CHILD-RESISTANT PACKAGING OF HOUSEHOLD SUBSTANCES

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMERCE AND FINANCE

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-FIRST CONGRESS

SECOND SESSION

ON

H.R. 6179, H.R. 6180, H.R. 16541, H.R. 16884, and S. 2162

BILLS TO PROVIDE FOR CHILD-RESISTANT PACKAGING TO PROTECT CHILDREN FROM SERIOUS PERSONAL INJURY OR SERIOUS ILLNESS RESULTING FROM HANDLING, USING, OR INGESTING ANY HAZARDOUS SUBSTANCE, AND FOR OTHER PURPOSES

(And Similar Bills)

JUNE 8 AND 9, 1970

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Additional material submitted for the record by—

CHILD-RESISTANT PACKAGING OF HOUSEHOLD SUBSTANCES

MONDAY, JUNE 8, 1970

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCE AND FINANCE,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to notice, in room 2325, Rayburn House Office Building, Hon. John E. Moss (chairman) presiding.

Mr. Moss. The subcommittee will be in order.

This morning the Subcommittee on Commerce and Finance is beginning hearings on a number of similar bills designed to require household substances which are accessible to young children and which may cause injury or illness to be contained in special packaging that is significantly difficult for children under six years of age to open but not difficult for normal adults to properly use.

One of these bills is my own, H.R. 16541. Another, H.R. 16884, was introduced by our colleagues on this committee, Mr. Jarman and Mr. Rogers. Still another is S. 2162 which has already passed the Senate and was referred to this committee.

There is no need for any further statement on my part since I believe that this legislation is substantially noncontroversial.

(The text of H.R. 6179, H.R. 6180, H.R. 11783, H.R. 14094, H.R 16541, H.R. 16884, H.R. 17016, H.R. 17057, and S. 2162 and departmental reports thereon follow:)

[H.R. 6179, 91st Cong., 1st sess., introduced by Mr. Bell of California on February 5, 1969]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to protect children and others from accidental death or injury by authorizing safety closures to be required for drug containers.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. Paragraph (a) of section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 (a)) 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 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."

SEC. 2. Chapter V of such Act is amended by adding the following new section at the end thereof:

"REGULATIONS PRESCRIBING SAFETY CLOSURES

"SEC. 512. (a) The provisions of subsections (e), (f), and (g) of section 701 shall apply to and govern proceedings for the issuance, amendment, or repeal of any regulations under clause (5) of paragraph (a) of section 501 (relating to safety closures for retail containers for drugs). In the development of any such regulation, the Secretary shall consult with appropriate interested persons, including representatives of industries which would be affected by such regulation, and shall give consideration to—

"(A) the latest available data in the field of safety closures for retail containers for drugs;

"(B) safety closures for retail containers for drugs currently recommended by (i) other Federal agencies, and (ii) public or private groups having an expertise in the field of safety closures for such containers; and

"(C) the technical and economic feasibility of complying with such regulation.

"(b) (1) The Secretary shall appoint an advisory committee (hereafter in this subsection referred to as the 'committee') which he shall consult before prescribing any regulation under clause (5) of paragraph (a) of section 501 (relating to safety closures for retail containers for drugs). The committee shall be composed of not less than fifteen members who shall be fairly representative of (A) industries manufacturing containers to which such regulation may apply, (B) independent testing laboratory personnel, (C) public and private nonprofit scientific and professional organizations expert on safety closures for such containers, and (D) the general public. Each member appointed by the Secretary shall hold office for not more than two years, except that any member may be reappointed.

"(2) Members of the committee who are not officers or employees of the United States shall, while attending meetings or conferences of the committee or otherwise engaged in the business of the committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding $100 per diem (including traveltime), and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized in section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently."

[H.R. 6180, 91st Cong., 1st sess., introduced by Mr. Bell of California on February 5, 1969]

A BILL

To amend the Hazardous Substances Act to provide safe packaging of toxic household substances in order to protect children.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Hazardous Substances Act (15 U.S.C. 1261–1273) is amended by inserting:

"TITLE I—MISBRANDED AND BANNED HAZARDOUS SUBSTANCES"

immediately above the heading of section 1, by striking out "this Act" wherever it appears in such Act (other than in section 1) and inserting in lieu thereof "this title", by renumbering sections 1 through 18 and references thereto as

sections 101 through 118, respectively, and by adding at the end thereof the following new title:

"TITLE II—PACKAGING OF TOXIC HOUSEHOLD SUBSTANCES

"SEC. 201. This title may be cited as the 'Safe Packaging Act.'

"PROHIBITION

"SEC. 202. (a) It shall be unlawful for any person engaged in the packaging of any toxic household substance (as defined in this title) for distribution in commerce, or for any person (other than a common carrier for hire, a contract carrier for hire, or a freight forwarder for hire) engaged in the distribution in commerce of any packaged toxic household substance, to distribute or to cause to be distributed in commerce any such substance if such substance is contained in a package which does not conform to the standards established pursuant to this title.

"(b) The prohibition contained in this subsection shall not apply to persons engaged in business as wholesale or retail distributors of toxic household substances except to the extent that such persons (1) are engaged in the packaging or labeling of such substances, or (2) determine by any means the nature, form, or content of packages in which such substances are contained.

"REGULATIONS

"SEC. 203. (a) It shall be the duty of the Secretary, by regulation, to set forth the identity of each substance or mixture of substances distributed in commerce which is a toxic household substance.

"(b) As soon as practicable after the effective date of this title, the Secretary shall promulgate regulations establishing standards for the packaging of any toxic household substance, or any class or kind of such substances, designed to prevent or substantially reduce the hazard of serious personal injury or illness to children reasonably likely to handle, use, or ingest any such substance.

"(c) The provisions of sections 551 through 559, 701 through 706, 3105, 3344, 5362, and 7521 of title 5 of the United States Code shall apply to all regulations promulgated under this title.

"(d) Regulations promulgated under this title shall specify an effective date for the packaging of each class or kind of toxic household substance which shall not be sooner than one hundred and eighty days or later than one year from the date such order is issued, unless the Secretary finds, for good cause shown, that an earlier or later effective date is in the public interest, and publishes his reasons for such finding.

"(e) The Secretary may promulgate regulations amending or revoking any standard for the packaging of toxic household substances established under this title upon his own initiative or upon application made by any person affected by that regulation, whenever the Secretary determines that such modification is necessary to conform to the requirements of this title or to any change occurring in the method of packaging of any toxic household substance.

"(f) In promulgating regulations under this section, the Secretary shall—

"(1) consult with the Federal Trade Commission with respect to the packaging of any toxic household substance that is not a food, drug, device, or cosmetic as each such term is defined by section 201 of the Federal Food, Drug, and Cosmetic Act, and, upon request, with the Special Assistant to the President for Consumer Affairs with respect to the packaging of any such substance;

"(2) publish in the Federal Register reasonable advance notice of his intention (A) to declare a substance a toxic household substance or (B) to establish any such proposed standards;

"(3) accord to persons who could be affected thereby reasonable opportunity to be heard with respect to any such declaration or proposed standard; and

"(4) consult with such other business concerns, consumer organizations, and public agencies as he deems appropriate.

"FURNISHING SAMPLE PACKAGES

"SEC. 204. Upon written request made, by the officer or employee designated by the Secretary for the purposes of this title to establish packaging standards as to any toxic household substance of any class or kind, to any producer or distributor thereof, such producer or distributor shall transmit promptly to that officer or agency a true and correct sample of each package used or to be used by that producer or distributor for or in connection with the distribution in commerce of any particularly described toxic household substance of that class or kind. Any person who, with intent to evade compliance with the requirement of this section fails to transmit any such sample to such authority promptly upon receipt of such request shall be fined not more than $1,000, or imprisoned not more than one year, or both.

"ENFORCEMENT

"SEC. 205. (a) The distribution in commerce or the causing to be distributed in commerce of any toxic household substance in violation of any of the provisions of this title or the regulations promulgated pursuant to this title, shall constitute a violation of section 301 of the Federal

Food, Drug, and Cosmetic Act and shall be subject to enforcement under the provisions of sections 302, 303, 305, 306, and 307 of such Act.

"(b) In the case of any imports into the United States of any toxic household substance covered by this title, the provisions of section 203 of this title shall be enforced by the Secretary of the Treasury pursuant to section 801 (a) and (b) of the Federal Food, Drug, and Cosmetic Act.

"ADMINISTRATION

"SEC. 206. (a) The Secretary, in exercising the authority under this title, shall utilize the services, research, and testing facilities of public and competent private agencies to the maximum extent practicable in order to avoid duplication in such facilities and services.

"(b) A copy of each regulation promulgated under this title shall be transmitted promptly to the Director of the National Bureau of Standards, who shall (1) transmit copies thereof to all appropriate State officers and agencies, and (2) furnish to such State officers and agencies information and assistance to promote to the greatest practicable extent uniformity in State and Federal standards for the packaging of toxic household substances. Nothing contained in this subsection shall be construed to impair or otherwise interfere with any program carried into effect by the Secretary of Health, Education, and Welfare under other provisions of

law in cooperation with State governments or agencies, instrumentalities, or political subdivisions thereof.

"REPORTS TO THE CONGRESS

"SEC. 207. The Secretary shall transmit to the Congress in January of each year a report containing a full and complete report on the administration and enforcement of this title during the preceding fiscal year.

"DEFINITIONS

"SEC. 208. As used in this title—

"(1) The term 'toxic household substance' means any substance or mixture of substances which (A) is toxic and (B) is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household if such substance or mixture of substances may reasonably cause serious personal injury or serious illness to children. Such term includes any substance which the Secretary by regulation finds, pursuant to the provisions of such section 203, meets the requirements of this paragraph, and such term includes any substance whether or not regulated as to packaging or labeling by other provisions of Federal law. Such term does not include any source material, special nuclear material, or byproduct material as defined in the

Atomic Energy Act of 1954 and regulations issued pursuant thereto by the Atomic Energy Commission.

"(2) The term 'toxic' means, with respect to household substances, any such substance which has the capacity to produce personal injury or illness to a child through ingestion, inhalation, or absorption through any body surface.

"(3) The term 'package' means any container or wrapping in which any toxic household substance is enclosed for consumption or use by individuals for purposes of personal care or the performance of services ordinarily rendered within the household, but does not include—

"(A) shipping containers or wrappings used solely for the transportation of any consumer commodity in full or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or

"(B) shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers.

"(4) The term 'commerce' means (1) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, or any territory or possession of the United States, and any place outside thereof, and (2) commerce within the District of Columbia or within any territory or possession of the United States not organized

with a legislative body, but shall not include exports to foreign countries.

"(5) The term 'person' includes any firm, corporation, or association.

"(6) The term 'Secretary' means the Secretary of Health, Education, and Welfare."

EFFECTIVE DATE

SEC. 2. The amendment made by this Act shall take effect on the first day of the sixth month beginning after the date of enactment of this Act.

[H.R. 11783 and H.R. 14094, 91st Cong., 1st sess., introduced by Mr. Corman on June 2, 1969, and by Mr. Rosenthal on September 30, 1969, respectively, and

[H.R. 16541 and H.R. 17016, 91st Cong., 2d sess., introduced by Mr. Moss on March 18, 1970, and by Mr. Jarman on April 15, 1970, respectively, are identical as follows:]

A BILL

To amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, 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 "Poison Prevention Packaging Act of 1969".

SEC. 2. (a) Section 2 (f) (2) of the Federal Hazardous Substances Act (15 U.S.C. 1261 (f) (2)) is amended to read as follows:

"(2) The term 'hazardous substance' shall not apply

to economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act, nor to foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, nor to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house, but such term shall apply to any such substance for purposes of child-resistant packaging as authorized by this Act. The term 'hazardous substance' 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) Section 2 of such Act is amended by adding at the end thereof the following:

"(r) The term 'package' means any container or wrapping in which any hazardous substance is contained for consumption or use by individuals for purposes of personal care or the performance of services ordinarily rendered within or about the household, but does not include—

"(1) shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or

"(2) shipping containers or outer wrapping used

by retailers to ship or deliver any commodity to retail customers unless it is the only such container or wrapping."

SEC. 3. Section 3 of the Federal Hazardous Substances Act (15 U.S.C. 1262) is amended by redesignating subsection (d) as subsection (e) and by adding immediately following subsection (c) the following new subsection (d):

"(d) (1) If the Secretary finds that, notwithstanding cautionary labeling or any other requirements made pursuant to this Act, the Federal Insecticide, Fungicide, and Rodenticide Act, or the Federal Food, Drug, and Cosmetic Act, or any other provision of Federal law, the degree or nature of the hazard involved in the presence or use of any hazardous substance in or around households is such that the objective of the protection of the public health and safety of children requires the special packaging thereof, he may, after consultation with the members of the technical advisory committee provided for in paragraph (2) of this subsection, and subject to the procedures set forth in paragraph (2) of subsection (a) of this section, establish, by regulation, standards for the child-resistant packaging of such substance. Standards established under this subsection shall be designed to prevent or substantially reduce the hazard of serious injury or serious illness to children likely to handle, use, or ingest such substance.

"(2) For the purpose of assisting in developing such standards, the Secretary shall appoint a technical advisory committee composed of not more than fifteen members who are equally representative of the Department of Health, Education, and Welfare, manufacturers of household consumer products and widely recognized independent packaging consultants. The Secretary shall consult with the members of the technical advisory committee before finally establishing any standards pursuant to this subsection."

"(3) Members of such technical committees who are not regular full employees of the United States shall, while attending meetings of such committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding $100 per diem, including traveltime, and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently."

SEC. 4. (a) Section 4 (a) of the Hazardous Substances Act (15 U.S.C. 1263 (a)) is amended to read as follows:

"(a) The introduction or delivery for introduction into interstate commerce of any misbranded hazardous substance, banned hazardous substance or hazardous substance in a

package failing to comply with standards established pursuant to section 3 (d)."

(b) Section 4 (c) of such Act is amended to read as follows:

"(c) The receipt in interstate commerce of any misbranded hazardous substance, banned hazardous substance, or hazardous substance in a package failing to comply with standards established pursuant to section 3 (d) and the delivery or proferred delivery thereof for pay or otherwise."

(c) Section 4 (g) of such Act is amended to read as follows:

"(g) The manufacture of any misbranded hazardous substance, banned hazardous substance in a package failing to comply with standards established pursuant to section 3 (d) within the District of Columbia area or any area not organized with a legislative body."

SEC. 5. The amendments made by this Act shall become effective on the date of enactment of this Act except that the amendments made by section 4 (a) shall become effective on the first day of the second month after regulations have been established pursuant to the amendments made by section 3 of this Act.

[H.R. 16884 and H.R. 17057, 91st Cong., 2d sess., introduced by Mr. Jarman (for himself and Mr. Rogers of Florida) on April 9, 1970, and Mr. Jarman on April 16, 1970, respectively, and
[S. 2162, 91st Cong., 2d sess., referred to the Committee on Interstate and Foreign Commerce on May 12, 1970, are similar as follows:]

AN ACT

To provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, 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 "Poison Prevention Packaging Act of 1970".

SEC. 2. For the purpose of this Act—

(a) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(b) The term "household substance" means any substance customarily produced or distributed for sale for con-

sumption, use, or storage by individuals in or about the household and which is—

(1) any hazardous substance as that term is defined in section 2(f) of the Federal Hazardous Substances Act (15 U.S.C. 1261(f));

(2) any economic poison as that term is defined in section 2(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(a)); or

(3) any food, drug, or cosmetic as those terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(c) The term "package" means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, but does not include—

(1) shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof, or

(2) shipping containers or outer wrapping used by retailers to ship or deliver any commodity to consumers unless it is the only such container or wrapping.

(d) The term "special packaging" means packaging that is designed or constructed to be significantly difficult for children under six years of age to open or obtain a toxic or

harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

SEC. 3. (a) The Secretary, after consultation with the technical advisory committee provided for in section 5 of this Act, may establish in accordance with the provisions of this Act, by regulation, standards for the special packaging for any household substance if he finds that—

(1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such subtance; and

(2) the special packaging required by such standard is technically feasible, practicable, and appropriate for such substance.

(b) In establishing a standard under this section, the Secretary shall consider:

(1) the reasonableness of such standard;

(2) available scientific, medical, and engineering data concerning special packaging, childhood accidental

ingestions, illness, and injury caused by household substances;

(3) the manufacturing practices of industries affected by this Act; and

(4) the nature and use of the household substance.

(c) In carrying out the provisions of this Act, the Secretary shall publish his findings, his reasons therefor, and citation of the sections of statutes which authorize his action.

(d) Nothing in this Act shall authorize the Secretary to prescribe specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 4(1)(ii) of this Act, labeling.

(e) The Secretary, on his own initiative or upon petition of any interested party, and after consultation with the technical advisory committee, may exempt, in whole or in part, any category of product containing any substance subject to regulation, where he finds that such regulation, as applied to that category of product, is not necessary to protect children from serious personal injury or serious illness.

SEC. 4. For the purpose of making a household substance for which a standard has been established pursuant to this Act readily available to elderly or handicapped persons who may be unable to use special packaging, such household substance may be packaged in packages not complying with such standard provided that—

(1) such substance is (i) available in special packaging, and (ii) packaged in noncomplying packaging of only a single size which bears conspicuous labeling stating: "This package for households without young children": *Provided, however,* That the Secretary may prescribe by regulation a substitute statement to the same effect for packaging too small to accommodate such labeling, or

(2) such substance is (i) dispensed pursuant to the order of a physician, dentist, or other licensed medical practitioner who is authorized to prescribe, and (ii) noncomplying packaging is requested by the purchaser.

SEC. 5. (a) Proceedings for establishing, amending, or repealing of any standard pursuant to section 3 of this Act shall be promulgated pursuant to the provisions of section 701 (e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act, except that—

(1) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearings) shall be subject to the requirements of section 409 (f) (2) of the Federal Food, Drug, and Cosmetic Act; and

(2) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph

(2), and with the provisions of paragraph (3), of section 409 (g) of the Federal Food, Drug, and Cosmetic Act.

(b) For the purpose of assisting in carrying out the purposes of this Act, the Secretary shall appoint a technical advisory committee, designating a member thereof to be chairman, composed of not more than eighteen members who are equally representative of (1) the Department of Health, Education, and Welfare, (2) the Department of Commerce, (3) manufacturers of household substances subject to this Act, (4) scientists with expertise related to this Act and licensed practitioners in the medical field, (5) consumers, and (6) manufacturers of packages and closures for household substances. The Secretary shall consult with the technical advisory committee in making findings and in establishing standards pursuant to this Act.

(c) Members of the technical advisory committee who are not regular full-time employees of the United States shall, while attending meetings of such committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding $100 per diem, including traveltime, and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently.

SEC. 6. (a) Section 2(p) of the Federal Hazardous Substances Act (15 U.S.C. 1261(p)) is amended by striking out "which substance" and inserting in lieu thereof "if the packaging or labeling of such substance is in violation of an applicable regulation prescribed pursuant to sections 3 and 4 of the Poison Prevention Packaging Act of 1970 or if such substance".

(b) Section 2(z)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(z)(2)) is amended by striking out the period at the end of paragraph (h) of such section and inserting in lieu thereof a semicolon and the word "or" and by adding at the end thereof a new paragraph as follows:

"(i) if its packaging or labeling is in violation of regulations issued pursuant to sections 3 and 4 of the Poison Prevention Packaging Act of 1970."

(c) 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 subsection as follows:

"(n) If its packaging or labeling is in violation of regulations issued pursuant to sections 3 and 4 of the Poison Prevention Packaging Act of 1970."

(d) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end thereof a new subsection as follows:

"(p) If it is a drug and its packaging or labeling is in violation of regulations issued pursuant to sections 3 and 4 of the Poison Prevention Packaging Act of 1970."

(e) Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amended by adding at the end thereof a new subsection as follows:

"(f) If its packaging or labeling is in violation of regulations issued pursuant to sections 3 and 4 of the Poison Prevention Packaging Act of 1970."

SEC. 7. Whenever a standard established by the Secretary under this Act is in effect no State or political subdivision shall have any authority either to establish or continue in effect, with respect to any household substance, any standard for the special packaging or labeling of such substance which is not identical to the standard established under section 3 of this Act.

SEC. 8. This Act shall become effective on the date of its enactment. Each regulation establishing a special packaging standard shall specify the date such standard is to take effect which shall not be sooner than one hundred and eighty days

from the date such regulation is final. No such standard shall be effective as to household substances subject to this Act packaged prior to the effective date of such final regulation.

DEPARTMENT OF AGRICULTURE,
Washington, October 11, 1969.

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 June 4, 1969 requesting a report on H.R. 11783.[1] The bill is entitled "To amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, and for other purposes."

The bill would amend the Federal Hazardous Substances Act to extend the provisions of the Act for protecting the public health and the safety of children. The bill would authorize the Secretary of Health, Education, and Welfare to promulgate regulations establishing standards for the packaging of any hazardous substance designed to prevent or substantially reduce the hazard of serious injury or serious illness to children likely to handle, use, or ingest any such hazardous substance. The term "package" is defined under the bill. The interstate shipment of any hazardous substance, as defined under the Act (15 U.S.C. 1261), would be prohibited unless the package complies with the standards established by the Secretary. The term "hazardous substance" as defined under the bill does not apply to economic poisons regulated by this Department under the Federal Insecticide, Fungicide, and Rodenticide Act as now provided for under the Federal Hazardous Substances Act. This exemption notwithstanding, Section 3 (d) (1) contains provisions for establishing standards for the packaging of any hazardous substance, as defined under the bill, when the Secretary of Health, Education, and Welfare determines that the degree or nature of the hazard involved in the presence or use of any substance, as defined, is such that the objective of protecting the public health and safety of children requires special packaging.

