on Accident Prevention of the American Academy of Pediatrics.
From: Samuel C. Southard, M.D., Chairman.
Subject: Food for Thought.

The enclosed copy of a speech by Colonel Kidwell, retired U.S. Army, documents in a small and modest way the extensive and continued efforts by one man to reduce one small accidental hazard to children. The reason I am sending this letter and speech to you is that we need more such dedicated people as Colonel Kidwell.

Over the years, he has almost singlehandedly stimulated the participation of numerous governmental and industrial agencies and groups to take an active role in attempting to eliminate suffocation deaths by entrapments in refrigerators. Admittedly, when compared with national statistics, this is a minor cause of death; but if you wish to eat an elephant the best way to do is to take a bite and start chewing. To my own personal knowledge, his efforts have been much more extensive than those chronicled in the speech.

As members of a national committee of a high prestige organization such as the American Academy of Pediatrics, we are privileged to meet and correspond with many people who are interested in accident prevention. I suggest and recommend to you that each of these people who contact you in your various home locations be encouraged, stimulated and invited to share their experiences and problems with our Committee.

This gives us the opportunity to extend our knowledge of children and their accidents through many different channels all working toward the same goal.

With best wishes to you and yours for a Happy New Year, I remain,

Sincerely yours,

SAMUEL C. SOUTHARD, M.D.,
Chairman.

REMARKS BY COL. GAYLORD B. KIDWELL, U.S. ARMY (RET.), BEFORE THE SOUTH ARLINGTON LIONS CLUB, DECEMBER 8, 1965

Gentlemen: It is a great privilege for me to address you today as a representative of the Arlington Safety Council of which I am a member.

In selecting a safety subject which I hoped would be worthy of your attention I was mindful of the reecnt tragic accident in which an Arlington child was entrapped and suffocated in an idle dishwasher. While this is the first instance, I have noticed, of a child's being fatally involved in an accident in a dishwasher, it brings into focus the growing number of children being suffocated annually in idle household refrigerators and freezers. *The year 1964 had the highest number of deaths ever recorded in one year—with nine occurring over one summer's week-end.* I therefore thought I would briefly review developments in this long standing hazard to playing children over the past decade. That these useful and convenient modern appliances are a menace to children under some circumstances is regrettable—but facts are facts.

Perhaps a good point at which to start may be the year of my retirement from active military service—1953.

About this time public concern was very high over these distressing child-deaths as evidenced by the fact that bills were introduced by the Honorable Michael J.

Mansfield of Montana, and the Honorable John D. Sparkman of Alabama in the Senate, and by the Honorable Kenneth A. Roberts of Alabama in the House. Each of these bills required that future manufacture of refrigerators provide doors that could be easily pushed open from the inside. Between the years of 1954 and 1956 three hearings were held. Each hearing was quite similar in substance with the other.

The industry representatives deplored the fact that their products presented a menace to children, and gave assurances that with more time they could come up with a solution without the enactment of legislation. Much discussion was devoted to gasket pressures that could be tolerated and conceivably could be overcome by the efforts of an entrapped child—and yet maintain a low temperature that would protect food from spoilage.

It was at a hearing in 1956 before the House Committee on Health and Safety that I was invited to testify, as I have been at each subsequent hearing on this subject, including that considering legislation for the establishment of National Accident Prevention Center. I had become vitally interested in this safety problem in my retirement, and had held some encouraging discussions with the Bureau of Standards in which I was urged to give my views to the congressional committee soon to hold hearings. At these hearings I proposed that the prospect for the perfection of a "fool-proof" safety device to be activated by the efforts of an entrapped child was extremely pessimistic. I held this was not due to lack of technical talent in American industry, but entirely to the uncertainty of what a captured child would—or would not—do in this situation. I urge that the search be expanded to seek some simple and standard means to be incorporated in future manufacture whereby an owner could ventile a box at any time it was out of service and exposed to possible entry by playing children. I cited a removable "port-hole" in the door as one possibility.