This Department recommends the enactment of H.R. 11783 if amended as follows:

On p. 3, line 10, after the "comma" delete "the Federal Insecticide, Fungicide, and Rodenticide Act,".

On p. 3, line 12, after the word "law" insert the following "with the exception of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended".

A more detailed statement in support of this position is enclosed for your information.

This Department works closely with the Department of Health, Education, and Welfare on matters relating to pesticides. We will continue to coordinate activities relating to safe packaging standards for pesticides in protecting the health and safety of all persons using pesticides, especially children.

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

Sincerely,

CLIFFORD M. HARDIN,
Secretary of Agriculture.

EXPLANATION OF USDA POSITION ON H.R. 11783

The Department of Agriculture is responsible for administering the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended. This Act requires that all economic poisons moving in interstate commerce must be registered with this Department. In the registration process we are directly concerned with the avoidance of any kind of hazard involving the use of economic poisons, generally known as pesticides. We do not register a product until a determination is made that the product is both effective and safe for intended use according to directions on the product label. Labels that are easy to read and understand are a necessity. In March 1964, we strengthened our regulations with respect to labeling of registered products. Key warning and caution statements are required to be shown in a prominent place on the front panel of the pesticide label. The label must include the statement "Keep Our of Reach of Children" or its equivalent and a "signal" word—such as "Danger", "Warning" or "Caution"— which draws the user's attention to the necessity for handling the product with care. The registered label must be affixed to a package so as to be easily read.

[1] An identical report on H.R. 14094, dated October 16, 1969, was received by the committee.

The Act, as amended, does not presently include an affirmative provision specifically relating to packaging of pesticides. We do, however, refuse or cancel registration of pesticides if it is determined that the form in which the product is marketed is such that it may be considered an "attractive nuisance" especially to children or that it may be a hazard in some other manner. For example, registration has been refused or cancelled for rodent baits which have the appearance of cookies or candy, and ant baits in bottle caps. Also, the size of the package is considered. Limitations on package sizes of the more hazardous products are made in order to avoid or preclude purchase by the homeowner or inexperienced user. We intend to continue pursuing this aspect of pesticide registration to the fullest extent possible under our present authority.

In addition, we are considering a legislation proposal to amend the FIFRA in several respects. One of these is to strengthen the present authority regarding packaging of pesticides required to be registered. With respect to pesticides, this Department's proposal would cover more types of products than those which would include "the degree or nature of the hazard involved in the presence or use of any hazardous substance in or around households is such that the objective of the protection of the public health and safety of children requires the special packaging thereof".

Pesticides regulated under the FIFRA are now exempt from the Hazardous Substances Act (15 U.S.C. 1261(f)(2)). This Department recommends that this expemption be continued with respect to safe packaging requirements on the basis that (a) similar authority is being considered for packaging of pesticides by amendment to FIFRA: and (b) that enforcement of safe packaging requirements can be conducted more effectively by this Department as a condition of registration required in order for pesticide products to move in interstate commerce.

DEPARTMENT OF AGRICULTURE,
Washington, D.C., November 28, 1969.

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 February 12, 1969 requesting a report on H.R. 6180. The bill is entitled "To amend the Hazardous Substances Act to provide safe packaging of toxic household substances in order to protect children."

The bill would amend the Hazardous Substances Act to require the safe packaging of toxic household substances in order to protect the health and safety of children. It would authorize the Secretary of Health, Education, and Welfare to identify those substances consumed or used by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household which are potentially hazardous to children. The bill authorizes the Secretary to establish standards for packaging of toxic household substances designed to eliminate or reduce the threat of accidental poisoning to children. The interstate shipment of a toxic household substance, as defined in the bill, would be prohibited unless such substance was contained in a package which conformed to the standards established by the Secretary.

This Department is responsible for administering the Federal Insecticide, Fungicide, and Rodenticide Act, (FIFRA) as amended. This Act requires that all economic poisons moving in interstate commerce must be registered with this Department. In the registration process we are directly concerned with the avoidance of any kind of hazard involving the use of economic poisons, generally known as pesticides. We do not register a product until a determination is made that the product is both effective and safe for intended use according to directions on the product label. Labels that are easy to read and understand are, therefore, a necessity. In March 1964, we strengthened our regulations with respect to labeling of registered products. Key warning and caution statements are required to be shown in a prominent place on the front panel of the pesticide label. The label must include the statement "Keep Out of Reach of Children" or its equivalent and a "signal" word—such as "Danger", "Warning" or "Caution"—which draws the user's attention to the necessity for handling the product with care. The registered label must be affixed to a package so as to be easily read.

The Act, as amended, does not presently include an affirmative provision specifically relating to packaging of pesticides. We do, however, refuse or cancel

registration of pesticides if it is determined that the form in which the product is marketed is such that it may be considered an "attractive nuisance" especially to children or that it may be a hazard in some other manner. For example, registration has been refused or cancelled for rodent baits which have the appearance of cookies or candy, or ant baits in bottle caps. Also, the size of the package is considered. Limitations on package sizes of the more hazardous products are made in order to avoid or preclude purchase by the homeowner or inexperienced user. We intend to continue pursuing this aspect of pesticide registration to the fullest extent possible under our present authority.

In addition, we are considering a legislative proposal to amend the FIFRA in several respects. One of these is to strengthen the present authority regarding packaging of pesticides required to be registered. With respect to pesticides, this Department's proposal probably would cover more types of products than those which would be covered under the definition of a "toxic household substance" in Section 208, of H.R. 6180.

Pesticides regulated under the FIFRA are now exempt from the Hazardous Substances Act (15 U.S.C. 1261(f)(2)). This Department recommends that this exemption be continued with respect to safe packaging requirements on the basis that (a) similar authority is being considered for packaging of pesticides by amendment to FIFRA; and (b) that enforcement of safe packaging requirements can be conducted more effectively by this Department as a condition of registration required in order for pesticide products to move in interstate commerce.

Therefore, this Department favors enactment of H.R. 6180 if amended as follows:

On p. 7, line 22, after the word "law" delete the period and add the following clause: "except for economic poisons subject to the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended."

This Department works closely with the Department of Health, Education, and Welfare on matters relating to pesticides. We will continue to coordinate activities relating to safe packaging standards of pesticides in protecting the health and safety of all persons using pesticides, especially children.

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

Sincerely,

J. PHIL CAMPBELL,
Under Secretary.

U.S. ATOMIC ENERGY COMMISSION,
Washington, D.C., November 21, 1969.

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

DEAR MR. STAGGERS: Thank you for the opportunity to comment on H.R. 6180, a bill "To amend the Hazardous Substances Act to provide safe packaging of toxic household substances in order to protect children."

The Atomic Energy Commission has no objections to H.R. 6180.

We note that Sec. 208(1)(B) clearly excepts from the definition of "toxic household substance" source material, special nuclear material or byproduct material. We endorse this approach since it clearly avoids any implication of dual regulation concerning these materials.

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

Cordially,

C. E. LARSON,
Acting Chairman.

DEPARTMENT OF COMMERCE,
OFFICE OF THE GENERAL COUNSEL,
Washington, D.C., November 28, 1969.

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. 11783, a bill "To amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, and for other purposes."

The Federal Hazardous Substances Act (15 U.S.C. 1261 ff) requires that a hazardous substance (e.g., a substance which is toxic, corrosive, an irritant, a strong sensitizer, flammable, or generates pressure through decomposition, heat, or other means, and which may cause substantial personal injury or illness) bear a warning label containing specified information. The Act also authorizes the Secretary of Health, Education, and Welfare to ban and seize hazardous substances introduced into or while in interstate commerce.

H.R. 11783 would authorize the Secretary of Health, Education and Welfare to establish by regulation standards for "child-resistant packaging" when he finds that the degree or nature of the hazard involved in the presence or use of any hazardous substance in or around households requires special packaging. These standards would be designed to prevent or substantially reduce the hazard of serious injury or serious illness to children likely to handle, use, or ingest such substances. Before establishing standards, the Secretary would be required to consult with the technical advisory committee, composed of representatives of Health, Education and Welfare, manufacturers of household consumer products, and independent packaging consultants.

The Department of Commerce supports the enactment of H.R. 11783 as a means to protect consumers, especially children, from injury due to improper use of hazardous substances.

However, to provide for the maximum utilization of the efforts of private and public organizations, H.R. 11783 should provide that after the Secretary of Health, Education and Welfare concludes that a Federal standard is necessary, he should, in determining any Federal standards to be promulgated, give appropriate weight to any existing standards of such organizations.

The Department of Commerce would be pleased to cooperate with the Secretary of Health, Education and Welfare in establishing appropriate standards for the packages involved. The Department has done considerable work in analyzing questions of economic feasibility and continually evaluates, processes, cost, investment, and financing of industrial and production and commercial enterprise. We might aid the Secretary in seeking to minimize industry's financial costs of developing approved containers and closures and making the necessary changes in filling/packaging lines and equipment to provide the maximum feasible protection for children at the minimum cost to manufacturers and consumers.

We have been advised by the Bureau of the Budget that there would be no objection to the submission of our report to the Congress from the standpoint of the Administration's program.

Sincerely,

JAMES T. LYNN,
General Counsel.

THE WHITE HOUSE,
PRESIDENT'S COMMITTEE ON CONSUMER INTERESTS,
Washington, July 23, 1970.

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

DEAR CHAIRMAN STAGGERS: This letter is in response to your request for the views of this office on S. 2162 as passed by the Senate, a bill "to provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes."

Ultimately it would be preferable to adopt a comprehensive approach to the whole field of product safety rather than attacking only one aspect of the problem. However, this proposed legislation is needed for the adequate protection of children from accidental poisoning. Despite the existing labeling laws, many thousands of young children each year are victims of accidental ingestion of common household products which are injurious to their health. In most instances, the toxic substances involved are packaged in containers easily opened by children. Precautionary labeling is also important to warn adults of the potential dangers, but such labels have no meaning for small children. What is needed is some type of container for potentially harmful household products which can be opened without difficulty by adults, but which will be resistant to being opened by children.

My office testified before the Senate Commerce Committee, Subcommittee for Consumers, in support of the objectives of S. 2162 as originally introduced in the Senate stressing that "our investment in our human resources—children—

is too great to permit continued inaction. The curiosity which killed the cat should not be allowed to continue to kill children. Children must be protected from themselves; the cost of doing nothing is too high."

I am pleased that S. 2162 as passed the Senate incorporates the recommendation which my office had made to the Senate Commerce Subcommittee—adding consumer representatives to the technical advisory committee.

S. 2162 as passed by the Senate would authorize the Secretary of Health, Education, and Welfare, after consultation with a technical advisory committee, to establish by regulation standards for the special packaging for any household substance if he finds that (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and (2) the special packaging required by such standard is technically feasible, practicable and appropriate for such substance.

The wording of Section 3-(a) (1) would benefit from simplification, since the degree or nature of the hazard *presented by a substance* should be clearly stated as the controlling factor in making findings of the need for special packaging.

I would recommend rephrasing to read "The degree or nature of the hazard presented to children by a substance is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance. . . ."

For the purpose of this Act, the term "household substance" means any substance customarily produced or distributed for sale for consumption, use, or storage by individuals in or about the household and which is a hazardous substance as defined in the Federal Hazardous Substances Act, an economic poison as defined in the Federal Insecticide, Fungicide, and Rodenticide Act, or any food, drug, or cosmetic as defined in the Federal Food, Drug and Cosmetic Act. "Package" as defined in the Act means the immediate container or wrapping in which any household substance is contained for consumption, use, or storage by individuals in or about the household, but does not include "shipping containers or outer wrapping used by retailers to ship or deliver any commodity to consumers unless it is the only such container or wrapping."

The Secretary is prohibited from establishing particular packaging designs, product content, package quantity, or except as authorized under the Act, labeling. The Secretary may exempt categories of products containing any substance subject to regulation where he finds such regulation is not necessary to protect children from serious personal injury or serious illness.

There may be some difficulty in establishing standards for the child-resistant packaging of some substances, but I do not believe the difficulties to be insuperable.

In light of the advanced stages of technological development within American industry, I would hope and expect that safety closures could be developed which would protect children, yet not appreciably increase the cost of the product.

In order to make a household substance for which a special packaging standard has been established readily available to elderly or handicapped persons who may be unable to use special packaging, S. 2162 would authorize marketing of a household substance in packages not complying with a prescribed standard, provided that (1) the product was available in special packaging; and (2) the product is sold in noncomplying packaging of only a single size which bears conspicuous labeling stating, "This package for households without small children." The Secretary could prescribe by regulation a substitute statement to the same effect for packaging too small to accommodate such labeling. Prescription drugs would be required to be available in special packaging. Noncomplying packaging could be used for prescription drugs only upon the request of the purchaser.

I recognize the worthiness of intent in the provision of the bill to make household substances available in noncomplying packaging for the benefit of elderly and handicapped persons who might have difficulty using special packaging. However, I am seriously concerned that this provision, in actuality, will leave a wide loophole in the effective protection of children.

This loophole is enlarged by two other weaknesses in the bill. "Package" as defined in the bill pertains only to the "immediate container or wrapping in which any household substance is contained for consumption." It does not include the outer wrapping used by retailers to deliver any commodity to consumers unless it is the only such container or wrapping.

The language of Section 4 relating to the "warning" on noncomplying special packaging would seem to apply only to the "immediate container." However,

in reality, this warning could be meaningless to the consumer at the time of purchase since it would not be required on the "outer wrapping used by retailers to deliver any commodity to consumers."

I recommend that the definition of "package" be amended to clarify that the warning statement required for noncomplying packaging must appear on the outside container of the package in which the product is delivered by the retailer to the consumer as well as on the inside container.

Neither do I believe that the innocuous "warning" statement prescribed in the bill for the noncomplying package—"This package for households without young children"—will effectively alert the consumer as to the reason why the product should not be purchased for use in households with young children.

Unfortunately, in practice, the one-size noncomplying package could well be given major display on the retail shelf while the special packaged product would not be available or not so prominently displayed. Couple this with the ineffective labeling statement, and we would have only "look-good" legislation. If we mean to adequately protect children, let us do it.

I respectfully urge the Committee to amend Section 4 of S. 2162 to authorize the Secretary to determine on a case-by-case basis whether noncomplying packaging should be permitted for a particular household substance.

In this connection, I would recommend that the Secretary be given authority to revoke a product's special packaging exemption if the Secretary finds that the manufacturer or distributor is using this exemption to defeat the intended purposes of the Act by such practices as packaging substantially all of a product in exempt packaging where the ultimate consumers are not entirely the handicapped or the elderly.

I also suggest that while the Secretary be denied authority to prescribe specific packaging design, he be authorized to prohibit certain designs which may be particularly attractive or confusing to children (as packaging designs for hazardous products which are similar to soft drink bottles). Industry, which will be represented on the technical advisory committee, would be expected to accept as its social responsibility development of such product design.

I also urge that the exact wording of the "warning" statement for noncomplying packaging not be specified in the legislation, but that the Secretary be authorized to prescribe a warning more directly related to the nature of the hazard, and that he be further authorized to specify the prominence and type size of labeling required on any noncomplying package.

I would also strongly recommend that the specific warnings prescribed by the Secretary include not only a verbal warning statement but a uniform set of symbols and illustrations indicating the type and degree of danger. Considerations also should be given to the inclusion of basic first aid information on the labels.

The Canadian Department of Consumer and Corporate Affairs has already promulgated regulations requiring warning labels on poisonous, flammable, explosive and corrosive products in everyday household use which include a uniform set of symbols showing both the type and degree of hazard as well as warning statements and basic first aid language. The new set of Canadian symbols were pre-tested in Ottawa area schools where a high precentage of children grasped their meaning instinctively. (Information and illustrations relating to the Canadian system are enclosed.)[1]

I would suggest that Section 7 relating to the effects of this Act on state and local laws and regulations be clarified in order to assure that states are not proscribed from regulating packaging of substances for which no Federal standard has been established.

With these recommended changes, this legislation should substantially contribute to the reduction in the number of needless accidental injuries and deaths of children. I am also hopeful that enactment of this legislation will foster voluntary competition among manufacturers to develop and promote as their social responsibility the safest possible household product containers.

I am advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration programs.

Sincerely,

VIRGINIA H. KNAUER,
Special Assistant to the President for Consumer Affairs.

Enclosures.[1]

* * *

[1] See pp. 34–37, this hearing.

DEPARTMENT OF CONSUMER AND CORPORATE AFFAIRS,
Canada, March 13, 1970.

BASFORD ANNOUNCES NEW WARNING LABELS

Consumer and Corporate Affairs Minister Ron Basford today announced regulations that will require new warning labels on poisonous, flammable, explosive and corrosive products in everyday household use.

Under the new requirements:

1. A uniform set of symbols will show both the type and degree of hazard.

2. Warning statements and basic first aid information will also appear on the labels in both official languages.

"Mounting evidence in poison control centres and hospital emergency wards across the country demonstrates the need for this measure," Mr. Basford said. "Thousands upon thousands of deaths, injuries and poisonings can be avoided by helping people know the dangers of products found in every household.'

The new set of symbols have been pretested in Ottawa area schools where a high percentage of children have grasped their meaning instinctively.

"It will still be necessary to educate children on the precise meaning of the symbols," the minister emphasized. "I hope we will have the support of parents and educators in making this program as effective as possible."

The new regulations, the first issued under the Hazardous Products Act, deal specifically with consumer chemical products such as bleaches, polishes, sanitizers, glues and cleansers.

The symbols developed by the Consumer Affairs Bureau represent four hazards. A skull and cross bones mean poison. A flame means flammable. An exploding ball means explosive. A hand inserted into a container of liquid means corrosive.

Each of these symbols is placed inside an outline which shows the degree of severity of the hazard. An octagon, like a traffic stop sign, means danger. A diamond, like a traffic warning sign, means warning. A triangle, like a traffic yield sign, means caution. There are 12 symbols in the full series which may be used in various combinations.

Describing the symbols, Mr. Basford said a skull and cross bones in an octagon, means danger, poison—it can kill you. A skull and cross bones in a diamond means warning, poison—it can make you very ill and can injure you. A skull and cross bones in a triangle means caution, poison—it can make you ill.

All consumer chemical products set out in the regulations must carry the appropriate symbols for poison, flammable, explosive, or corrosive, on the principal display panel of the container. The regulations also stipulate that the symbols must be a certain size depending on the size of the container. The degrees of hazard, danger warning, or caution must also be stated below the symol in a size of print related to the size of the container in order to assure easy recognition. In addition, a warning statement nad first aid treatment must aso appear on the container.

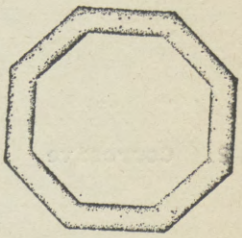
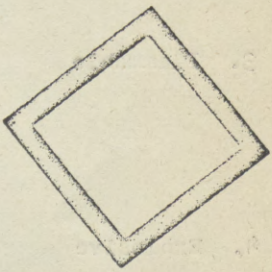
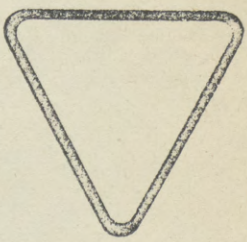
For example, a tube of glue for plastic or polystyrene would be labeled with two symbols: a flame in a diamond, and a skull and cross bones in a triangle. Directly below those symbols the words "warning, vapour harmful, flammable" must appear. The warning statement, "Use under well-ventilated conditions", must also appear on the tube with the recommended first aid treatment: "Contains toluene and acetone. If swallowed, do not induce vomiting. If overcome by fumes, give patient air. Call physician immediately". All wording required must be both in English and French. The rules apply to all regulated products whether manufactured in Canada or imported.

Mr. Basford stressed that while many such products are hazardous, they are also necessary and useful. The purpose of the regulations is to assure that consumers are warned of the hazard so they can take the proper precautions in handling the product, especially where small children are concerned.

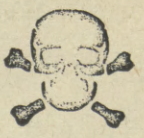
Establishment of these regulations means that literally all prescribed consumer chemical products sold in Canada must be relabelled. To give manufacturers reasonable time to do this, the regulations are set to come into force on June 1, 1971.

After that date a failure to comply with these regulations could result in a fine of $1,000 and/or imprisonment for six months on summary conviction, or imprisonment for two years for an indicatable offence.

Schedule A

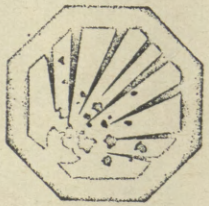
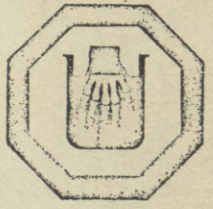
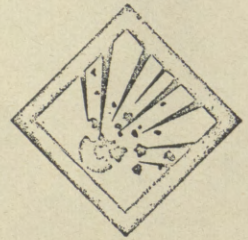
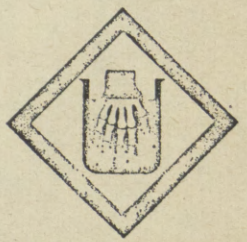
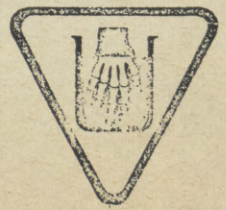
Degree of Hazard	Symbol
1. Danger	
2. Warning	
3. Caution	

Schedule B

Nature of Primary Hazard	Symbol
1. Poison	
2. Corrosive	
3. Flammable	
4. Explosive	

Schedule C

Rates of Size of Nature of Hazard Symbol to Degree of Hazard Symbol

	Poison	Flammable	Explosive	Corrosive
Danger				
Warning				
Caution				

FEDERAL TRADE COMMISSION,
Washington, D.C., July 23, 1970.

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

DEAR MR. CHAIRMAN: In response to a request by Chairman John E. Moss, Subcommittee on Commerce and Finance, Interstate and Foreign Commerce Committee, at the hearings before the Subcommittee on June 8, 1970, we are forwarding our views and comments on H.R. 16884, a bill "To amend the Federal Food, Drug, and Cosmetic Act and other laws to provide for child-resistant packaging to protect children from handling, using, or ingesting any hazardous substance, and for other purposes."

The Commission supports enactment of this proposed legislation which parallels the revised version of S. 2162, passed by the Senate on May 11, 1970.

H.R. 16884 may be cited as the "Poison Prevention Act of 1970." The purpose of the Act is to reduce injuries to, and illnesses of, young children arising from ingestion of toxic or harmful substances customarily produced or distributed for sale for consumption, use, or storage by individuals in or about the household. The Act authorizes the Secretary of Health, Education, and Welfare to require safe packaging of any hazardous substances as defined by the Federal Hazardous Substances Act (15 U.S.C. 1261(f)), any economic poison as defined by the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135(a)), and any food, drug, or cosmetic as defined by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

The Secretary is authorized to establish standards for special packaging for any such household substance if he finds that (1) the degree of hazard from such product requires such action for the protection of the public health and safety of children, and (2) the special packaging required by any such standard is technically feasible, practicable, and appropriate for such substance. The Secretary is directed to appoint a technical advisory committee composed of members representing Government, industry, the scientific and medical profession, and the public to assist in developing these standards. Failure to conform to any special packaging standard prescribed pursuant to the provisions of this Act would result in the substance being deemed misbranded under applicable provisions of the Federal Hazardous Substance Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act.

The bill also provides that the effective date of any regulation issued by the Secretary shall not become effective sooner than 180 days from the date such regulation is final. It is further provided that no State or political subdivision shall establish or continue in effect, any standard for special packaging or labeling which is not identical with Federal standards promulgated pursuant to the provisions of this Act.

The Commission believes that the need for the protection which this bill would provide has clearly been established by relevant statistics.

Each year up to two million children in this country swallow some substance that is poisonous to them; each year upwards of a million of these children require emergency medical treatment; each year upwards of three hundred of these children under five years of age die as a result of such poisoning. Many such cases require lengthy hospitalization and produce injuries from which the child may never recover. The substances which cause such tragic results are not primarily those commonly thought of as being toxic, but are such everyday products as aspirin, vitamin pills, cough medicines, soap, bleaches, furniture polish, and similar products.

The Commission, therefore, supports this proposed legislation designed to make children's primary environment—their home—a safer place in which to live. The Commission is of the belief that many incidents of ingestion of toxic substances can be averted, and the degree of potential injury substantially reduced by relatively simple and inexpensive container modifications. The Commission is also hopeful that enactment of this proposed legislation will promote competition among manufacturers to develop and promote the safest possible containers for household substances.

The regulatory scheme envisioned by this proposed legislation invests the Secretary of Health, Education, and Welfare with rulemaking authority to determine the products which constitute special hazards for children, and for which special safety packaging is feasible. A technical advisory committee to advise the Secretary is to be established. This procedure for rulemaking will

directly involve the public in the rulemaking process and provide needed flexibility to meet the needs of different industries producing diverse products. The Commission particularly supports the inclusion of consumers as members of the technical advisory committee.

The Commission is aware of the problems raised by special packaging for our elderly citizens and our handicapped citizens, and is of the opinion that any problems in this area can be satisfactorily resolved by the provision that substances for which special packaging standards have been established may nevertheless be marketed in one size of noncomplying packaging, or if dispensed by prescription, may be sold in ordinary packaging at the purchaser's request, for use of the elderly and the handicapped. The single-size container must bear conspicuous labeling stating: "This package for households without young children."

It is suggested, however, that the Secretary be given authority to revoke a product's special packaging exemption where a manufacturer or distributor is using this exemption to defeat the purposes of the Act; *i.e.*, packaging substantially all of a product in exempt packaging where the ultimate consumers are not entirely the handicapped or the elderly.

At the hearing on June 8, 1970, the Commission was requested to comment specifically on section 3(d) of the Act, which states that the Secretary is not authorized to prescribe "specific packaging designs," and on section 7 of the Act, which provides that States shall not have authority to establish or continue in effect, any standard for special packaging of any household substance which is not identical to Federal standards established under this Act.

The Commission is in accord with the intention of the provision that the Secretary shall not have authority to prescribe specific packaging designs. The establishing of specific packaging designs should best be left to industry. On the other hand, however, the Commission believes that the Secretary should be authorized to prohibit certain designs which may be particularly attractive or confusing to children; *e.g.*, packaging designs for hazardous products which resemble soft drink bottles.

The Commission is also of the opinion that Federal regulations in respect to special packaging of hazardous substances, once established by the Secretary, should preempt State regulations on the same subject, unless identical to or no less stringent than Federal regulations.

In conclusion, the Commission supports enactment of H.R. 16884.

By direction of the Commission.

CASPAR W. WEINBERGER, *Chairman.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., July 23, 1970.

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

DEAR MR. CHAIRMAN: This letter is in response to your requests for reports on H.R. 6179, a bill "To amend the Federal Food, Drug, and Cosmetic Act to protect children and others from accidental death or injury by authorizing safety closures to be required for drug containers;" H.R. 6180, a bill "To amend the Hazardous Substances Act to provide safe packaging of toxic household substances in order to protect children;" H.R. 11783 and H.R. 14094, identical bills "To amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, and for other purposes;" and S. 2162, a bill "To provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes."

H.R. 6179 would amend the Federal Food, Drug, and Cosmetic Act to authorize the promulgation of regulations requiring the use of safety closures for retail containers of drugs. In developing such regulations, the Secretary would consult with interested persons and with an advisory committee, composed of not less than fifteen members representing industries manufacturing containers to which the regulation would apply, independent testing laboratory personnel, public and private non-profit scientific and professional organizations expert on safety closures for such containers, and the general public.

H.R. 6180 would amend the Federal Hazardous Substances Act to redesignate present provisions of the Act as Title I and to add a new Title II regarding the packaging of toxic household substances distributed in interestate commerce. "Toxic household substance" would be defined as any substance or mixture of substances which is toxic (i.e., capable of producing personal injury or illness to a child through ingestion, inhalation, or absorption through any body surface) and which is customarily sold through retail channels for use by individuals for personal care or performance of services in the household if such substance or mixture may cause serious personal injury or serious illness to children.

The Secretary would be required to promulgate regulations identifying and establishing saftey packaging standards for "toxic household substances," which may include any substance whether or not its packaging or labeling is regulated by other provisions of Federal law (except materials defined in the Atomic Energy Act and implementing regulations). Distribution of toxic household substances not in conformity with such packaging standards would be prohibited and would be subject to enforcement under provisions of the Federal Food, Drug, and Cosemetic Act. The Secretary would be required to submit to the Congress an annual report on the administration and enforcement of the new Title II of the Federal Hazardous Substances Act.

H.R. 11783 and H.R. 14094 would amend the Federal Hazardous Substances Act to authorize the Secretary to establish standards for the child-resistant packaging of any hazardous household substances when he finds that the degree of hazard requires such action for the protection of public health and safety of children. For purposes of child-resistant packaging, as authorized by these bills, the term "hazardous substance" would apply to substances currently within the scope of the Act; economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act; foods, drugs, and cosmetics subject to the Federal Food Drug, and Cosmetic Act; and substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house. The Secretary would be directed to appoint, for the purpose of assisting in developing these standards, a technical advisory committee of not more than 15 members equally representative of the Department of Health, Education, and Welfare, household consumer products manufacturers, and widely recognized independent packaging consultants. Secretary consultation with committee members is required prior to the final establishment of any standards authorized by the bills. Formal rule-making procedures outlined in section 3(a)(2) of the Federal Hazardous Substances Act would govern proceedings for the establishment, amending, or repeal of packaging standards.

S. 2162 would authorize the Secretary, after consultation with a technical advisory committee, to establish standards for the special packaging of any household substance if he finds that (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and (2) the special packaging required by such standard is technically feasible, practicable, and appropriate for such substance. For the purpose of this Act, the term "household substance" means any substance customarily produced or distributed for sale for consumption, use, or storage by individuals in or about the household and which is a hazardous substance as defined in the Federal Hazardous Substances Act, an economic poison as defined in the Federal Insecticide, Fungicide, and Rodenticide Act, or a food, drug, or cosmetic as defined in the Federal Food, Drug, and Cosemetic Act. Categories of products containing any substance subject to regulation may be exempted where the Secretary finds such regulation is not necessary to protect children from serious personal injury or serious illness. The Secretary is prohibited from establishing particular packaging designs, product content, packaging quantity, and except as described below, labeling.

In order to make a household substance subject to a special packaging standard readily available to elderly or handicapped persons, the bill would authorize the marketing of a household substance subject to a packaging standard in noncomplying packaging. This would be permitted only if the product is also available in special packaging and if the product is sold in noncomplying packaging of only a single size which bears conspicuous labeling stating, "This package for households without small children." The Secretary could prescribe by regulation a substitute statement to the same effect for packaging too small to

accommodate this statement. Prescription drugs would be required to be available in special packaging, and noncomplying packaging could be used for prescription drugs only upon the request of the purchaser.

The Secretary would appoint a technical advisory committee with which consultation would be required prior to making findings, establishing standards, or making exemptions pursuant to this Act. The committee would be composed of not more than eighteen members equally representative of the Department of Health, Education, and Welfare, the Department of Commerce, manufacturers of household substances, scientists with expertise related to poison prevention packaging and medical practitioners, consumers, and manufacturers of packages and closures for household substances.

Proceedings for establishing, amending, or repealing packaging standards would be identical to those specified in section 3(a)(2) of the Federal Hazardous Substances Act. Each regulation establishing a packaging standard would specify the date the standard is to take effect which shall not be sooner than 180 days from the date the regulation is final. No such standard may apply to household substances packaged prior to the effective date of the final regulation.

Household substances in violation of this Act would be considered misbranded under the Federal Hazardous Substances Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act and subject to the penalties imposed under these Acts. Whenever a standard established under this Act is in effect, no State or political subdivision may establish or continue in effect, with respect to any household substance, any standard for the special packaging or labeling of such substance which is not identical to the standard established under this Act.

In view of the widespread and continuing involvement of small children in accidental poisoning episodes, the Department of Health, Education, and Welfare concurs fully with the objectives of the proposed legislation. We firmly believe our Department's educational and enforcement programs have made a significant impact in reducing the number of deaths and injuries caused by hazardous household substances. A high incidence of these accidents persists, however, especially among children. The National Center for Health Statistics of the Public Health Service recorded the death of 325 children from accidental poisoning in 1967, the last year for which the complete mortality data are available.

In 1969, 420 poison control centers reported over 116,000 ingestions of drugs and potentially toxic household products. Children under five years of age were involved in 76,155 of these ingestions, and 3,844 hospitalizations occurred within this age group as a result of these accidents.

The State of Illinois reported 12,503 ingestions in children under five years of age in 1968. The Los Angeles California poison control center, which services much of Southern California, reported 13,404 cases in 1968. These reports are made whenever a physician or parent, following an ingestion of a product by a child, contacts the center for information. Thus, the product involved does not always represent a hazardous substance. Many physicians who are already familiar with treatment procedures for certain drug intoxications and household products ingestions do not need to seek treatment information. Consequently, the number of total ingestions is unquestionably higher than the figures reported from the centers.

Statistics compiled by the National Clearinghouse for Poison Control Centers have shown that drugs and medicines consistently account for about fifty percent of the total poisoning accidents involving small children. Aspirin is the most frequently involved drug product. Cleaning and polishing agents, cosmetics, turpentine and related paint products, pesticides, petroleum products, and plants followed drugs in descending frequency in the accidental ingestions reported in 1969.

At first glance, the total of 325 child deaths from accidental poisoning reported for 1967 may not seem large in relation to the 116,000 incidents reported for this age group. But surely everyone concerned with his problem will agree that even one avoidable death is one too many and that every effort should be made to reduce the number of such deaths. It should be pointed out that the morbidity reported among these children, rather than the number of deaths reported, is often a better indication of the hazard involved. Morbidity relates to those children who survive the injury resulting from the accident. Some chemicals cause serious illness requiring lengthy hospitalization and produce injuries from which the child may never fully recover. Mere reading of these

statistics does not communicate the underlying tragedy; this can be appreciated only by those who have visited or treated hospitalized children who have ingested furniture polish containing petroleum distillates, lye, dishwasher detergents, of other hazardous products commonly found about the home. We believe that many child poisoning incidents could be averted or, at the very least, the degree of potential injury could be substantially reduced by relative simple modifications in product containers or closures.

The Department of Health, Education, and Welfare testified on October 1, 1969 before the Subcommittee on the Consumer of the Committee on Commerce, in support of safety packaging legislation when the original version of S. 2162 was being considered by the Senate. H.R. 11783 and H.R. 14094 are identical to that version. Subsequent to the hearing, we have worked with the Senate Committee staff regarding some of the changes we suggested in our statement and on several amendments to S. 2162 which were proposed.

Of the five bills that are the subject of this report, we believe that S. 2162, as passed by the Senate on May 11, 1970, offers the most suitable format for legislation to provide for child-resistant packaging of hazardous household substances. However, as our witnesses indicated during their appearance before your Committee on June 8, 1970, we do have a number of reservations about certain provisions of S. 2162. We believe that a number of changes need to be made in the bill, a discussion of which follows, to effect the purpose for which the bill is intended. Our comments in this regard also apply to H.R. 16884 and H.R. 17057, two bills which were considered at your recent hearings but on which we have not been asked to report.

1. We are concerned about the provisions of section 4 of the bill which would allow the marketing of household substances in noncomplying packages. We recognize that the stated intent of this section is worthy, i.e., to make household substances available to handicapped and elderly persons who may have difficulty using special packaging. However, we fear that this section, by permitting across-the-board the marketing of any household substance subject to a packaging standard in noncomplying packaging, opens a vast loophole which could seriously deter us in our efforts to use this legislation to reduce the incidence of accidental ingestions of these products by young children.

We would prefer that the Secretary be authorized to determine those cases in which noncomplying packaging should be permitted for particular household substances, based upon findings that (1) the substance will be widely marketed in special packaging which conforms with standards established under the Act; and (2) noncomplying packaging is necessary to permit such substance to be readily used by elderly or handicapped persons.

2. We believe further than the warning statement required for noncomplying packaging should not be specified in the statute, but that the Secretary should be authorized to prescribe specific warnings more directly related to the nature of the hazard of the product involved. The statement specified in section 4(1)(ii) of the bill is so innocuous as to be hardly recognizable as a "warning" and thus would be ineffectual in alerting consumers with small children to purchase the product contained in special packaging.

3. During our appearance before the Committee, we were requested to consider the need for amending the bill to specify the prominence and type of the required labeling of noncomplying packaging. We believe a preferable approach would be to insert a provision in the bill authorizing the Secretary to prescribe by regulation the specifications for prominence and type size of labeling required on noncomplying packaging.

It may be desirable to amend S. 2162 to provide for general authority to promulgate regulations for the efficient administration of the Poison Prevention Packaging Act, including refinements of definitions stated therein and specifications for conspicuousness of labeling. (Such regulation-making authority is available for the enforcement of this Act under provisions of the Federal Hazardous Substances Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act.)

4. During our appearance before your Committee, we were requested to provide assistance to the Committee regarding the feasibility of amending the administrative provisions of sections 5 of S. 2162 and similar bills. The Committee may wish to consider the substitution of the procedural and judicial review provisions specified in section 3(e) of the Federal Hazardous Substances Act as recently enacted by the Child Protection and Toy Safety Act of 1969

(P.L. 91-113). Under section 3(e) of the Act, determinations by the Secretary are made in accordance with section 553 of title 5 of the United States Code unless the Secretary elects formal rule-making procedures as provided in section 701(e), (f), and (g) of the Federal Food, Drug, and Cosmetic Act, and judicial review of such determinations is provided when requested by adversely affected parties. These provisions—together with the broad representation (including representatives of affected industries) and the important role of the technical advisory committee in assisting the Secretary—should provide adequate procedural safeguards for interested persons and should at the same time permit the Department to take necessary action to protect the health and safety of children.

5. We also believe that section 7 of the bill regarding the affect of this Act on State and local law and regulations should be clarified. In present form this section, if read literally, would seem to outlaw a State or local safety standard for child-resistant packaging of a household substance even if there is no Federal standard for that substance, once a Federal standard has been established for *any* household substance. Minor changes in the wording of this section are needed to clarify that States are not proscribed from regulating packaging of substances for which no Federal standard has been established.

Our comments on other provisions of the bill are discussed in the enclosed memorandum. We would be pleased to provide all possible technical assistance to the Committee staff in its work on this legislation.

The Department of Health, Education, and Welfare favors enactment of S. 2162; subject to the changes recommended in this report. We believe this legislation can substantially contribute to a reduction in the annual number of accidental injuries and deaths caused by many consumer products found in the home environment.

We are advised by the Bureau of the Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

ELLIOT L. RICHARDSON, *Secretary.*

Enclosure.

MEMORANDUM TO ACCOMPANY REPORT BY THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON S. 2162

In addition to the changes in S. 2162 suggested in our report, we would also recommend that these points be clarified.

1. We believe that the definition of "package" needs to be amended to clarify that the warning statement required on the immediate label of noncomplying packaging must also appear on the outside container of the package in which the product is displayed by the retailer to the consumer. While this point may already be established in the legislative history of S. 2162 by its discussion in the Senate Committee Report (Report No. 91-845) we believe clarifying amendments to correct this flaw in the definition of "package" in section 2(c) of the bill would be most desirable.

2. We would prefer that section 3(a)(1) of the bill be rephrased to read "the degree or nature of the hazard presented to children by a substance is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance . . ." We feel that the degree or nature of the hazard *presented by a substance* should be stated as the controlling factor in making findings of the need for special packaging. The degree or nature of the hazard of a substance is evidenced in statistics and data on involvement of products in child ingestions, morbidity, and mortality. Certainly "the availability of a substance, by reason of its packaging" is a factor in the hazards presented by a substance implicated in poisoning episodes.

We believe that the present wording of this section is unduly circuitous and that simplification would be desirable.

3. In section 6 of S. 2162, there is need for a provision amending section 503(b)(2) of the Federal Food, Drug, and Cosmetic Act in order to clarify that prescription drugs as dispensed to the patient would be misbranded unless their packaging complies with section 3 of the "Poison Prevention Packaging Act of 1970."

4. In setting radiation standards for electronic products under section 358(c) of the Public Health Service Act, the Secretary is authorized to prescribe an effective date earlier than that specified in the statute when such action is in the

public interest. We believe that insertion of such a provision in S. 2162 would be desirable and recommend that the second sentence of section 8 of the bill be dephrased to read "Each regulation establishing a special packaging standard shall specify the date such standard is to take effect which shall not be sooner than one hundred and eighty days from the date such regulation is final, unless the Secretary, for good cause found, determines that an earlier effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier date shall apply."

5. The definition of "household substance" in section 2(b) of S. 2162 should be amended to cover "substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house," as provided in the original version of the bill. The hazards presented by such substances are evidenced in statistics on childhood poisoning accidents.

DEPARTMENT OF JUSTICE,
OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D.C., July 23, 1970.

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 S. 2162, a bill "To provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes."

The bill would amend the Federal Hazardous Substances Act (15 U.S.C. 1261 (p)), the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135(z) (2)), and the Federal Food, Drug and Cosmetic Act (21 U.S.C. 343; 352, and 362) to make it violations of those acts for packaging or labeling not to conform to regulations promulgated by the Secretary of Health, Education, and Welfare, after consultation with a technical advisory committee. The bill is intended to provide increased protection for the consuming public by establishing standards for special packaging of certain household substances (as defined in the bill) to make it difficult for young children to open and/or ingest the contents of packages containing hazardous products.

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 Office of Management and Budget has advised that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

RICHARD G. KLEINDIENST,
Deputy Attorney General.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF MANAGEMENT AND BUDGET,
Washington, D.C., July 24, 1970.

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 requests for our views on H.R. 6179, a bill "To amend the Federal Food, Drug, and Cosmetic Act to protect children and others from accidental death or injury by authorizing safety closures to be required for drug containers"; H.R. 6180, a bill "To amend the Hazardous Substances Act to provide safe packaging of toxic household substances in order to protect children"; H.R. 11783 and H.R. 14094, identical bills "To amend the Federal Hazardous Substances Act to provide for child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance, and for other purposes"; and S. 2162, a bill "To provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes."