It was at this hearing that plans were disclosed to conduct tests with live children to observe their reactions to escape devices.

It was also at these hearings that the patience of the committee seemed to be overtaxed. The Chairman, near the end of the session, said, "It is the general feeling that the industry is dragging its feet on this proposition." * * * * unless something shows up in the very near future we are going to be put in the position of trying to get this legislation enacted, and I think you are going to be surprised at the popularity of this bill with the membership of the House. *The Bill was enacted into Public Law 930, on August 2, 1956—about sixty days later.*

This is the law which provides the magnetic door closures on all late model refrigerators with which I am sure you are familiar.

It may be interesting to note a more recent congressional committee reaction to industry's safety performance as expressed by the Honorable Abraham Ribicoff, Chairman of the Senate Committee considering automobile safety last March. Senator Ribicoff said (quote) "Yet I felt, and I still feel, that the great American industry, which is the backbone of the whole American industrial complex, has been dragging its feet in the field of safety features" (end of quote).

In announcing a new book last week, titled "Unsafe at Any Speed", by Ralph Nader, an attorney who helped do the background work for the hearing conducted by Senator Ribicoff, the Washington Post said (quote) "A blistering attack on the auto industry and the traffic safety organizations for foot dragging on auto safety devices, Nader says the National Safety Council, which compiles traffic safety statistics, is industry-dominated, and conducts no safety research. Its message is that only Federal regulation can make automobiles as safe as they should be." (end quote). It might be recalled that automobile manufacturers are also large producers of refrigerators, and that the National Safety Council has long been the "fountainhead" for public safety advice operating under a charter from the Congress.

Recently a large refrigerator manufacturer introduced a number of new models on the market which feature a wide assortment of "pop" art on the doors. One of these models makes the box resemble an outdoor telephone booth we now see on corners, roadsides, etc. which pictured young people piled high inside—one upon the other. This seemed like the antics of some college students a few years back. Many people were shocked at this model in view of the concern the industry had claimed in behalf of child safety. The General Federation of Women's Clubs, and the American Academy of Pediatrics vigorously protested the introduction of this model into homes as an invitation to children to imitate and risk entrapment and suffocation. *They both were politely told by the manufacturer that the model would remain on the market.* I cannot

imagine a more respected and reliable authority on child behavior and the danger in this design to children than the mothers of the General Federation of Women's Clubs, and the physicians comprising the American Academy of Pediatrics.

This all adds up, I think, to a reasonable doubt that the refrigerator hazard, or any other vital public safety problem requiring refined coordination and creative safety research, will be completely met by corporate management and the present national safety structure.

More and more it appears that something akin to a *National Accident Prevention Center* is needed that would conduct safety research and "clearinghouse" performance on a national industry-wide basis. Such a center has been proposed in the Congress and is frequently mentioned as a solution. Two hearings have been held on such a proposal by the House Committee on Health and Safety.

In 1957 as promised, the National Bureau of Standards and the National Electrical Manufacturers Association jointly conducted tests in which live children, volunteered by their parents, were used as subjects. These tests were designed to observe the escape efforts of children under simulated entrapment. My granddaughter, then 3 years old, was one of the subjects. She did not push her way out. She is now 12 and it is my hope she will not have children of her own to care for, before this problem is satisfactorily met. These tests were very skillfully conducted, producing no emotional disturbance to the children, and reflected an accurate picture of what a child would—or would not—do under actual entrapment.

I think the reports of the tests received rather shallow publicity on a national basis. Mr. Nate Haseltine, the distinguished writer on health and safety for the Washington Post, in a very comprehensive analysis, said "The results were somtimes ominous. Many of the 2-year old children made no escape attempt at all; they showed far less fear—or apprehension—than the 4 and 5-year olds. *They would have surely suffocated had the 'plaything' been a real refrigerator.*"

The Washington Star said, editorially, "A test of 201 children between 2 and 5 years of age, designed to study the reaction of a youngster trapped in a refrigerator has produced findings which do not make pleasant reading—only 97 of the 201 children tested were able to release themselves."