In a report being furnished your Committee, the Department of Health, Education, and Welfare sets forth its reasons for recommending the enactment of S. 2162, with certain modifications, in lieu of H.R. 6179, H.R. 6180, H.R. 11783 and H.R. 14094.

We concur in the views of the Department of Health, Education, and Welfare, and, accordingly, recommend the enactment of S. 2162, subject to the changes recommended by the Department.

Sincerely,

WILFRED H. ROMMEL,
Assistant Director for Legislative Reference.

Mr. Moss. Mr. Keith, do you have any comment you would like to make at this time?

Mr. KEITH. I have no comment except to express the hope that you are right in your estimate.

Mr. Moss. I join you.

Our first witness this morning is Dr. Wegner, Deputy Assistant Secretary for Legislation (Health) from the Department of Health, Education, and Welfare.

STATEMENT OF DR. GLEN E. WEGNER, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH), DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY DALE C. MILLER, ASSISTANT DIRECTOR, DIVISION OF CASE GUIDANCE, BUREAU OF FOOD, PESTICIDES, AND PRODUCT SAFETY, FOOD AND DRUG ADMINISTRATION; HENRY L. VERHULST, DIRECTOR, POISON CONTROL DIVISION, OFFICE OF PRODUCT SAFETY, FOOD AND DRUG ADMINISTRATION; AND THEODORE ELLENBOGEN, CONSULTANT, HEW

Dr. WEGNER. Good morning.

Mr. Chairman, I am accompanied this morning by Dale C. Miller who is the Assistant to the Director, Division of Case Guidance of the Bureau of Foods, Pesticides, and Product Safety in the Food and Drug Administration; Henry L. Verhulst, Director of Poison Control Division of the Office of Product Safety, Food and Drug Administration; and Mr. Theodore Ellenbogen who is now Consultant to the Department of Health, Education and Welfare.

Mr. Chairman, with your permission I will go through the statement rapidly and my colleagues and I will be happy to answer any questions that you may have.

I am pleased to have this opportunity to discuss with you the several bills now before your committee which would require the use of child-resistant packaging of certain hazardous substances.

As you know, Mr. Chairman, the Department of Health, Education, and Welfare testified on October 1, 1969, before the Senate Commitee on Commerce, Subcommittee on the Consumer, in support of such legislation when the original version of S. 2162 was being considered by the Senate. Subsequent to that hearing, we have worked with the Senate committee staff regarding clarification of some of the points raised in our previous testimony and on several amendments to the bill which had been proposed.

The five bills now under consideration by this committee fall into two categories: (1) those which parallel the original version of S.

2162; namely, H.R. 16541 and H.R. 17016, and (2) those which parallel the revised version of S. 2162 which the Senate passed on May 11, 1970; namely, H.R. 16884 and H.R. 17057.

These proposals would authorize the Secretary of Health, Education, and Welfare to require safe packaging of any hazardous substance as defined by the Federal Hazardous Substances Act, any economic poison as defined by the Federal Insecticide, Fungicide and Rodenticide Act and any food, drug and cosmetic as defined by the Federal Food, Drug and Cosmetic Act. The bills provide that the Secretary shall establish standards for "child-resistant" or "special" packaging when he finds that the degree of hazard from a household substance requires such action for the protection of the health and safety of children. The Secretary is directed to appoint a technical advisory committee to assist in developing these standards.

As you know, Mr. Chairman, this Department has been vitally interested in prevention of accidental poisoning for a number of years and has discharged specific program responsibilities in this area since July 1957. At that time, the National Clearinghouse for Poison Control Centers was established in the Public Health Service.

The primary function of this unit is to gather formulation data from all available sources with respect to household chemical specialty items, drugs, and other potentially hazardous items such as poisonous plants. As these data are obtained, product information index cards are developed for distribution to the Nation's poison control centers. The information presented on these reference card sets include product ingredients—when obtainable—and information on toxicity, symptomatology and treatment. This effect has helped save many lives. It has also lessened the severity of many injuries caused by hazardous household substances, by facilitating the prompt administration of antidotes and other emergency treatment procedures. A system has been devised to obtain voluntary reports of ingestions of chemicals from the poison control centers.

The National Clearinghouse, now operated by the Office of Product Safety in the Food and Drug Administration, also conducts an educational program for health professionals through the publication of a bimonthly "Bulletin." This publication contains information on new treatments, references to special hazards such as the glue sniffing problem and other relevant educational material.

In 1961, Congress enacted Public Law 87–319 authorizing the President to proclaim the third week of March as National Poison Prevention Week. The Division of Poison Control in the Food and Drug Administration serves as a program coordinator for these activities, which include private agencies and industry as well as governmental participation.

The Food and Drug Administration, through its enforcement of the Federal Hazardous Substances Labeling Act as amended by the Child Protection Act of 1966, has played a key role in our efforts to reduce the number of injuries and deaths attributable to such substances. The 1966 amendments provided for the banning of toys and other children's articles which are or which bear or contain hazardous substances and also authorized the banning of hazardous substances when cautionary labeling could not adequately protect the public health and safety.

Under the broadened authority of the Child Protection Act amendments the FDA has seized and banned large quantities of imported flammable dolls, do-it-yourself bomb and fireworks kits, and flammable fabric-covered play tunnels. We are currently in the final stages of banning carbon tetrachloride for household uses as well as the sale to the general public of large explosive fireworks for any use other than a bonafide crop protection purposes. Seizure actions have also removed from the market an extremely flammable water proofing masonry paint (now banned), necklaces made of the poisonous jequirity bean and numerous other hazardous household substances.

Mr. Chairman, we firmly believe our Department's educational and enforcement programs have made a significant impact in reducing the number of deaths and injuries caused by hazardous household substances. A high incidence of these accidents persists, however, especially among children. The National Center for Health Statistics of the Public Health Service recorded the death of 325 children from accidental poisoning in 1967, the last year for which the complete mortality data are available.

In 1969, 420 poison control centers reported over 116,000 ingestions of drugs and potentially toxic household products. Children under 5 years of age were involved in over 76,000 of these ingestions and nearly 4,000 hospitalizations occurred within this age group as a result of these accidents.

The State of Illinois reported 12,503 ingestions in children under 5 years of age in 1968. The Los Angeles, Calif., center which services much of southern California reported 13,404 cases in 1968. These reports are made whenever a physician or parent, following an ingestion of a product by a child, contacts the center for information. Thus, the product involved does not always represent a hazardous substance. Many physicians who are already familiar with treatment procedures for certain drug intoxications and household products ingestions do not need to seek treatment information. Consequently, the number of total ingestions is unquestionably higher than the figures reported from the centers.

Statistics compiled by the National Clearinghouse for Poison Control Centers have shown that drugs and medicines consistently account for about 50 percent of the total poisoning accidents involving small children. Aspirin is the most frequently involved drug product. Cleaning and polishing agents, cosmetics, turpentine and related paint products, pesticides, petroleum products, and plants followed in descending frequency in the accidental ingestions reported in 1969.

At first glance, the total of 325 child deaths from accidental poisoning reported for children under 5 years in 1967 may not seem large in relation to the 105,000 incidents reported for this age group. But surely everyone concerned with this problem will agree that even one avoidable death is one too many and that every effort should be made to reduce the number of such deaths.

It should be pointed out that the morbidity reported among these children in contrast to the number of deaths reported is often a better indication of the hazard involved. Mr. Chairman, morbidity, as you know, relates to those children who survive the injury resulting from the accident.

Some chemicals cause serious illness requiring lengthy hospitalization and produce injuries from which the child may never fully recover. The importance of considering morbidity in determining the seriousness of the problem is best illustrated by data collected by FDA.

Consider, for example, furniture polishes containing petroleum distillates. On ingestion these petroleum distillates are readily aspirated into the lungs by children and may lead to severe chemical pneumonitis in a matter of minutes.

In 1968, the Food and Drug Administration received reports of 782 children under age 5 who accidentally ingested petroleum distillate furniture polish. Of this number, 178 were hospitalized. In 1967, 675 ingestions and 170 hospitalizations were reported. In 1966, there were 567 ingestions and 100 hospitalized. Deaths occurring in this age group from ingestion of these furniture polishes numbered eight in both 1966 and 1967. Six such deaths have been recorded for 1968, although the mortality data for that year are not yet complete.

Mere reading of these statistics does not communicate the underlying tragedy; this can be appreciated only by those who have visited or treated these hospitalized children.

Children with a history of lye ingestion have been found to have corrosive burns of the esophagus, which on healing may cause stricture of the gullet and difficulty in swallowing. In spite of vigorous treatment, some of these children die within a few days from shock, infection, or perforation of the esophagus or stomach. Treatment of the other victims consists, in part, of dilation of the esophagus to relieve the strictures and relieve the blockage of the food passage. This surgical procedure is performed under general anesthesia and may have to be repeated many times. In one reported case, the child required 44 different hospital admissions and still was not fully recovered.

In other cases, reconstructive surgery of the intestinal tract becomes necessary. One 23-month-old child, as a result of lye ingestion, was hospitalized for over 5 months and required multiple operations. Despite this treatment, the patient subsequently died from a complication of the original injury.

In March 1967, the FDA, through a trade association, advised manufacturers of petroleum-based furniture polishes of our concern about the ingestion and aspiration hazard such products presented to small children. A conference with several major furniture polish manufacturers was arranged to consider ways of reducing this hazard. The three principal alternatives discussed were: (1) product reformulation to reduce the injury hazard; (2) attempting to make the products less attractive to children by changes in product color, fragrance, and/or methods of product packaging; and (3) classifying the products as banned hazardous substances under the Federal Hazardous Substances Act. As a result of that meeting, one of the firms started utilizing a type of child-resistant packaging. Another firm has reformulated their product to substantially reduce the aspiration hazard. The Food and Drug Administration is continuing to monitor these developments.

The hazard that packaging itself can add to corrosive products is illustrated by a household drain cleaner that has recently come to our

attention. The product, composed of 94 percent concentrated sulfuric acid, is packaged in a tightly capped pliable plastic container. Two accidents have been reported in which the person trying to unscrew the cap has been severely burned about the face, neck, and eyes when the contents sprayed explosively out of the bottle. The necessity of applying a gripping pressure on the pliable container in order to loosen the cap resulted in the sudden expulsion of the acid. A more rigid container would have prevented this particular hazard.

In view of the continuing and widespread involvement of small children in serious accidental poisoning episodes, this Department concurs fully with the objectives of the proposed legislation. We believe, Mr. Chairman, that many such incidents could be averted or, at the very least, the degree of potential injury could be substantially reduced by relatively simple container modifications. For example, liquid containers for furniture polishes might be designed to emit the product a few drops at a time. This would not seriously inconvenience adult users of the product but could well reduce the ingestion hazard for small children.

In November 1966, the Food and Drug Administration convened a meeting of distinguished pediatricians, public health officials, and top industry executives representing aspirin and over-the-counter salicylate product manufacturers. The purpose of this conference was to consider ways to more effectively control poisoning accidents among small children involving such products. Congressional hearings on the Child Safety Act of 1966 had focused national attention on the problem and the major item on the agenda of the FDA conference was the question of limiting voluntarily the quantity of children's aspirin per bottle. At that meeting, the industry members agreed to limit the number of 1¼ grain flavored aspirin to 36 tablets per retail container. The voluntary action became effective in July 1967.

The conference also considered the matter of safety closures and other forms of safe packaging for aspirin and other drugs. A safety closure committee was appointed to make a continuing study of improved safety closures for tablets containing salicylate. The appointment of this committee was an important and constructive result of that conference. The safety closure committee has met several times to consider criteria for performance standards against which safety closures and other forms of safe packaging for potentially hazardous household products can be measured. The committee's progress, as well as the difficulties it has encountered in certain areas, serve as a useful index to some of the problems that FDA would have to resolve following the enactment of child-resistant packaging legislation.

The committee has recognized that evaluation of safety closures must include consideration of the relative ease with which they can be opened and resealed by normal adults, as well as persons afflicted with arthritis and other conditions limiting use of the hands. A closure that results in too much consumer inconvenience will either be left open or the contents of the container may be transferred to another container, usually without proper labeling.

Furthermore, in developing performance standards for child-resistant closures, it may be necessary to accept certain levels of failure. In other words, some children of unusual dexterity, strength, or ingenuity will be able to open an otherwise effective safety closure.

Hence, it will be necessary to test designs for closures and other types of safety packaging in use situations in order to confirm their efficacy.

Mr. Chairman, I would now like to enumerate some of the provisions of H.R.16884, H.R. 17057, and S. 2162 as passed by the Senate on May 11, 1970.

These bills define "special packaging" as "packaging that is designed or constructed to be significantly difficult for children under 6 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time." The bills make it clear that special packaging should not be difficult for normal adults to use properly but recognize that special packaging cannot be relied upon to protect all children under 6 from access to substances in such packages.

Another provision of these bills is that they would allow the marketing of household substances in conventional packages in order not to impose the requirement of special or child-resistant packaging upon the handicapped or elderly individual who does not have young children in the household. Section 4(1)(ii) requires a statement "This package for households without young children" to appear on noncomplying packages. Prescription drugs could be dispensed in conventional packages only upon the request of the purchaser.

Section 3(d) of the proposals would prohibit the Secretary from prescribing specific packaging designs, product content, package quantity or labeling with the exception of the warning statement which I discussed a moment ago.

The bills provide furthermore for broad representation on a technical advisory committee and an important role for that committee in assisting the Secretary in establishing packaging standards. Under these bills, the Secretary would be required to consult with the committee before making any findings, before final establishment of standards, and before exempting products from a standard.

Under section 7 of the bills, States or political subdivisions would be prohibited from establishing or continuing packaging or labeling standards for household substances unless such standards are identical with established Federal standards. We do have some specific recommendations for changes in this language and we plan to incorporate them in our formal report which we will submit to the committee shortly.

Mr. Chairman, because of the severe time constraints we have faced in preparing for this morning's hearing, there are a number of aspects of the Senate-passed legislation which we have not had an adequate opportunity to fully assess. However, as I mentioned, we will submit our detailed comments and specific recommendations to this committee in the very near future. In addition, we will be most pleased to provide all possible technical assistance as your consideration of these proposals progresses.

I would reiterate at this point that the Department of Health, Education, and Welfare fully supports enactment of these proposals. We will, however, be making recommendations as to specific provisions in our report on these bills. We believe that these bills embody provisions which can substantially contribute to a reduction in injuries and deaths caused by many products found in the home environment.

Thank you for this opportunity to discuss this legislation. My col-

leagues and I will be happy at this time to attempt to answer any questions the committee may have and, if necessary, to submit further questions submitted at a later time. The gentlemen accompanying me are experts in this field. I really want to emphasize that this is potentially strong legislation and we want to give you every cooperation to move this as rapidly as possible.

Mr. Moss. Thank you very much, Dr. Wegner.

In reference to your statement on page 11 that because of the constraints of time you have not had an opportunity to deal with all of the substantive changes in the Senate legislation, I want to acknowledge the fact that indeed there were serious constraints placed upon you in preparing this presentation. In view of that fact, however, at what date would you feel the report referred to would be available to the committee?

Dr. WEGNER. I checked with our program people this morning. As you may know, the Food and Drug Administration has several very important items before the committee on the Hill at this time and they do have severe manpower restraints. Most of the data I feel are available to us now. It is a matter of putting that together and getting it through the office of the Secretary, Bureau of the Budget clearance process. I would estimate that in somewhere around 10 days to 2 weeks we ought to be able to have a cleared report for you. Again may I emphasize we will do our best to beat that deadline and we are certainly available on specific items, the entire staff, to help in any way possible.

Mr. Moss. I would hope that you could beat the 10 days.

Dr. WEGNER. We will do our best to move it very promptly.

Mr. Moss. The committee will be very anxious to go into markup on this legislation.

Mr. Moss. Mr. Keith.

Mr. KEITH. No questions, Mr. Chairman.

Mr. Moss. Mr. Blanton.

Mr. BLANTON. I have no questions, Mr. Chairman.

Mr. Moss. Mr. Eckhardt.

Mr. ECKHARDT. No questions.

Mr. Moss. I have some questions.

On page 2 in reference to the index card report of potentially hazardous items which is distributed to the Nation's poison control centers you use the phrase "the information presented on these reference card sets include product ingredients, when obtainable."

Dr. WEGNER. Yes.

Mr. Moss. What prevents you from obtaining in each instance the ingredients?

Dr. WEGNER. Well, we have an expert here that I will ask to comment specifically. It is my understanding that in many cases the manufacturers simply are not required to list all potential ingredients and therefore they may not be available to us.

Do either of you gentlemen want to comment more specifically?

Mr. VERHULST. There is no law requiring them to furnish them to us although most of industry has been most cooperative in doing so.

Mr. Moss. In order that I have a full understanding of this, there are hazardous substances which can be gotten to by children which do not require on the label the listing of contents?

Mr. VERHULST. The complete formulation is not required.

Dr. WEGNER. Very frequently they list many of the major components but not all of those of lesser percentages.

Mr. Moss. Are they required by the Hazardous Substances Act?

Mr. MILLER. The Hazardous Substances Act requires that the ingredients that contribute substantially to the hazard be named. That is so that the treating physician will know what kind of first aid is needed. Some of the products that are not subject to the Hazardous Substances Act will be covered by this new bill. I cannot speak for them.

Mr. Moss. Which new bill?

Mr. MILLER. The packaging bill. That includes pesticides, food, drugs, and cosmetics, all of which are exempt from the Federal Hazards Substances Act.

Mr. Moss. As to the need for packaging, not as to the need to list upon the package the ingredients contained therein, is that correct?

Mr. MILLER. That is right.

Dr. WEGNER. That is right.

Mr. Moss. I thought that in the amendments to the Hazardous Substances Act of 1966 or 1967 we gave the Secretary authority where there was an urgent problem to formulate immediately the regulations requiring disclosure or to remove the articles from the market.

Mr. MILLER. Remove them from the market.

Mr. Moss. Isn't that the leverage that can be used in either removing them from the market or labeling them?

Mr. MILLER. To remove them from the market requires a lengthy procedure.

Mr. Moss. No. We gave you some emergency powers there, too. I was the author of that piece of legislation in the House.

Mr. MILLER. Many of these products probably do not have the high degree of hazard contemplated by the banning provisions. They would be hazardous but not so hazardous that adequate labeling could not be written when the banning is restricted to.

Mr. Moss. Has there been a request made by the Department for expanding authority to require the listing of ingredients in the products which have shown up in this index as being hazardous?

Mr. MILLER. I don't know of any.

Dr. WEGNER. Not to my knowledge specifically in this area. In other areas we have requested expanded authority but not in relation to this legislation.

Mr. Moss. Apparently it is significant because you take the time in your statement in referring to the card sets to state that they do include product ingredients and then you modify that "when obtainable," so it must cause concern on some occasions.

Dr. WEGNER. I think General Counsel may have something to add.

Mr. ELLENBOGEN. I am a little puzzled. Under the Federal Hazardous Substances Act if it is a hazardous substance as defined in that act, as Mr. Miller just mentioned the label must state all of the ingredients and components which contribute substantially to the hazard.

Now under the Food and Drug Act if it is a drug the active ingredients must be stated on the label. If it is a food, it would probably become much involved here. If it is a cosmetic, however——

Mr. Moss. It is exempted if it is a cosmetic. That is one of the great voids in the law.

Mr. ELLENBOGEN. When it comes to economic poisons which are also covered by this bill, I would not know offhand. I would have to check whether the ingredients must be stated.

Mr. Moss. I have noted recently as a matter of personal observation in purchasing certain household items that I know to be dangerous that ingredients are not listed.

Dr. WEGNER. That is correct.

Mr. Moss. And you have no idea as to the formula or the ingredients that might contribute substantively to the hazard which are not even listed?

Dr. WEGNER. These are the products to which we refer here and I think your point is excellent. We will check this point specifically.

Mr. Moss. Over the weekend I took home the proof print of the special study that was prepared for and submitted to the Commission on Consumer Product Safety. I believe this was the proof copy that was released on June 2, and in there there were rather significant allegations of failure to exercise the powers which are readily available under existing law in an effective manner. Are you familiar with the content of that report?

Dr. WEGNER. Yes, but not in specifics this morning. We have been through it.

Mr. Moss. I think at a future date, as early as we can consistent with the schedule of this committee, that we ought to review with you the charges in that report. I imagine they will be repeated and expanded upon in the final report filed with the committee by the Commission on Consumer Product Safety. I would strongly suggest that with your General Counsel you explore the authority already in the Department for requiring this type of information that should be obtainable in far more instances than it is at the present time. I think the authority is with the Department.

Dr. WEGNER. That is an excellent suggestion.

Mr. Moss. What has happened to hold up carbon tetrachloride so very long? That has been in process for 2 or 3 years.

Dr. WEGNER. It has been a very lengthy procedure. Again I will ask one of these two people to comment more specifically, but basically as I understand it the procedure which we must use is 701(e) of the Food, Drug, and Cosmetic Act which is a terrible cumbersome procedure requiring public hearings and many other ways of delaying the process. We are now in the final stages of that process and I believe we do have other routes available to us under some of the newer forms of legislation.

For example, 3(e) in the 1969 amendments for the Child Protection Act allows an alternative where you can use either the 701(e) or this new streamlined procedure which allows you to essentially eliminate the cumbersome public hearings in regard to initial determinations by the Secretary with opportunity for a review at the appellate court level. If at this point the appellate court wishes the Secretary to consider more information through public hearing or whatever the petitioner may seek it, but the whole process is speeded up.

I think Mr. Miller might be able to comment more specifically, he works with this daily.

Mr. MILLER. Well, that is part of the problem on the carbon tetrachloride and part of the problem was internal, that is, lack of adequate personnel and some things like the attorney who was handling it resigned and left in the middle of it and then another attorney took over and had pneumonia, and several things like that happened. It was also our first experience with the hearing under this new amendment and will undoubtedly be faster the next time.

Mr. MOSS. When do you anticipate that work will be concluded on carbon tetrachloride?

Mr. MILLER. It should be in the very near future. It is pending only the resolution of one minor question which is the fact that there is one objection filed to the final order. That objection pointed out that many chemicals on the market contained trace amounts of carbon tetrachloride from the manufacturing process and they wanted some provision that would recognize these trace amounts which would not be harmful to health but also recognizing that it would be impossible to enforce a zero tolerance.

Dr. WEGNER. Mr. Chairman, if I may, on this point in terms of the general subject we would be most anxious to explore with the staff of the subcommittee as well as in our report the possibility of using this new streamlined procedure from the Child Protection Act of 1969 and incorporating that into this legislation which we feel in the long run would provide a less cumbersome process when such is necessary. As I understand the Senate-passed bill, it does not have this provision. We did not comment specifically on it in our testimony this morning, but as I say we will be most anxious to explore the possibility of the best process.

Mr. MOSS. Would you arrange with Mr. Borchardt to explore that possibility so that we can have this information?

Dr. WEGNER. I certainly will. Mr. Borchardt and I have worked very closely on other occasions and I think we can work this out very easily between us.

Mr. MOSS. On page 10 you state that the labeling provisions would be confined strictly to the warning: "This package for households without young children."

Dr. WEGNER. This is for noncomplying packages, you understand.

Mr. MOSS. And that is the only right you would have to prescribe standards on labeling?

Dr. WEGNER. Yes. This is one of the areas that we will certainly comment on very specifically in our formal report. We do have some difficulty with this provision because we fail to see how it really relates the manufacturing to the actual marketing process as such. I think the question is yet to be answered whether or not we should allow this whole section 4(1)(ii) to remain in the bill. We may have some stronger opposition to that as we clear it through the process, but there are some basic difficulties with this in terms of how it relates to the marketing process, whether or not this whole provision of allowing you to exempt one size package of each product can be used as a loophole to escape the basic provisions of the legislation itself.

Mr. MOSS. I am concerned with that, and I am also concerned with the fact that you can only require that a label bear a warning. I think

it is very important that you have discretion as to the prominence of the warning and as to the size of the type.

Dr. WEGNER. Yes. Certainly if the subcommittee insisted on this warning provision and this type of an exception, we certainly would want more in the way of signal words—for example, the words caution, danger, or warning in large letters and then have this provision below it. We feel that it is inadequate as it exists and we would like the opportunity to contemplate a bit further on this and then submit our suggestions to you in a formal report.

As it stands I could comment in terms of the Department and professionally in terms of a pediatrician who has some experience in this field. I think this is an inadequate provision as it exists but we do not have alternative language that we could submit to you this morning; however, it will be in our formal report.

Mr. Moss. On page 9 you say:

> The committee's progress, as well as the difficulties it has encountered in certain areas.

What are the difficulties encountered to which you referred in that statement?

Mr. VERHULST. Mr. Moss, the committee is developing a standard testing procedure and we have found that even slight modifications in the number of children in a group will change the test results in determining the final data. Because of this, we are going to have to run another group-size test. We feel that we are closer to the determination of the size group necessary, number of children in the group and how many groups, so that we will come up with one set standard for testing procedures.

Dr. WEGNER. As you know, Mr. Chairman, Mr. Verhulst is a member of the Safety Closure Committee and has been since its creation.

Mr. Moss. I think it might be helpful at this point to have you supply for the record the names and the affiliations of the members of the committee and the name of the person who appointed them.

Dr. WEGNER. Yes, Mr. Chairman, it will be submitted at this time. We have it before us.

(The following letter was received for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., June 19, 1970.

Hon. JOHN E. MOSS,
Chairman, Subcommittee on Commerce and Finance, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. MOSS: During my appearance on June 8, 1970, before your Subcommittee concerning H.R. 16541, et al., the "Poison Prevention Packaging Act of 1970," you asked that we submit for the record a list of the members of the Safety Closure Committee, their affiliations, and by whom they were appointed.

Enclosed is a list showing the members of the Joint Industry-FDA Committee on Safety Closures and their affiliations.

The Safety Closure Committee came into being as a result of a conference of distinguished pediatricians, public health officials, and over-the-counter salicylate product manufacturers held November 21, 1966, by the Food and Drug Administration. The conference had been called to develop a voluntary agreement limiting the number of flavored aspirin tablets which may be packaged in a single container.

During the conference discussions, the subject of safety closures arose. Commissioner Goddard asked Edward Press, M.D., now Oregon State Health Officer, to chair an ad hoc committee to determine the state of the art in the develop-

ment and evaluation of safety closures. Dr. Press designated other members of the Committee, who are listed on the enclosure.

The Committee has continued to meet periodically, primarily to establish methodology to be used to test the efficacy of safety closures.

If we can be of any further assistance to you or other members of the Committee regarding this legislation please let us know.

Sincerely yours,

GLEN WEGNER, M.D.
Deputy Assistant Secretary for Legislation (Health).

JOINT INDUSTRY—FOOD AND DRUG ADMINISTRATION COMMITTEE ON SAFETY CLOSURES

1. Edward Press, M.D., Chairman, State Health Officer, Oregon State Board of Health, P.O. Box 231, Portland, Oregon 97201.
2. Jay M. Arena, M.D., Director, Poison Control Center, Duke University, Durham, North Carolina 27700.
3. Abe Bass, Ph.D., Plough, Incorporated, 3022 Jackson Avenue, Memphis, Tennessee 38101.
4. John B. Carroll, Assistant to the General Manager, Glass Container Manufacturers Institutes, Inc., 330 Madison Avenue, New York, New York 10017.
5. Lawrence A. Carvey, Secretary, Z66 Sectional Committee, American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.
6. Stanley L. Harrison, M.D., Secretary for Committees, American Academy of Pediatrics, 1801 Hinman Avenue, Evanston, Illinois 60204.
7. G. V. Mumford, Owens-Illinois, Inc., Duraglas Center, Box 1035, Toledo, Ohio.
8. Peter D. Orahovats, M.D., Vice President, Scientific Director, Bristol-Myers Products, 345 Park Avenue, New York, New York 10022.
9. M. L. Tainter, M.D., 90 Park Avenue, New York, New York 10016.
10. Henry L. Verhulst, Chief Poison Control Division, Department of Health, Education, and Welfare, 200 C Street, S.W., Washington, D.C. 20201.
11. Arthur Weaver, Vice President, Whitehall Laboratories, 685 Third Avenue, New York, New York 10017.

Mr. Moss. Now we get around to the packaging and labeling. You mentioned plants. How do we deal with plants, the poisonous types of plants?

Are there any proposals under consideration at this time?

Dr. WEGNER. Well, specifically we handle them on a case-by-case basis and gather data as the accidents happen. I think this is not an adequate procedure. We of course have some luck in terms of the botany of what goes on with poisonous plants and they are on record but in terms of the children and their reactions to the poison this could only be collected really in a retrospective manner. We have no long-range prospective study, however, that takes 40,000 children and then waits for their exposure to poisonous plants.

Mr. Moss. Would a packaged plant offered for sale be required to have a caution or a warning on it?

Dr. WEGNER. An ordinary plant or one that is potentially poisonous?

Mr. Moss. Let's take an oleander.

Dr. WEGNER. I don't know that we specifically addressed that question and I think it is a good one. We would like to explore that possibility.

Mr. Moss. There are other plants that are equally dangerous.

Dr. WEGNER. Yes. Our usual experience there, the difficulty of gathering data or getting that data reduced to index cards, is the fact that most poisonous plants that cause poisoning to children do grow wild and therefore the problem is a real one. The question you raise,

I am just not aware of it. If the problem has been specifically addressed we will report the findings to you.

Mr. Moss. We are increasingly packaging everything.

Dr. WEGNER. Yes, we are.

Mr. Moss. I have no further questions.

Mr. Borchardt, do you have any questions at this time?

Mr. BORCHARDT. No.

Mr. Moss. Gentlemen, I want to thank you for your appearance.

Mr. Thompson.

Mr. THOMPSON. I would like to ask several questions if you don't mind, Mr. Chairman.

Mr. Moss. Certainly.

Mr. THOMPSON. I notice in the statement that apparently there was a voluntary act to suggest that aspirin not be sold in containers which would contain over 36 one and a quarter grain tablets. What if a child were to take 25 aspirin, a 4-year-old child? Would it be fatal?

Dr. WEGNER. Well, I must respond by saying that the toxicity is a dose related phenomenon in terms of body weight and metabolic balance. The salicylates are absorbed by the body and produce many problems. There is also an individual variation as to how a particular patient responds. It is also related to several other factors such as the child's state of hydration and degree of alkalyosis. So a 4-year-old child who has ingested 25 one and a quarter grain tablets likely would not die. Fatalities are averted in many other more serious cases by prompt medical attention including stomach lavage, proper hydration, and alkalization.

Mr. THOMPSON. I was wondering why the 36.

Dr. WEGNER. Again we are trying to achieve balance. I think the administration well realizes that the industry has some real problems. Advertising itself necessitates attractive packaging and different types of packaging, and the necessity of people to have aspirin in the home in terms of the frequency with which they must purchase it requires a certain basic number. What we are searching for is an equity of the two interests.

This package number is relatively safe, it will take care of most people and yet it is not unduly cumbersome upon the consumer. I think 36 is a very reasonable number, especially if those 36 are in a safe container from which it is difficult for a young child to remove the contents.

Mr. THOMPSON. You speak of removing the top. The very last legal case that I had before coming to Congress involving a child, I guess about 15 months old, who swallowed some tranquilizers that the mother had obtained by prescription and had in her pocketbook. The child took the tranquilizers. They rushed the child to the doctor and the doctor did not pump the child's stomach although he knew the number of tranquilizers she had swallowed. The child died several hours later. Had that prescription container been so constructed that it was more difficult to open, the child would not have obtained these attractive tranquilizers.

Now do you have any proposals to these bills for prescription drugs?

Mr. Moss. Yes.

Dr. WEGNER. You are getting at the very core of what we are after here, Mr. Thompson. We would like this; professionally this is exact-

ly what we would like. We know that many medicines are attractive and that people who tend to be ill tend to be more careless and they have the medicine out that they are taking at the time; and, children do tend to ingest these medicines. Tranquilizers are very common ingestants.

Relating to the aspirin case that you just presented, this is one of the things that we are getting at here, to have everything labeled well enough so that a first aid person or physician can identify the product. Contact the local poison control center and get adequate aid. In some cases stomach lavage is not indicated; however, tranquilizers are taken in large numbers should be removed from the stomach.

Mr. THOMPSON. Now you mentioned on page 4 that approximately two-thirds of the cases reported to the 420 poison control centers involved children of 5 years of age.

Dr. WEGNER. Yes.

Mr. THOMPSON. In these instances do you feel that a container which was difficult, if not impossible, for a child to open would have drastically reduced the number of cases of the children under 5?

Dr. WEGNER. Without question. That is the very core of the legislation.

Mr. THOMPSON. Getting back to the aspirin point again, basically the container and not necessarily the number of tablets in there would be the prime factor. You would not want a child to take 30 aspirin tablets or you would not want him to take 100 tablets, but you would prefer to have a container so that it would be almost impossible for him to open.

Dr. WEGNER. Yes, that is absolutely true. You have to understand historically though at the time we had voluntary compliance of aspirin manufacturers we did not have adequate containers. The other thing is that aspirins do present a special problem. Over half of these routine child ingestions of drugs are aspirin, and especially the candy flavored aspirin which is a particularly attractive product.

There are professionals who argue that even though it is easier for a mother to entice a child to take a candy coated aspirin there are those who feel that they should be banned from the market. Here again you are balancing equity; the consumer on one side, the other side the law that restricts the manufacturer to the point where he cannot have a different enough product for the consumer to purchase.

Mr. THOMPSON. You make a point in here about furniture polish containing petroleum distillates. Would it be advisable possibly to require some type of a chemical which would have an immediate bad taste to be added to something like this in addition to possibly packaging?

Dr. WEGNER. Definitely these are theoretical possibilities. It turns out that hydrocarbons are very difficult to mask in terms of taste. Actually they are fairly distasteful products in themselves, but I think there particularly we can do a lot in the way of packaging. Ordinarily furniture polish requires only a few drops for a particular chair or table or piano, and it is not unduly cumbersome for the mother or the consumer to have to squeeze a few times to get this out, yet a few extra drops would be enough in a child's mouth to give a repulsive taste so that further ingestion would not ensue. A child

may vomit, have a fever or slight infection as a result of this but it is very unlikely that that would be fatal to that child. On the other hand, I can take you to stores and show you furniture polish bottles that look very much like baby bottles and it is just natural for young children to ingest the contents of such containers.

Mr. Moss. And some of them, if the gentleman would yield, have been recently given very appealing odors.

Dr. Wegner. Oh, yes. Yes, indeed.

There are two or three furniture polishes that are well known to every medical student, intern, nurse, et cetera. On an emergency ward there are just two or three that you just always know. A child can come in and you can smell his breath and you can make a diagnosis not only of the type of ingestion but often the brand. There are increasingly sophisticated techniques, of course, for identifying those which it is harder to determine but there are a few of these that certainly need new containers, there is no question about it.

Mr. Thompson. If they are in an aerosol container, it would be more difficult for a child.

Dr. Wegner. It could be, but it may be more dangerous. It is unlikely that a child would pour into his mouth from the bottle but he might try. However, he may spray caustic contents from the container into his eyes.

Mr. Thompson. If you are going to have large volume sales and your type container must be adjusted to the different type, a smaller container, I can see how you can supply a degree of protection to the child. If you get into the larger container where you are going to sell 5 gallons of polish or floor wax, it would be more difficult.

Dr. Wegner. Yes, Mr. Thompson. There you have again an attempt, I think, by the big stick of the Federal Government to balance against the equities that a consumer has and the product manufacturer has. It is not our intent to unduly restrict the manufacturer; it is our intent to get voluntary compliance, to work with them wherever possible and then to take a hard look at the data. If further Federal leadership is necessary, we plan to ask for it. If it is not, we would far prefer to stay out of it.

Mr. Thompson. In your statement you point out that it may be necessary to accept certain levels of failure. First of all, no one desires that any child ever be accidentally poisoned. I question whether or not, regardless of the most restrictive packaging you can possibly design, that you would completely eliminate accidents that would occur.

Dr. Wegner. That is right.

Mr. Thompson. So you do have to strike a reasonable balance.

Dr. Wegner. That is absolutely right. We don't want to create an impression that we want to have this unbalanced on one side. We feel we have an obligation to protect the children of this country and if industry can do that and work with us and help us, we desire that route. If they cannot, and if solid statistics show that they have not, then I feel that we must work with the Congress on the Hill to develop legislation that will provide some leadership. That is not meant in any way to be a threat but simply to look upon it as the facts exist. I have stated it about as diplomatically as I can state it.

Mr. Thompson. Do you find most industrial organizations and firms are willing to cooperate, and do you feel that there is an overt effort

made by industry to try to package their products in such a manner that it would be difficult for a child to open or do they simply not even consider it?

Dr. WEGNER. We might ask these two men on my left and right to respond. It is my impression that there is a great deal of variation in the manufacturers. We find some that are just bending over backwards to help in any way because they are looking down the road far enough to see that if they can really sell this idea of safe packaging educationally, that their product will then become the attractive product because once parents realize this is the safe product for the children, most would purchase it.

On the other hand, there are those—and I think the statistics show this—that have not been cooperative. This may be in part because of our failure in not moving ahead and asking them to work with us. We are doing everything we can to correct that. I think it is not the major problem.

I think if we just look at the statistics we see that even though many firms have tried and their attempt has been good, the goal of eliminating child poisoning has not been achieved. Their rhetoric has always been marvelous but when you look at the actual number, it is not good enough. One child is too many to die if we can prevent it let alone 325 in 1967.

Mr. THOMPSON. Well, let me ask you something else. Certainly you are not a design engineer of containers but cost-wise from the fringe knowledge you have on this would you say that there would not be a great increase in cost to change design of many containers that are on the market now and make them safe when you get into mass production of the container?

Dr. WEGNER. I will ask Mr. Verhulst to respond. I think there is some cost involved depending upon the type of container and design. If you have the individual punch-out type medicine—you know, you punch through a foil or sort of a plastic device—that is obviously going to be more expensive than to make 36 or 50 of these and put them all in one bottle.

Some of the more rigid containers that have a possible combination type device for removing the lid is certainly going to cost more than a screw top. We feel that the importance of this, however, outweighs the additional cost. Obviously, if you have product manufacturers before your committee they may have different feelings about it. I think it is a matter of what is important to us. We feel an obligation to lay out before the committee that this is important and outweighs the added cost.

Mr. THOMPSON. I just wonder if it would not be possible to design a somewhat complicated—not so complicated that the average adult could not get to the medicine but a somewhat complicated container that under mass production the cost differential would be very small.

Dr. WEGNER. We have some quite simple devices.

Would you like to comment?

Mr. VERHULST. From what some members of industry have told us, some of the safety closures that are being presently used or promoted have a very minimum increase in cost. So we could indicate that we might reach a good closure at a very small increase.

Dr. WEGNER. Mr. Miller has a comment, too.

Mr. Moss. Isn't it also true in some instances there might be a reduction in cost?

Mr. THOMPSON. Because of superior design.

Mr. VERHULST. We do not have a case in mind.

Mr. Moss. Let's take a petroleum distillate-based product that is presently dispensed in an aerosol can and it is decided to put this in a plastic container with a screw cap or maybe even one of these lift devices. That would probably cost less and not more, would it not?

Dr. WEGNER. It is possible, especially if it is mass produced.

Mr. Moss. It is in the realm of types of changes.

Mr. VERHULST. Yes.

Dr. WEGNER. Mr. Miller has something in reference to the furniture polish.

Mr. MILLER. As Dr. Wegner mentioned, we have been working for a couple of years with one of the trade associations on this furniture polish problem. It takes less than a teaspoon of this to be fatal if it gets into the lung. One of our suggestions was and still is that a very simple type of thing that might substantially reduce this is a shaker top where you could get out a few drops, enough to do the job. You see it on Worcester sauce, for instance, and soy sauce. It would be very inexpensive and enough polish could be gotten out to do the job but the child could not take a big drink of it.

Mr. THOMPSON. There again something like that may not be practical because it may clog.

Mr. MILLER. Not with these products.

Mr. THOMPSON. After several applications and sitting on the shelf.

Mr. MILLER. In this particular case it would not be true. One of the firms we talked to did that very promptly, others have not done it and that is one of the reasons for this kind of legislation which would enable us to get the rest of them to do it.

Mr. THOMPSON. Thank you very much.

Thank you, Mr. Chairman.

Mr. Moss. Thank you, gentleman. We will look forward to receiving the further information. You will work with Mr. Borchardt.

Dr. WEGNER. We will.

Mr. Moss. Our next witness is Mr. Gerald Thain, Chief of the Food and Drug Advertising Division of the Federal Trade Commission.

Mr. Thain.

STATEMENT OF GERALD J. THAIN, CHIEF, DIVISION OF FOOD AND DRUG ADVERTISING, BUREAU OF DECEPTIVE PRACTICES, FEDERAL TRADE COMMISSION; ACCOMPANIED BY EDWARD F. DOWNS, SENIOR TRIAL ATTORNEY

Mr. THAIN. Mr. Chairman, I am accompanied by Mr. Edward F. Downs who was the acting chief of the division which I now head until 2 weeks ago, and is now the senior trial attorney in that particular division.

I would like to request to submit the formal statement of the Commission subsequent to my testimony today. Because of the press of time I would like, not to change my prepared statement but to present it in a little more seemly fashion for the subcommittee.

Mr. Moss. In other words, you would like the opportunity to expand upon your statement by submitting additional comments for the record.

Mr. THAIN. Yes.

Mr. Moss. There is no objection to the request?

Hearing none, the record will be held open to receive the material.

Mr. THAIN. Thank you.

Mr. Chairman and members of the Commerce and Finance Subcommittee, I wish to thank you for this opportunity to present the views of the Federal Trade Commission concerning the bill to provide for special packaging to protect children from serious personal injuries or serious illness resulting from handling, using, or ingesting household substances and for other purposes. Chairman Weinberger had a longstanding commitment which prevented his appearance before you today, and he directed that I substitute for him.

The Commission supports the proposed legislation in the form in which it was passed by the Senate as S. 2162, the "Poison Prevention Packaging Act of 1970."