Nothwithstanding the fact that the industry, through the National Electrical Manufacturers, was collaborating and sharing costs of these tests, some manufacturers embarked on national advertising programs claiming extravagant "child-safety" benefits in push-open doors. The Federal Trade Commission induced the discontinuance of this advertising.

Another test, with 201 live children, was made in 1962—to test whether a luminous marker inside the refrigerator would improve the escape rate.

It did not.

For many years public safety guidance on this and other public safety hazards, has emanated from the National Safety Council in Chicago. This hazard was treated by the Council with great emphasis on discarded boxes in a guide (copyright 1954), titled "*Hazards of Discarded Iceboxes*". This guide recommended that doors, locking hardware and gaskets, be removed, or holes bored in the cabinets with an electric drill. That a temporarily idle box be turned faced against a convenient wall. Although press reports for many years showed that many children were being suffocated in idle, but serviceable boxes, that were in no sense discarded, and child behavior studies showed underdependability in safety protection from "push-open" doors, this advice remained unchanged until 1963.

It remained for a lesser known agency to supply the first "breakthrough". In 1963, the Federal Safety Council in the Department of Labor, published a refrigerator safety guide for use of government departments, many of which operated public housing for employees and their families. This guide clearly indicated the danger to exist in any idle unit, whether having positive locking mechanisms, or "push-open" doors, and advocated several novel safeguards for each. Later, the U.S. Public Health Service in the Department of Health, Education and Welfare, published a similar guide in which some additional improvised safeguards were added—but all having the same methods to prevent child entrapment—either to secure the doors tightly closed or slightly ajar to admit ventilation to the inside of the cabinet. It was my privilege to serve in a consulting capacity in the preparation of both of these official safety guides.

While these improvised safeguards are the best found after a decade of search, and *must be depended upon for child protection in the case of a rather constant national inventory of 80 to 90 million units of present design in use,*

they are still cumbersome for a housewife or an owner to employ. It is very doubtful if they should stand as the ultimate in child protection in this hazard. The General Federation of Women's Clubs stated at the last congressional hearing in 1963 that the "General Federation of Women's Clubs applauds the improved protection that may be afforded by the standards under Public Law 930, but feels that the child behavior studies of 1957 and again in 1963, indicate *more improvement should be sought in future manufacture.*"

Congressman Broyhill, who has taken many outstanding and positive actions to improve child protection has had a bill before the House Committee on Health and Safety for quite some time. His bill would amend PL 930 by requiring further safety improvement through design in future manufacture. This bill has been endorsed by the American Academy of Pediatrics, the General Federation of Women's Clubs, the Veterans of Foreign Wars, the Arlington Safety Council, and other safety organizations. Congressman Broyhill is presently considering extending the provisions of his bill to include air-tight dishwashers. I mention these facts in event you may wish to evaluate the effort at correction through amending existing national legislation.

In 1954 a Virginia law was enacted which generally required that doors be removed from air-tight cabinets under some circmustances. The Arlington Safety Council recently passed a resolution asking the Arlington delegation to cause a review to be made of this law in the light of developments since its enactment.

I believe that the last eleven years of concerned public attention to this preventable childhood hazard has produced these results:

(a) That the standard safety devices under a public law afford less than 50% of the child protection hoped for in its enactment.

(b) That cumbersome and difficult improvised safeguards must be employed to protect children in all presently designed models.

(c) That the best hope for improvement lies in inducing the industry to build into future design and manufacture one simple manual safeguard that would replace these numerous improvisations.

(d) That the long delay in partial improvement in the child-refrigerator problem, and now the general dissatisfaction with automobile safety, strongly suggests a need to review the adequacy of our overall national safety structure.

This concludes my remarks and if there are any questions I shall be happy to try to answer them.

(Whereupon, at 11:35 a.m., the subcommittee was adjourned, subject to call.)

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