The purpose of the bill is to reduce injuries to, and illnesses of, young children arising from the ingestion of toxic or harmful substances customarily produced or distributed for sale for consumption, use, or storage by individuals in or about the household. The bill would require that such household substances be contained in special packaging which would be significantly difficult for children under 6 years of age to open or obtain a toxic or harmful amount of such substances within a reasonable time, but which would not be difficult for normal adults to use properly. This approach is clearly practicable; it takes into account the lesser strength and dexterity of young children and, although there are relatively few child-resistant containers on the market at present, a number of such containers are now in development, we understand. Furthermore, the efficacy of child-resistant containers in preventing access to the contents of the container by small children is established. Tests indicate that as much as 90 percent of poisoning due to medicines may be prevented by dispensing medicines in child-resistant containers or special containers. In addition, laboratory tests have indicated that child-resistant containers may baffle as many as 75 percent of the children confronted with them.

The scope of the proposed legislation extends across all product lines and types and includes all substances customarily produced or distributed for sale for consumption, use, or storage in or about the household. The Secretary of Health, Education, and Welfare is authorized to determine whether a substance should be contained in special packaging on the basis of its degree or nature of hazard to children. The Secretary would be empowered, after consultation with a technical advisory committee, composed of members representing industry, the public and members of the scientific and medical profession, to establish performance standards for special packaging designed to protect young children against obtaining harmful amounts of the packaged substances. Failure to conform to special packaging standards will result in the substance being deemed misbranded under applicable provisions of the Federal Hazardous Substances Act, the Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act and subject to the penalties therein prescribed.

The bill provides that the effective date of regulations will not be sooner than 180 days after final promulgation of said regulations. The bill further provides that States may not establish or continue in effect standards not identical with Federal standards.

Mr. Chairman, the Federal Trade Commission believes that the need for this kind of law has clearly been established by relevant statistics. Each year, up to 2 million children in this country swallow some substance that is poisonous to them; each year upwards of a million of these children require emergency medical treatment; each year upwards of 300 of these children under 5 years of age die as a result of such poisoning. I believe 325 deaths in 1967 are shown by the most recent statistics. The substances which cause such tragic results are not primarily those commonly thought of as being toxic but such everyday products as aspirin, vitamin pills, cough medicines, soap, bleaches, furniture polish, and similar products.

Perhaps even more telling than cold figures is the testimony of individuals who have experienced the severe pain of seeing what ingestion of household substances may do to their young children. The testimony of Mr. Alfred Snodgrass of Renton, Wash., before the Consumer Subcommittee of the Senate Committee on Commerce concerning the near death of his 18-month-old son as a result of ingesting dishwasher detergent power is illustrative. The child survived, fortunately, but his esophagus and windpipe were burned severely, his mouth and lips were blistered, and he required a tube in a hole in his throat for breathing, a tube sticking out of his abdomen for feeding, plus recurrent stretching, by another tube, of his scarred esophagus to stretch it back to usable size.

Personally, as the father of a 3-year-old child, instances such as these point up to me the need for such legislation as is before the subcommittee.

Such incidents indicate the necessity for legislation to protect this country's young children. It would be ideal, perhaps, to have comprehensive legislation covering all aspects of product safety for all members of the population enacted in one package. However, the luxury of time which would be required for the adoption of such legislation cannot be afforded.

The Federal Trade Commission is aware of the real problems raised by special packaging for our elderly citizens and our handicapped citizens, particularly those who suffer from arthritic conditions or otherwise which would make dexterity of their hand less than that of a normal adult, and it believes any problems in this area have been satisfactorily handled by the provision that substances for which special packaging standards have been established by nevertheless be marketed in one size of ordinary container not complying with the special packaging standard, or if dispensed by prescription may be sold in ordinary packaging at the purchaser's request for use of the elderly and the handicapped. The single size container must bear the label statement: "This package for households without young children."

If I could digress, Mr. Chairman, the Commission believes that such statement on these noncomplying packages clearly would have to be clear and conspicuous in order to achieve the purposes of the law and that, if it is not clear under the proposed legislation. That this must be so, we would support any amendments which would accomplish that purpose more clearly.

The Federal Trade Commission believes that the language of S. 2162 and H.R. 16884 making clear that economic poisons, subject to the Federal Insecticide, Fungicide, and Rodenticide Act; and foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act as well as hazardous substances as defined by the Hazardous Substances Act are covered may be preferable to other proposed approaches. This approach should dispel concern for any alleged ambiguity in the definition of the substances to be covered by the act.

Mr. Chairman, the Federal Trade Commission is hopeful that enactment of the proposed legislation and, perhaps, even the hearings on the subject will promote strong competition among manufacturers to develop and promote to the public the safest possible containers for household substances.

Again thank you very much for this opportunity to appear before the subcommittee and present the views of the Federal Trade Commission on this significant legislation.

(Mr. Thain's prepared statement was subsequently received for the record:)

STATEMENT OF GERALD J. THAIN, CHIEF, DIVISION OF FOOD AND DRUG ADVERTISING, BUREAU OF DECEPTIVE PRACTICES, FEDERAL TRADE COMMISSION

Mr. Chairman and members of the Commerce and Finance Subcommittee, I wish to thank you for this opportunity to present the views of the Federal Trade Commission concerning the bill to provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, and for other purposes. Chairman Weinberger had a long-standing commitment which prevented his appearance before you today, and he directed that I substitute for him.

The bills now under consideration by this Committee fall into two categories, (1) those which parallel the original version of S. 2162, namely H.R. 16541 and H.R. 17016, and (2) those which parallel the revised version of S. 2162 which the Senate passed on May 11, 1970, namely H.R. 16884 and H.R. 17057. The Commission supports the proposed legislation in the form in which it passed the Senate.

The purpose of the bill is to reduce injuries to, and illnesses of, young children arising from ingestion of toxic or harmful substances customarily produced or distributed for sale for consumption, use or storage by individuals in or about the household. The bill would require that such household substances be contained in special packaging which would be significantly difficult for children under six years of age to open or obtain a toxic or harmful amount of such substances within a reasonable time, but which would not be difficult for normal adults to use properly. This approach is clearly practicable; it takes into account the lesser strength and dexterity of young children and, although there are relatively few child-resistant containers on the market at present, a number of such containers are now in development. Furthermore, the efficacy of child-resistant containers in preventing access to the contents of the container by small children is established. Tests indicate that as much as 90% of poisoning due to medicines may be prevented by dispensing medicines in child-resistant containers. In addition, laboratory tests have indicated that child-resistant containers may baffle as many as 75% of the children confronted with them.

The scope of the proposed legislation extends across all product lines and types and includes all substances customarily produced or distributed for sale for consumption, use, or storage in or about the household. The Secretary of Health, Education and Welfare is authorized by the bill to determine whether a substance should be contained in special packaging on the basis of its degree or nature of hazard to children. The Secretary would be empowered, after consultation with a technical advisory committee, composed of members representing industry, the public, and members of the scientific and medical profession, to establish performance standards for special packaging designed to protect young children against obtaining harmful amounts of the packaged substances. Failure to conform to special packaging standards will result in the substance being deemed misbranded under applicable provisions of the Federal

Hazardous Substances Act, the Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act and subject to the penalties therein prescribed.

The bill provides that the effective date of regulations will not be sooner than 180 days final promulgation of regulations. The bill further provides that states may not establish or continue in effect standards not identical with Federal standards.

The Federal Trade Commission believes that the need for this kind of law has clearly been established by relevant statistics. Each year, up to two million children in this country swallow some substance that is poisonous to them; each year upwards of a million of these children require emergency medical treatment; each year upwards of 300 of these children under 5 years of age die as a result of such poisoning. The substances which cause such tragic results are not primarily those commonly thought of as being toxic, but such everyday products as aspirin, vitamin pills, cough medicines, soap, bleaches, furniture polish, and similar products.

Perhaps even more telling than cold figures is the testimony of individuals who have experienced the pain of seeing what ingestion of household substances may do to their young children. The testimony of Mr. Alfred Snodgrass, of Renton, Washington, before the Consumer Subcommittee of the Senate Committee on Commerce concerning the near death of his 18 month old son as a result of ingesting dishwasher detergent powder, is illustrative. The child survived, but his esophagus and windpipe were burned severely, his mouth and lips were blistered, and he required a tube in a hole in his throat for breathing, a tube sticking out of his abdomen for feeding, plus recurrent stretching, by a tube, of his scarred esophagus to stretch it back to usable size.

Such incidents indicate the necessity for legislation to protect this country's young children. It would be ideal, perhaps, to have comprehensive legislation covering all aspects of product safety for all members of the population, enacted in one package. However, the luxury of time which would be required for the adoption of such legislation cannot be afforded.

The Federal Trade Commission is aware of the real problems raised by special packaging for our elderly citizens and our handicapped citizens, particularly those suffering from arthritis conditions or other ailments affecting use of the hand. The Commission believes any problems in this area have been satisfactorily handled by the provision that substances for which special packaging standards have been established may nevertheless be marketed in one size of ordinary container not complying with the special packaging standard, or if dispensed by prescription, may be sold in ordinary packaging at the purchaser's request, for use of the elderly and the handicapped. The non-conforming single size container must bear the conspicuous label statement: "This package for households without young children."

The Federal Trade Commission believes that the language of S. 2162 and H.R. 16884 making clear that economic poisons, subject to the Federal Insecticide, Fungicide, and Rodenticide Act; and foods, drugs, and cosmetics subject to the Federal Food, Drug and Cosmetic Act, as well as hazardous substances as defined by the Hazardous Substances Act are covered, is preferable to other proposed approaches. This approach should dispel concern for any alleged ambiguity in the definition of the substances to be covered by the Act.

The Commission is pleased that the bill which passed the Senate specifically calls for representation of the consumer on the technical advisory committee. The Commission believes it is vital for the public to have a direct voice to present the consumer's views at this level.

The Federal Trade Commission is hopeful that enactment of the proposed legislation and, perhaps, even these hearings on the subject will encourage competition among manufacturers to develop and effectively promote to the public the safest possible containers for household substances for use by all consumers.

Thank you very much for this opportunity to present the views of the Federal Trade Commission on this subject.

Mr. Moss. Thank you, Mr. Thain.

I am awfully sorry that Chairman Weinberger was unable to appear and that we did not have the time available to give the advance notice we like to be given.

Mr. THAIN. We are fully cognizant of that. I am certain Chairman Weinberger would have been here if it had been at all possible. He is,

as you may know, announcing to the press and to the staff of the Commission today the basic reorganization of the Commission and this is something which has been planned and scheduled for today for a long period of time.

Mr. Moss. I will be very interested. I had the pleasure of working with him off and on for the last 22 years. I have high regard for his ability.

Mr. THAIN. Thank you, sir.

Mr. Moss. Mr. Thompson.

Mr. THOMPSON. Thank you, Mr. Chairman.

One thing that concerns me with packaging, with the top, for example, if it is difficult for an adult to open it, what if the adult does not replace the top?

Mr. THAIN. Of course this is a possible danger. It was pointed out, I believe, in hearings before the Consumer Subcommittee of the Senate that certainly you can never completely control the actions of parents in insuring that their children are not exposed to dangers of this nature, but what we can do is make it more difficult for this type of human error to result in tragedy.

Mr. THOMPSON. Would we under some designs possibly have a top so difficult to take off that it is more difficult to return to its normal place and therefore may be creating a reason for the person not to replace it?

Mr. THAIN. I suppose it is conceivable that such designs could be achieved. However, I would think that the HEW and the Technical Advisory Committee would certainly not recommend that any such container tops be used as appropriate containers under this legislation. I would like to add one thing: what the Commission is very pleased with concerning S. 2162 is that it specifically provides for representatives of the public or the consumers to sit on the Technical Advisory Committee.

Mr. THOMPSON. May I ask you, you mentioned in here the incident involving the dishwashing detergent.

Mr. THAIN. Yes.

Mr. THOMPSON. For example, have you given any thought yourself as to how you would package a product such as that that should be dispensed more or less, I guess, in granular form, or you could have a liquid possibly. At present I understand your boxes are so long and they have a little pullout aluminum spout.

Mr. THAIN. Yes; that was the type of container which was involved in one Washington State incident, I believe.

Mr. THOMPSON. Have you given any thought as to what type of a packaging would overcome a problem such as that?

Mr. THAIN. Well, of course it would depend on what is feasible as well as what is practical. Again the proposed legislation calls for this to be taken into account by the Technical Advisory Committee and by the Department of Health, Education, and Welfare.

I must be candid and state that this subject is not directly within the jurisdiction of the Federal Trade Commission and I personally have not had an opportunity to recommend to you or to have the Commission make a recommendation as to what would be the most appropriate type of container for each type of household substance. I would assume that the Technical Advisory Committee in the Department of HEW would have the expertise to answer that more cogently than I could.

Mr. THOMPSON. Thank you very much.

Thank you, Mr. Chairman.

Mr. MOSS. Mr. Eckhardt.

Mr. ECKHARDT. I just had this question.

On page 4 of the bill, that is, S. 2162, it says: "Nothing in this act shall authorize the Secretary to prescribe specific packaging designs, product content, package quantity, or, with the exception of authority granted in section 4(1)(ii) of this act labeling."

I suppose that means that he can make general rules in this respect but cannot establish, for instance, the exact quantity of aspirin that would be in a bottle.

Mr. THAIN. That is my general understanding of that. I believe that the purpose of this provision is to indicate that the interest of the Government in prescribing this type of container is strictly with safety and is not concerned with designs or content or any such things which would be a matter of marketing or product design unrelated to safety.

Mr. ECKHARDT. I think that might be a little difficult to interpret as to what constitutes a specific package design, what constitutes a reasonable rule. It seems to me that language is terribly restrictive there, particularly with respect to not permitting any requirement of the labeling. I suppose all you can say is that you have got to state in general that this material is hazardous to children.

Mr. THAIN. As the representatives from HEW indicated just prior to my appearance here, it may be that analysis of this will show that there is a loophole in here. We at the Commission would certainly support closing of any such loophole. As I said, and as I am sure the members of this subcommittee well know, the Federal Trade Commission has many times stated it would be very appropriate and suitable to have product safety handled in one package or one bill. In this particular instance, though, when we are talking about possible deaths of several hundred of our young children, we feel it is necessary to have the quickest possible and as comprehensive as possible in terms of covered legislation.

Mr. ECKHARDT. I am noting that also in connection with section 7 on page 8 which provides that the Federal legislation will preempt any State legislation.

Mr. THAIN. Yes.

Mr. ECKHARDT. For instance, since the Federal legislation is quite general, as it needs to be it seems to me under this subsection (d) of section 3, suppose a State wants to say specifically what the labeling should be on a product which may be unsafe for children. It would seem to me that though the Federal Government is prevented from doing it under (d), the Federal Government having gotten into the general field and made a general field would preempt the State. In that way we might possibly do more harm than good with respect to good legislation in the progressive State.

Mr. THAIN. If, of course, it were possible to have an exception which would allow for, in effect, a more stringent legislation by the State than that of the Federal Government, that might be preferable. At the same time, of course, I am sure there is considerable difficulty in having uniformity when you are dealing with these packages which primarily move in interstate commerce throughout all the States.

Mr. ECKHARDT. That would be true if the act permitted the Secretary to prescribe specific package design or specific labeling, but since

nothing but general package design and general labeling is permitted it would seem to me that that conflict would not be so likely to exist. I see no reason to preempt the field here; perhaps it should be. Of course, obviously, the Federal standard would govern and if the State standard were in conflict it would fall, or if the State standard were not as high as the Federal standard, the Federal standard would be in addition to it. I see no reason for preemption in this bill.

Mr. THAIN. Certainly the Commission will take those comments under consideration. As I am sure the chairman knows, we were informed of these hearings Friday afternoon. I have been authorized by the chairman to present the views of the Commission as to this legislation, only in general terms. On specific matters of this nature you have raised. I believe it would be appropriate to have an opportunity for the Commission to consider and discuss these matters and present the subcommittee with a more specific analysis of the bill, section by section.

Mr. Moss. Would the gentleman yield?

Mr. ECKHARDT. Yes. I have completed.

Thank you, Mr. Chairman.

Mr. Moss. What would be the earliest date the Commission could authorize such comment?

Mr. THAIN. I would hope that we could submit something to you this week.

Mr. Moss. Would you then contact Mr. Borchardt and see that he is supplied with it?

Mr. THAIN. Yes, I will.

Mr. Moss. Without objection the record will be held open at this point to receive it.

(For information requested see letter dated July 23, 1970, from Hon. Casper W. Weinberger, Chairman, FTC, to Chairman Staggers, p. 38, this hearing.)

Mr. Moss. I recognize that generally the Commission would be more concerned with the monitoring of the advertising and the promotion of products once the standard was promulgated by the Secretary of HEW. That would be your primary responsibility.

Mr. THAIN. Yes, it would, Mr. Chairman.

Mr. Moss. Mr. Borchardt, do you have any questions?

Mr. BORCHARDT. One question.

Are you aware of any patent problems that might be involved in this legislation concerning a closure device?

Mr. THAIN. I am not specifically aware of any such problem, Mr. Borchardt. I am, of course, not an expert in patent law.

Mr. Moss. Are there further questions?

If not, I want to thank you, Mr. Thain, for appearing on behalf of the Federal Trade Commission on what was admittedly short notice. We will look forward to the additional statement from the Commission.

That concludes the witnesses scheduled for this morning's session. The subcommittee will stand adjourned until tomorrow morning at 10 o'clock when we will convene again in this room with witnesses from the industry.

The subcommittee is adjourned.

(Whereupon, at 11:30 a.m., the subcommittee adjourned, to reconvene at 10 a.m., Tuesday, June 9, 1970.)

CHILD-RESISTANT PACKAGING OF HOUSEHOLD SUBSTANCES

TUESDAY, JUNE 9, 1970

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCE AND FINANCE,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to notice, in room 2325, Rayburn House Office Building, Hon. John E. Moss (chairman) presiding.

Mr. Moss. The subcommittee will be in order.

We will resume our hearings today on a series of bills to provide for special packaging to protect children.

The first witness is Mr. Richard M. Markus, first vice president, American Trial Lawyers Association.

STATEMENT OF RICHARD M. MARKUS, FIRST VICE PRESIDENT, AMERICAN TRIAL LAWYERS ASSOCIATION

Mr. MARKUS. Congressman Moss, I apologize for the fact that I do not have a prepared statement. I was notified of the committee hearing relatively recently.

Mr. Moss. Let the Chair apologize. The Chair was also notified of the hearing date at approximately the same time you were and therefore recognizes the difficulties of preparing a statement and submitting the customary number of copies. We will not require that in this instance.

Mr. MARKUS. Thank you.

The American Trial Lawyers Association has had a continuous, strong interest in matters of safety legislation generally.

I believe the previous testimony of the president of our association on the related legislation before the Senate subcommittee expresses those views. Perhaps it is appropriate to point out that this association is made of approximately 25,000 lawyers and law professors who are actively interested in litigation, and who have been actively involved in a multitude of safety campaigns in a large variety of areas.

Some of the members of this association now act as consultants to various safety groups, including the United States Institute of Standards.

I suppose the reason for this interest is that our members typically hear the wails of sorrow which come from the consumer more directly than even our Congressmen or Senators might hear them.

We hear them directly from the consumer when the tragedy has immediately resulted from some product which has caused a very seri-

ous personal and family disaster. We, therefore, see them not as statistics but as suffering individuals and suffering families.

Generally, our association strongly favors this type of legislation. I might put it this way: For many, many years safety was considered to be a concept of education in which people were taught how to be more careful. And although such an approach has real merit, it is certainly not the total solution.

We have noted in the industrial accident situation that accident prevention took the form not merely of education but of structuring the physical situation so as to eliminate accident situations.

If we go into a factory today, we will see carefully marked roadways for the vehicles used to transport materials. We will see machines which are designed so that an individual who works with the machine cannot put his hands where there could be danger to those hands. He must keep them out in order to make the machine operate.

So, similarly, the structuring of machinery, products, and equipment is an important part of accident prevention and safety advancements.

We must assume that people are distracted, inattentive, or even careless, and that for their benefit, efforts must be made to structure the physical surroundings that will eliminate or minimize the accident circumstance.

This is particularly true for children who are typically unable to care for themselves, and who are therefore dependent upon others—elders, parents, or suppliers—to recognize that they are indeed distracted, inattentive, or even careless.

This legislation attempts to establish a procedure by which standards can be created for the packaging of materials potentially hazardous to children. I suppose one of the most extensive sets of regulatory efforts now dealing with packaging of hazardous materials is that established by the Interstate Commerce Commission for the transportation of hazardous materials; they are indeed voluminous.

They have shown that realistic regulations can be made for specific forms of packaging to maintain a less hazardous situation for the handling of hazardous materials.

There has been reference, I think, in discussing this type of legislation, to cost of fabrication as a significant factor. But more realistically, I believe that we see what is a common controversy in modern business, a controversy between the engineering department and the sales department.

The engineering department can and does make realistic recommendations for safety advances. But the sales department, regrettably, sometimes feels that such safety features are not as palatable from the sales viewpoint, are not as pleasant from the sales viewpoint. Therefore, the internal controversy that comes within commerce between the engineering and the sales departments of a particular company must be supplemented by governmental assistance to the engineering department.

I would comment that there are two separate kinds of regulation that are effective in this area, and that I think both must be realistically recognized.

One is the type with which we are here concerned, that of governmental regulation, which has a very broad application when it is effective. A second form of regulation is that of private remedies which

are, of course, a subject with which the members of my association are particularly familiar.

The private litigation remedy, particularly in the product area, has been the leader of product safety. I think I can safely say that private litigation led the way, and Government regulation followed.

I do not say that in any sense in a deprecatory fashion, because it is typical that private remedies are at the forefront of many forms of reform.

Certainly, if there are regulatory steps taken, private remedies will follow from the regulatory action. And private remedies in the form of private litigation are indeed more flexible than Government regulation can possibly be.

They will conform typically to community standards and adapt to new technology much more quickly than any form of Government regulation could possibly do.

They provide much more widespread enforcement than any governmental agency, Federal or State, could hope to provide, because they have a force of interested enforcing personnel made up of the entire private bar and all their clients, all of the people with whom they would deal.

It is because of this second remedy that I suggest that the committee may wish to consider some minor modifications to the legislation that is before the committee.

Mr. Moss. In directing your comments to modifications, I wonder if you might direct them to S. 2162 in order to clarify the matter for the members.

Mr. MARKUS. I would be happy to.

In section 3(a) of S. 2162, which appears in the printed form I have on page 3, line 9, it may be salutary for the Congress to insert the word "minimum" before the word "standards."

Let me explain why I make that as a possible suggestion. Certainly any standards adopted by the Secretary pursuant to this legislation would be intended by the Secretary, and I assume by the Congress, to be minimum standards, in the sense that additional regulation can be imposed by industry itself or by the particular manufacturer. And, in addition, the private remedy is in no way reduced by the insertion of the explicit statement that this is a minimum standard.

There have been instances in private litigation in which suppliers have argued that standards established by the Government were necessarily total compliance with due care, and I don't believe that that is the intendment of either the Congress or the Secretary. I think that perhaps such a minor modification might be salutary.

On the second area of attention I do not have specific language to suggest, but perhaps a concept to consider. It concerns the advisory committee that is discussed in S. 2162, particularly in section 5.

While advisory committees are often very helpful because they can supply additional information to the regulatory body, they can in some instances be less helpful that we would wish.

There are instances in which such advisory committees fail to make coherent recommendations, or indeed make recommendations that the much more conservative than necessary.

Experience has indicated that in some instances advisory committees are heavily dominated by the regulatees, those who are to be regulated

and, as a result, are less prone to favor remedies that are appropriate.

Perhaps what I am saying is that in line 15 on page 6 of the printed form of S. 2162 Congress may wish to consider inserting this brief phrase after the words "advisory committee": "and may consider their views."

This would be an effort to indicate that the Secretary is not bound to follow the recommendations. Certainly, I think that the present language does not compel the Secretary to follow the recommendations of the advisory committee, but there is some ambiguity that some reviewing judicial tribunal, some court, may find a basis for saying that a regulation was unreasonable because it disregarded the actions of the advisory committee.

Mr. KEITH. At this point, may I ask a question?

Mr. MOSS. Yes, Mr. Keith.

Mr. KEITH. There are, throughout the Federal Government, numerous advisory boards, and the general terminology, as I recall it, is that the Secretary shall consult with that advisory board or committee.

Is this a departure that you are suggesting, or does this amendment conform with established custom?

Mr. MARKUS. Congressman Keith, I would say that what I have been discussing is perhaps more a language change than a substantive change.

I think the purpose as expressed here is the same purpose which you have orally suggested, and I am only suggesting language that it may be appropriate for convenience.

Mr. MOSS. I think Mr. Keith's question really goes to the question of whether this is the regular boiler-type thing, or whether the addition of the words "may consider their views" would be a departure from the normal, so-called boiler plate language.

Mr. KEITH. From your experience in dealing with other statutes of a comparable nature and purpose, have you found that the usual language has been unsatisfactory so that you would now recommend this as a necessary change?

Are we establishing some kind of a precedent here contrary to an existing procedure? Has it worked out badly in the past or has it worked out well?

Mr. MARKUS. I cannot report any specific legal decision which has turned upon the language which we are discussing. I have heard such comments made by lawyers in discussing such legislation in the past.

Mr. KEITH. Thank you, Mr. Chairman.

Mr. MARKUS. If I may refer to section 7 of S. 2162, which appears in the printed form on page 8, section 7, it is a partial preemption or occupation of the field by the Federal legislation.

Certainly to the extent that the Federal legislation would prohibit any State from imposing lesser regulations, I think it is not only appropriate but necessary.

But I wonder whether it is either appropriate or necessary to prevent State groups from making supplementary regulations. So I suggest that the committee and the Congress might wish to consider the insertion of the words "or supplementary" in line 15 after "identical."

This would enable States to add to the regulations adopted under authority of this legislation. There are effective State bodies in some

of our States, in many of our States, who can give thoughtful additional suggestions.

I would regret to see, with the adoption of legislation of this sort, the drying up of such State action that might further the common goal that we all are seeking.

If I were to make any single conclusion as to the views of my association, it would be that the rather ancient maxim "let the buyer beware," is no longer an acceptable doctrine, particularly in the areas of safety.

It may now be stated "Let the seller be wary," or at least "let the Government be effective, so that the seller be wary, so that the consumer be safe."

I have no further remarks, unless there are some questions from the committee, Mr. Chairman.

Mr. Moss. Thank you, Mr. Markus.

Mr. Keith, have you any question at this time?

Mr. KEITH. No questions, Mr. Chairman. I would make the observation that we have noticed in the last few years a great change in the thrust of legislation; the philosophy is increasingly to let the seller be wary instead of letting the buyer beware.

Mr. Moss. Mr. Eckhardt.

Mr. ECKHARDT. Mr. Markus, I think you have given us some very excellent suggestions. I would like to go into them a little bit with you.

Why not leave out all that language in the bill, which would eliminate the advisory committees altogether? I would agree that advisory committees are usually chosen from among those who are likely to be effected. Therefore, they are attempting to dampen the effect rather than sharpen it.

Mr. MARKUS. This is a policy question which I am really not prepared to comment upon. I think there are conflicting and balancing interests, favorable interests.

One is that they can provide outside information that can be helpful to governmental regulatory bodies, and the other is that they can also be retarding.

If I may give a specific example, regulation that was adopted relating to flammable fabrics has been severely criticized by many lawyers, who have felt that it resulted principally from recommendations by regulated portions of the industry and, therefore, established standards that were essentially minimal or even meaningless.

Mr. ECKHARDT. It seems to me, though, that when we create advisory committees we tend to confuse the judge with the advocate.

I have no objection whatsoever to having interested groups come before the regulating agency. As a matter of fact, I think this is most desirable, just as we have persons who are advocates come before this committee and take one position or another.

But they don't sit on this committee. It seems to me exactly the same situation exists with respect to the administrative agency.

Mr. MARKUS. I can only say that I see considerable merit in the suggestion that you are making generally.

On the other hand, I do recognize some merit in advisory committees, and I am not in a position to give any final conclusion as to which is the preferable approach, only to suggest that the advisory commit-

tee should be limited in its effectiveness so that the Secretary is relatively free to act independent of the advisory committee.

Mr. ECKHARDT. I have a similar question with respect to section 7 on page 8 of the bill. Why not leave that out altogether? If it were left out, as I understand it, this act then would, in effect, set a minimum Federal standard and no State could adopt a standard contrary to it.

But a State could establish supplementary standards or could even establish stricter standards. Frankly, I believe in utilizing the States in a true federalist sense to experiment in these areas and then perhaps at some time, if we find that those experiments conflict, we may preempt the field.

It would appear to me we should not preempt while we are as much experimenters as the States are experimenters.

Mr. MARKUS. You can see from my comments that I am generally in agreement with your views, also.

The question, again, is the vehicle by which those views can be accomplished. If section 7 were eliminated, I fear that the courts in interpreting the effect and impact of this legislation would then be in doubt as to whether there was or was not a preemption or occupation of the field, and to what extent there was a preemption or occupation of the field, and to what extent there was not a preemption or occupation of the field.

The inclusion of language which specifically indicates that supplementary regulation is available by States would, I think, eliminate any doubt.

Mr. Moss. Would the gentleman yield?

Mr. ECKHARDT. Yes, I yield to the chairman.

Mr. Moss. I think the question of intent could be dealt with quite adequately in the report accompanying the bill to the floor of the House.

Mr. MARKUS. Hopefully, Mr. Chairman, though I also have seen instances in which the ultimate report was disregarded by the courts, saying that the clear intendment of the language of the enactment was something other than that expressed in the report.

Mr. Moss. That is where it is quite clear on its face. I doubt if this bill, with the section removed, would be in that category.

Mr. ECKHARDT. I can see, Mr. Chairman, why the witness is concerned there. That is, if we don't say one way or another whether we preempt or do not preempt, we might leave that question to the court.

It had been my feeling that if the statute does not express an intent to preempt, under such circumstances the provisions of the bill would be paramount to State action and would control as against contrary legislation, but would not preempt with respect to supplemental legislation.

My feeling was that the law would be substantially what you suggested it be, Mr. Markus, when you add "supplementary," but that we do run into perhaps fuzzy questions of construction with respect to what constitutes a special packaging or labeling standard rather than a general one.

I also have trouble with this proposition, that on page 4 of the bill there is a specific provision that—

> nothing in this Act shall authorize the Secretary to prescribe specific packaging design, product content, package quantity, or with the exception of authority granted in Section 412 of this Act, labeling.

So this act does not permit the Secretary to prescribe specific action in these fields, but it still would apparently preempt the States from providing special packaging or labeling.

In many instances it would seem to me that this would leave no authority either with the State or with the Federal Government to deal with certain problems which should be dealt with especially or specifically.

That is one thing that troubles me.

I understand that the section I referred to on page 4 is probably necessary insofar as it does not permit the Secretary to prescribe specific packaging design, but it seems to me the rest of that sentence is unfortunate and probably too limiting.

There may be many, many cases in which the State would, for instance, want to provide for something respecting product content, package quantity or labeling, particularly labeling.

It seems to me the States ought to be permitted to go into the question of special provision with respect to labeling. Have you any comment on this field?

Mr. MARKUS. It appears that the provision of section 3(d) of S. 2162 limits the authority of the Secretary under this specific act. I am not sure that I understand why it would limit the authority of the Secretary or any other regulatory body of the Federal Government under other legislation which may give additional authority.

With reference to the actions by States, your comment may indeed have significance. Perhaps this is one of the reasons why I was suggesting, in section 7, that we add the words "or supplementary," because that would make it clear that the States could make regulation beyond those which were adopted pursuant to this act.

Mr. ECKHARDT. The only difficulty is that you get into the question of defining what is supplementary with respect to labeling when there is no authority under this act to require any labeling except the labeling that is prescribed in section 4(1)(2) on page 5, when there is no authority for any kind of labeling except that, and then when you provide that there may be supplementary labeling, for instance.

Well, what is supplementary labeling then? It seems to me you can't have anything supplementary to a vacuum, so to speak.

Mr. MARKUS. I think on the other hand it is very easy to have, as Alice in Wonderland, more than none. When offered the tea, she said she could not want more tea because she had had no tea. They said it was easy to have more than none.

If there is, in fact, no regulation applicable for a particular area then it is clear that any regulation is supplementary.

Mr. ECKHARDT. But this is a little different. This section says as far as this statute is concerned, as you correctly point out, there shall be no labeling, except with respect to the provisions of section 4(2).

In the face of that intended nullity or that intended area of no labeling whatsoever, it doesn't seem to me that section 7 providing for some supplementary action on the part of the State would give the State any authority whatsoever because it would be, in effect, supplementing something that the statute says should not be done at all, at least by the Federal Government.

I think you may be correct on it, but at the same time it seems to me that section 7, even with the words "or supplementary" is more re-

strictive than it should be, and that we might accomplish the better objective by simply striking it altogether.

For instance, as the chairman suggests, we might put it in the report, a statement that the legislation is not intended to encroach upon State regulation of the same matter.

Mr. MARKUS. I don't think I can make any further observations beyond those I have already suggested.

Mr. ECKHARDT. Thank you, sir.

Mr. Moss. I have no questions, Mr. Markus. I do want to express the appreciation of the committee for your appearance here this morning.

Mr. MARKUS. I thank the committee for the opportunity to appear.

Mr. BORCHARDT. For the record, you might want to state how your association goes about formulating your views that you express on behalf of this legislation?

Mr. MARKUS. The answer to the question varies depending upon the nature of the question.

On some matters we are able, by reason of time and circumstance, to have meetings of our governing board, which is nationally representative.

On some matters we must necessarily rely upon our elected officers to express the views which we believe are the reasonable intendment of the general membership.

In this instance I must state to the committee that our governing board has not had an opportunity to review the specific language changes, certainly, that we have talked about. To that extent I suppose I am speaking as an officer of the association, the first vice president.

There is no doubt in my mind that the overwhelming majority of our membership are very strongly in favor of the substantive views which I have expressed.

I say that on the basis of having participated in a multitude of programs dealing with this type of litigation and legislation.

Does that answer your question?

Mr. BORCHARDT. Yes. Thank you.

Mr. Moss. Thank you, Mr. Markus.

The next witness will be Mr. James F. Hoge, on behalf of the Proprietary Association.

STATEMENT OF JAMES F. HOGE, GENERAL COUNSEL, THE PROPRIETARY ASSOCIATION; ACCOMPANIED BY DANIEL F. O'KEEFE, JR., VICE PRESIDENT AND SECRETARY

Mr. HOGE. Mr. O'Keefe is vice president and secretary of the association, Mr. Chairman. He is located here in Washington at the offices of the association, 17th and Pennsylvania.

My name, Mr. Chairman, as you have mentioned, is James F. Hoge. I am from New York. I am a practicing lawyer, senior partner in the firm of Rogers, Hoge & Hills. Our address is 90 Park Avenue in New York City.

I have been general counsel to this association for 36 years. I said to the other Mr. Moss, Senator Moss, that perhaps I had a proprietary interest after so many years in these products and in this work. The Proprietary Association is located here in Washington at 1700 Pennsylvania Avenue, Northwest.

On October 2, 1969, I appeared on behalf of the Proprietary Association before the Consumer Subcommittee of the Senate Committee on Commerce. The bill was S. 2162 as originally introduced in May of 1969. H.R. 16541 and H.R. 17016 before you parallel that bill as so introduced. H.R. 16884 and H.R. 17057 parallel it as passed by the Senate.

I heard what you said, Mr. Chairman: that we will make references to the bill as it passed the Senate. So my references will be to S. 2162 as of the time it did pass the Senate.

I ask permission to submit a copy of the statement which I made before the Senate subcommittee. I realize, of course, that the bill before you now, as it passed the Senate, is different in a number of respects. But I think for background material and for our interest and general observations the statement which I made then is still pertinent. I ask your indulgence of it.

Mr. Moss. Without objection, the statement will be included in the record immediately following the statement you are making now. (See p. 85.)

Mr. Hoge. Thank you, sir. I would have had a new statement prepared except for the reasons already alluded to by other witnesses and by you, Mr. Chairman, that the time has been very short to do that. What I bring you today is what we have been able to do in the intervening hours since we received the notice.

The statement which we filed in the Senate and which is here before you now, by your grace in letting me put it here, has a number of appendices. But before referring to them and before referring to our views on particular points, let me say that the Proprietary Association is confined entirely in its interest to the application of this legislation to over-the-counter medicines. I am sure we all know that these are products which are advertised to the public, sold over the counter, with no prescription required for them. Illustrative of such articles are Vick's Vaporub, Listerine, Creomulsion, Anacin, Bayer Aspirin, St. Joseph's Aspirin, Bufferin, Alka-Seltzer, Contac, Phillip's Milk of Magnesia, and so on. There are 90 active members of the association and approximately 135 associate members. We are not authorized to comment on the effect of the legislation on the many other affected products, and there are many others. The bill would apply to any "household substance" as defined to be "any substance customarily produced or distributed for sale for consumption, use, or storage by individuals in or about the household. * * *" It includes any hazardous substance as defined in the Federal Hazardous Substances Act, any economic poison as defined in the Federal Insecticide, Fungicide, and Rodenticide Act, and any food, drug, or cosmetic as defined in the Federal Food, Drug, and Cosmetic Act.

It would be difficult to have a broader sweep of coverage than this definition and its inclusion by reference of the products as defined in these other acts. I am sure we all agree, upon reflection, that that is about as wide a coverage as we can have in consumer articles.

It would include the packaging of soaps, cleaners, bleaches, insecticides, disinfectants, gasoline, kerosene, lighter fluids, floor polishes, solvents, glue, adhesives, perfume, and other products too numerous to mention.

In the area of drugs, the word "drug" is comprehensively defined. It includes every article that is listed in the U.S. Pharmacopeia and

every article listed in the National Formulary. It includes any article, which is intended for use in the cure, treatment, mitigation, diagnosis, or prevention of disease in man or other animal. It includes also any article (other than food) which is intended to be used to alter or affect the structure or the function of the body of man or other animal. That, of course, is also a very broad definition.

So, our interest is confined to the application of the legislation to drug products as so defined. Child safety in the use of them is a subject with which the association and its members want to be involved, and with which they have been involved. It would have been more to our liking to have appeared in the Senate hearings as a supporter of the bill, as well as of the bill's objective. We would prefer to be so cast here.

I listened to the previous witness with his reference to the old doctrine of caveat emptor. This association, many years ago, passed that milestone. We no longer subscribe to that doctrine at all. We recognize that it is no longer pertinent in the field of consumer merchandise. I might say we don't want it to be pertinent. We think now it should be "let the vendor beware." So we are quite up-to-date on that.

Mr. Chairman, may I just say a word, perhaps a personal word? Sometimes I feel that I almost have to apologize in this day of intense consumerism for opposing any legislation that is branded for the benefit of the consumer or for public health.

I think my clients, and certainly I personally, are just as ardent in our devotion to the public health generally as anyone else. So, when we oppose bills, as we opposed this one in the Senate, we do so on what we think are good reasons, and certainly we try to be objective about it.

So, we come here to you wishing that we could be cast as ardent supporters of the bill. But we cannot, with respect to drugs.

I think I can say this to you, however, that the fact that we can't be supporters does not mean, as it did not mean in the Senate, that we can't work with the committee on trying to perfect the bill if the committee is determined to go ahead with it. We recognize the province of the bench. So, while we state our views, we give you assurance of a willingness to work with you.

Our view about the bill is that the art of safety packaging—certainly with respect to drugs—has not advanced to a point to permit proper standards to be prepared. The testimony of many qualified witnesses before Senator Moss' committee support that statement. I do not refer only to industry witnesses who might have some special interest. I refer to pediatricians. I refer to others in the health field who were not connected in any way with any industrial concern.

In order that the attitude of The Proprietary Association may not be misunderstood, let me insist that opposition to the bill is not synonymous with opposition to child safety and to necessary disciplines for accomplishing it. Before the Senate subcommittee, we suggested that the technical advisory committee, provided for in S. 2162, as introduced, be set up as a first step and that it should continue the efforts already advanced by the industry and others in their undertaking to perfect safety closures.

This undertaking and the need for further study were described in the testimony of Richard L. Cheney, executive director, Glass Container Manufacturers Institute; Charles C. Sullivan, representing the Committee for Continuing Study of Improved Safety Closures; Dr. Alan K. Done, professor of pediatrics, director of the Poison and Therapy Center, University of Utah; Dr. Roger J. Meyer, associate professor of pediatrics, Northwestern School of Medicine and executive director, Infant Welfare Society of Chicago; Dr. Harry C. Shirkey, professor of pediatrics, University of Hawaii Medical School and chairman of the FDA 1966 Conference on Prevention of Accidental Ingestion of Salicylate Products by Children; and others.

I would like to make a special reference to the FDA 1966 Conference. It evolved from hearings before this very committee, the overall Committee on Interstate and Foreign Commerce. It came out of the Subcommittee on Public Health which gave many hearing days in the summer of 1966 to several bills which were labeled as "Child Safety Bills." The full committee reported to the House on October 1 of that year. The report accompanied S. 3298 which was entitled the "Child Protection Act of 1966," and included reference to H.R. 13886, which related to packaging and labeling of children's aspirin. The report said: "The committee believes that the problems attacked legislatively in title I of H.R. 13886 can be more suitably handled by other means." It then said: "It is the feeling of the committee that the voluntary conference approach to limitation of amount of children's aspirin in a single retail container is desirable."

We strongly supported the idea of a voluntary conference, and members of our association were prominently represented in the conference when it was held under the auspices of the Food and Drug Administration in November 1966. The makeup of that conference included numerous pediatricians. In fact, an outstanding pediatrician, Dr. Harry Shirkey, was the presiding officer.

Its report was published in the Federal Register. A printed report was circulated before then that, and a copy of it is attached to the statement which I have filed with you. That report was very interesting, and I would like to mention it in further indication of the attitude of my people on these subjects.

We had proposed that the number of tablets in a package of children's aspirin should be limited to 25. But the pediatricians and the scientists who were present in that conference decided on 36. The tablets were to be limited to one and a quarter grains each. That would mean a quarter of the average five-grain tablet of aspirin. The pediatricians specifically recommended that children's aspirin continue to be flavored. They had medical reasons for it, I suppose, on the ease of getting a child to take the tablet if it was flavored. Just as distinctly, they said that the adult aspirin, the five-grain tablet, should not be flavored. I think the rational of that is clear.

The conference made numerous findings. One of them went to container closures. The bill in 1966 included several things. One was the matter of limiting the number of children's aspirin tablets in a package. Another, Mr. Chairman, went to the matter of labeling. It went to great length on labeling—to such great length that it conflicted with the Food and Drug Act provisions, and the committee would have no part of it in this connection.

That bill also proposed safety closures for drug products. The conference referred to that in saying that it recognized that an ideal safety closure would be desirable for aspirin and all drugs if possible. It recognized "previous and continuing efforts in producing safety closures."

It appointed a committee to "make a continuing study of improved safety closures for 'children's' and 'adult' aspirin-containing tablets." Dr. Edward Press, State Health Officer of the Oregon State Board of Health, is the chairman of that committee. At the time of his appointment he was chairman of the Subcommittee on Safety Closures of the American Academy of Pediatrics.

May I say, as further indicating our interest and participation in this matter, that the Proprietary Association is paying the expenses of that committee. That committee was appointed by the Food and Drug Administration. It was appointed by us. It is in no sense responsible or responsive to us, but we have undertaken the payment of its expenses.

The Proprietary Association and its members have not only been interested, but very active, in the matter of child safety with respect to medicines. Senator Magnuson introduced a packaging bill in the 90th Congress (S. 3547). That was the first packaging bill. Senator Magnuson said it was introduced to draw interest to the subject, and he expressly noted what he called invaluable work by the Council on Family Health, by the Proprietary Association, and by numerous governmental, professional, industrial, and university groups (Congressional Record, May 27, 1968, p. 6423).

Senator Magnuson again referred to the Council on Family Health in the Congressional Record of July 11, 1968. A copy of that reference is attached as appendix V to my statement. And yet again in the Congressional Record of May 27, 1969, page S. 5679, he referred to the Proprietary Association and what he called government-industry cooperation in this time of aroused consumerism.

The Council on Family Health was incoporated in Delaware in April 1966, as a nonstock corporation. It is supported financially by drug manufacturers, most of whom are members of the Proprietary Association; but the council is not a part of the association or responsible to it. It just happens that the main support comes from members of this association. The council deals with subjects of medicine, and endeavors—by radio spots and newsprint—to instruct and caution that all medicines should be used as directed and only as directed.

Members of the association who manufacture children's aspirin—notedly Bayer and Plough—have safety closures. They have had them for a number of years, improving them as time passed. They do not consider—and I think it is important that I say this in the context of our discussion—that they have yet achieved perfection, or even approximated it. They are still experimenting. But for several years they have used one form or another of safety closure.

In speaking for manufacturers of medicinal products, it is essential to their legal responsibility, and to your framing of such legislation as now proposed, that I call your attention to the very extensive regulation already existing with respect to packaging and labeling of such products. Federal regulation for them began with the passage of the Pure Food and Drugs Act of 1906; then came the extensive revision of 1938—which was in the Congress for 5 years, the bill being introduced

in June 1933 and passed in June 1938, of course coming through the Committee on Interstate and Foreign Commerce; then the Durham-Humphrey amendment in 1951.

That was a very important addition. It separated drugs into two classes: Those which should be sold only on prescription because of their danger or their potentiality for harm, or because of the need for expert guidance in administering. Thereafter one class of drugs was to be sold and used on prescription and the other on labeling. Then came the food additive amendments, which were an important addition to the law, and then the substantial amendments of 1962 which followed the so-called Kefauver hearings.

Of course, they all cleared through this committee. And they literally rewrote the Food and Drug Act in a great many important parts, pertaining to drugs; particularly to what are called "new drugs"—the drugs which have not yet been recognized generally by experts as being safe and effective. They have to go through Government clearance to get on the market.

Appendix I to my statement before the Senate subcommittee is a copy of the regulations with respect to directions and warnings which must appear on the labels of over-the-counter medicinal products. I put that there, Mr. Chairman—and I ask you to consider it when you come to it—because I thought the best way to show you the wide scope of the regulation of drug products under the Food and Drug Act was to give you the actual regulations as they have been promulgated and kept up to date.

You will find there in some nine pages of fine print warnings for practically every over-the-counter item that there is. It would be very difficult to think of one not covered. For instance, with respect to the salicylates, there are a number of warnings: "Keep this out of children's reach"; "In case of accidental overdose, contact physician immediately"; "If pain persists for more than 10 days or redness is present, consult a physician immediately"; and more on the same point.

I did want to say this: Aspirin is a salicylate, and is mentioned in hearings and in statistical tables as being high on the list of causative agents for injuries. Of course, one reason for that is that aspirin is sold by the ton. I don't have with me the actual figures of the tonnage which is produced in this country each year. We all have some imagination as to what it must be. The tables on the injuries which some ascribe to aspirin are written as "aspirin and other salicylates."

Methyl salicylate, for example, is recognized as a comparatively dangerous item, not to be compared with aspirin at all. Yet, referring to these tables, people are likely to say "Aspirin is the great causative agent." I am sure it has caused a great many things, for the reasons I have stated, but, if you will look at the table, you will find it is "aspirin and other salicylates." That gives a little different meaning.

I put the regulations in the appendix, Mr. Chairman, because it is highly important that in legislation of this sort—which goes as far as it does in discretionary regulation—you should know the extent to which Congress has already imposed controls on the drug industry.

I would like also to say with respect to drugs that there are two aspects to labeling: One is how to use the product and the other is how not to use it. That philosophy was recognized and articulated in the

act of 1938 when it was before this committee for so long. The salient thing about labeling is that it tells how to use an article, and how not to use it.

It was quite a forward step when the law recognized, and the industry accepted—as it had to, of course—that there were these two facets and that the sellers ought to tell people how not to use his products, and when not to use them.

Among these warnings, 33 of them are listed with respect to protection of children. Twenty-seven are against unsafe dosage. Of course, that would apply to children and adults. But 33 have specific reference to use by children.

Appendix II to the statement indicates some of the many and specific requirements of the Food, Drug, and Cosmetic Act as to the packaging. If a drug is found by the Secretary to be liable to deterioration, then it must be labeled according to regulations of the Secretary. If it is listed in the USP or the National Formulary, it is misbranded unless it is packaged and labeled as the Pharmacopoeia or Formulary requires. If a drug is a "new drug" as defined by the statute, then it is under a system of actual licensing and subject to regulation with respect to packaging, labeling, and practically all of them particulars.

The Fair Packaging and Labeling Act which was passed on November 3, 1966, makes further requirements as to the packaging of drug products along with all consumer commodities. Pharmacy acts of the 50 States apply in one way or another to drug products; so do State food, drug, and cosmetic acts; so do municipal ordinances. I think there is a food, drug and cosmetic act in each of the States, generally following the Federal act.

Legal procedures and sanctions may be onerous and sometimes severe. Criminal prosecution, civil penalty actions, injunctions, seizure, withdrawal of new drug permits, and publicity—official and unofficial—literally circumscribe and even prescribe the manufacture and marketing of drug products.

It is in that context that I say to you that legislation of the sort now contemplated—applicable to such a vast array of products—must be prepared with the understanding of, and with regard to, the particular circumstances pertaining to drugs and medicines.

It should also be formed in the knowledge that the art of safety closures is—as one of the witnesses in the Senate put it—in its infancy.

Mr. Chairman, that concludes my statement of position. I want to make several specific comments on the bill as it is before you.

The first one has to do with "consumer choice." That is a name we may have invented for it. At least it grew up in these discussions. That is the provision which appears in section 4, that would permit noncomplying packaging. You heard here yesterday from the government witness, and Senator Moss heard from them as well as from the makers of closures and others, that regard had to be had for elderly people, arthritics and others who might have physical handicaps in opening a package with a safety closure.

What you see in section 4 is the Senate committee's attempt to meet that situation which it recognized. I compliment the Senate committee on doing that. We appreciate its effort to meet the point. But we think it was too restrictive. The Senate restricted the noncomplying packages to a single one. We submit to you that that is too restrictive.

We don't have a formula at the moment that we could offer you, but we think there ought to be permitted three or four such noncomplying packages. I think you may understand our feeling about it when I tell you that 75 percent of the families in this country do not have small children.

I can't vouch for that figure. We got it in the course of these hearings. I think we got it with the aid of the staff in the Senate. It is an estimate, that only 25 percent of the families in this country have children that would be, say, under 5 or 6 years of age.

So we are legislating here—quite properly, as far as their needs are concerned—for that 25 percent. But we ought also to have due regard for the 75 percent. We would like the opportunity of working with you and your staff to see if section 4 couldn't be expanded to permit more than just one single noncomplying size.

Section 3(a), we think should be amended by inserting a new subdivision. That would appear on page 7 of the bill as it came to you from the Senate. We think there should be inserted "(3)", at the bottom of the page, following (2), in section 3(a)——

Mr. Moss. 3(a) in the Senate bill S. 2162 as reported to the House, or referred to the House, on May 12, 1970?

Mr. Hoge. I have a day later version.

Mr. Moss. That one contains 3(a) on page 2. "The Secretary after consultation"—that is on page 3, line 6, of the bill as it was received from the Senate.

Mr. Hoge. You realize we have several prints going.

Mr. Moss. I will ask the clerk to supply you with a copy of the bill as it came to us.

Mr. Hoge. We would ask you to provide that the Secretary, after consultation may establish standards, and so on, if he finds "(3) that the packaging required for such standard will so protect the substance as to assure the retention of the strength and quality to the same degree as packaging in compliance with such standard."

I may say to you, Mr. Chairman, that the report, I think, shows a disposition to do that, because the report says that the special packaging is appropriate for such substance. He must find that the standard is not detrimental to the integrity of the substance.

Mr. Moss. Would you carefully read that language again?

Mr. Hoge. Surely.

It would be "(3) the packaging required by such standard will so protect the substance as to assure the retention of the strength and quality to the same degree as packaging not in compliance."

Mr. Moss. I found myself totally confused.

Mr. Hoge. I had forgotten the word "not."

Mr. Moss. If it was a totally feasible packaging that was safer but which might, over a period of months, cause some reduction in strength, then the Secretary in that case would be precluded from requiring the safer packaging?

Mr. Hoge. We mean that he would make a finding that the packaging according to the standards which he promulgated will not result in a reduction in the strength or quality.

Mr. Moss. The practical effect, then, would be, that if it was found totally feasible to fashion a much safer package, but one which would have some effect upon the long term strength of the product, he would be foreclosed from requiring any diminishing of strength?

Mr. O'KEEFE. First of all, to clarify, I think you are correct. But if you would have a certain degree of deterioration under existing packaging, that same degree of deterioration could take effect.

Mr. MOSS. But if it was even slightly more, the Secretary would be foreclosed from adopting the safety package?

Mr. HOGE. No, he would have to make another standard. He can make new standards.

Mr. MOSS. I am attempting to apply your language to a hypothetical case. I can conceive very easily of one of these very fine borderline instances where a perfectly safe package could be devised which, over a period of a year might result in a greater loss of strength, not a significant loss but at least more loss than the present packaging. Under those conditions, under that proposed language, the Secretary would not be permitted to adopt the standards for the new packaging.

Mr. O'KEEFE. A part of our feeling on it, Mr. Moss, is that in dealing with medicines, which are different from other products, there should not be a reduction in strength and quality of a medicine product because of its packaging.

Mr. MOSS. But there is always, almost invariably. In fact, I think that in part of your advertising for the association you urge people not to keep medicines around the house for a long period because they do lose strength.

Mr. O'KEEFE. But if they are liable to deterioration, there are special legal requirements there.

Mr. MOSS. I realize that. But, remember, the fact that they are liable to deterioration, even to a slight degree more if put in a safer package, would be sufficient grounds to prohibit the Secretary from adopting the standard for the safer package.

I just want to be certain that I understood the intent of the language. If that is the intent of the language, I think it is extremely tight. It is a straightjacket.

I think within the bounds of reason this would have to be considered, but to say that no deviation at all would be permitted is unreasonable.

Mr. HOGE. We wouldn't want to be unreasonable about it. Of course, good manufacturing practices under the Food and Drug Act require the label to bear an expiration date if one is necessary to assure the maintenance of the identify, strength, and quality at the time of use.

Mr. MOSS. But there can be some diminishing strength even prior to that date.

Mr. HOGE. Yes, there can be. Age, itself, will diminish the strength. That is one of the problems we have with drugs—not so much with over-the-counter drugs.

Mr. MOSS. As a matter of fact, the mere exposure to oxygen, on occasion, and that is why they use very tight seals, can cause that, and exposure to light can cause it.

Mr. HOGE. That is one of the difficulties in trying to work out safety closures for these products.

Mr. MOSS. I think we must attempt to assume that there would be good faith in the administration of the law. We recognize, certainly I do, that you cannot legislate administration and you cannot legislate judgment. But reasonableness you can require. It is a fairly good test. I think to make it absolute, as would be proposed there, is not proper.

Mr. HOGE. The committee report recognizes the philosophy we are talking about.

Mr. Moss. But that is very clear on its face.

Mr. HOGE. It says that the Secretary must find that the standard is not detrimental to the integrity of the substance, which is the essence of what we are trying to say. We probably didn't say it right.

Mr. Moss. I just wanted to get your interpretation of your own language and your intent.

Mr. HOGE. Our intent, of course, is not to permit anything that would impair the initegrity of the product, as the committee report puts it. We are all driving at the same thing. We just recommended that something be put in the statute itself rather than to rely on the report for it.

Our third one, and the only other suggestion we have, is that the term "special packaging" is defined as packaging designed to be significantly difficult for children under 6 years of age to open or obtain a toxic or harmful amount of the substance contained therein.

We would ask that this be amended to make it applicable to children under 5 years of age. We say that because practically all of the tables and statistics in this area relate to children under 5 years of age. Also, with a child at 6 and over, the chances are he has strength by that time to open almost anything we designed.

They are our only specific suggestions, Mr. Chairman. I can only repeat that while we have thought that it was better to leave this matter of packaging drugs—and I speak only as to drugs—to other existing laws and regulations, we are here in the same spirit as are you, that is, to work on a very important subject and to whatever we can to help, whether you do what we think you ought to do or not.

Thank you very much for letting me talk to you about it.

(The statement of James F. Hoge, before the Senate Commerce Committee, on Oct. 2, 1969, and appendixes thereto follow:)

STATEMENT OF JAMES F. HOGE, ON BEHALF OF THE PROPRIETARY ASSOCIATION, ON S. 2162, BEFORE THE CONSUMER SUBCOMMITTEE OF THE SENATE COMMITTEE ON COMMERCE—OCTOBER 2, 1969

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 S. 2162 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—90 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, Anacin, Bayer Aspirin, St. Joseph Aspirin, Bufferin, Alka-Seltzer, Castoria, Murine and Phillips' Milk of Magnesia. There are also 135 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 enlarged by the subject matter of the proposed legislation, and by the importance of the questions which it engenders. The first and most important of those questions is whether the bill—at this time and in its present form—will achieve child safety.

Promoting child safety is a subject with which we want to be involved and to which we have a sensitive relation. There is—and can be—no question as to the virtue of the declared purpose of the bill to "protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any hazardous substance." The Proprietary Association genuinely supports that concept, and numerous of its members have given thought, effort and financial support to the realization of it.

We hope we may raise questions about the bill and advise against passage of it without being classed as opponents of safety packaging. We realize the risk of that. It is not easy to articulate this position clearly without running the risk of being so classified or, at least, of being misunderstood. We insist—and respectfully ask agreement—that being opposed to this bill is not synonymous with being opposed to child safety and to necessary disciplines for accomplishing it.

It is in this framework that we say, for reasons which we will set forth, that this particular bill at this particular time will not accomplish its declared purpose. We think that the legislative requirements contemplated by this bill would better come at a later time when studies and experimentation now in progress have advanced further.

THE BILL

S. 2162 is drawn as an amendment to the Federal Hazardous Substances Act. It would empower the Secretary of the Department of Health, Education and Welfare to establish—in accordance with stated procedures—standards for "child-resistant" packaging of substances which he determines should have special packaging for the protection of the public health and safety of children.

The sweep of this delegation is immesurable. It would embrace every household commodity which is designed for "consumption or use by individuals for purposes of personal care or the performance of service ordinarily rendered within or about the household." (Section 2(r)). The classes of products affected are many. The number of products are legion.

Does this authorization mean that the Secretary will formulate standards in the nature of guidelines or does it mean that he will actually regulate the packaging of soaps, cleansers, bleaches, insecticides, pesticides, disinfectants, gasoline, kerosene, lighter fluids, floor polishes, solvents and thinners, glue and adhesives, perfume, toilet water, cosmetics generally, drugs and medicines, and other products too numerous to mention?

DRUGS

The interest of The Proprietary Association is confined to the application of the bill to over-the-counter medicines. This Association is neither authorized nor qualified to comment on the application of the bill to the many other affected products. The first question is whether drugs and medicines should be classified as "hazardous substances" and the packaging of them regulated along with the packaging of products which have been more traditionally classed as "hazardous substances."

The answer to that question should have regard to the fact that drug products are now regulated to an extent and in a degree not applicable to other products. The Federal Food, Drug, and Cosmetic Act regulates the composition and the labeling of drugs. It imposes a form of licensing with respect to "new drugs" and antibiotics.

Congressional interest in safety packaging of drugs began long ago. The Federal Act, and regulations thereunder, contain numerous provisions designed to preserve and enhance the identity, quality and purity of drugs; to promote the intelligent and safe use of them.

Section 502(f) (21 USC 352) defines a drug as misbranded unless its labeling bears *adequate* directions for use and *adequate* warnings against misuse. The regulations, attached hereto as Appendix I, interpret the law as requiring "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-three suggested warnings with respect to children appear in Appendix I;

(c) unsafe dosage: twenty-seven suggested warnings against unsafe dosage appear in Appendix I;

(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.

Appendix II indicates some of the many and specific requirements of the Federal Food, Drug and Cosmetic Act as to the packaging of drug products. In addition to the requirements there shown, the recently enacted "Fair Packaging and Labeling Act" has required relabeling of most drug products.

OTHER LEGISLATIVE PROPOSALS

As recently as 1966, bills relating to safety packaging of drugs were introduced in the Congress. In the House of Representatives, H.R. 13886 (89th Congress, Second Session) contained a provision designed to authorize the Secretary of Health, Education and Welfare to require safety closures on the containers of all drug products.

The Subcommittee on Public Health of the Committee on Interstate and Foreign Commerce held numerous hearings during the summer of 1966. The full committee reported to the House on October 1 of that year: "Report No. 2166; 89th Congress, Second Session." The Report accompanied S. 3298 which was entitled "Child Protection Act of 1966."

The Report included reference to H.R. 13886, stating, on page 4: "The committee believes that the problems attacked legislatively in Title I of H.R. 13886 can be more suitably handled by other means"; and, on page 5: "It is the feeling of the committee that the voluntary conference approach to limitation of amount of children's aspirin in a single retail container is desirable."

Such a "voluntary conference" was organized and held at the Food and Drug Administration in Arlington, Virginia, on November 21, 1966. The emphasis in the Congressional hearings had been on provisions of H.R. 13886 to limit the quantity of children's aspirin in retail packages and to require safety closures. The emphasis throughout was on preventing accidental ingestion of salicylates by children.

The Conference reported what it called thirteen "significant decisions" with respect to content of children's aspirin, flavoring thereof, number of tablets to be packaged in retail containers, bottle closures, and warnings to appear in the labeling. These decisions were contained in a summary of the Conference dated 21 November 1966. A copy of it is attached as Appendix III. As provided in that summary, these decisions were publicized in the *Federal Register* for March 2, 1967 (pp. 3440–41) as "conclusions and recommendations of the Conference." A copy of such publication is attached as Appendix IV.

With respect to closures, the Conference reported this decision:

(6) It was recognized that an ideal safety closure would be desirable for aspirin and all drugs if possible (OTC and prescription). Previous and continuing efforts in producing safety closures were recognized. A committee was appointed to make a continuing study of improved safety closures for "children's" and "adult" aspirin-containing tablets.

The Committee was constituted. The Chairman was, and is, Dr. Edward Press. He was then Chairman, Subcommittee on Safety Closures, American Academy of Pediatrics. He is now the State Health Officer of the Oregon State Board of Health. That Committee is continuing its study into safety closures. The expense of its studies is being borne by The Proprietary Association. But the Committee was not appointed by the Association and is in no respect responsible to it.

EDUCATIONAL PROGRAMS

The 1966 Conference also took this decision:

10. Educational programs should point out the dangers of accidental ingestion of "adult" aspirin, "children's" aspirin, and therapeutic overdosage. Industry pointed out that the Council on Family Health would be active in educational programs for the public to point out dangers from misuse of salicylates, other drugs and hazardous substances, as well as accidents in general.

The Council on Family Health was incorporated in Delaware on April 6, 1966 as a non-stock corporation. It has actively functioned ever since. It is supported financially by drug manufacturers, most of whom are members of The Proprietary Association. But the Council is not a part of the Association or responsible to it.

Senator Magnuson, at the time he introduced S. 3547 in the 90th Congress, took note of what he called "invaluable work" by the Council on Family Health, by The Proprietary Association, and by numerous governmental, professional, industrial, and university groups (Congressional Record, May 27, 1968, page 6423). Senator Magnuson again referred to the Council on Family Health in the Congressional Record of July 11, 1968. A copy of his statement at that time is attached as Appendix V.

Much more has now been done, and is continuing, by individual companies and by others in governmental, industrial and scientific circles. The common effort is to create and promote educational programs for enhancing the effective and safe use of medicines in the home—by adults as well as by children.

On November 5 and 6, 1964, at a conference in the Waldorf-Astoria Hotel in New York City, sponsored by the New York Academy of Sciences, a series of papers was presented on self-medication. These papers were published in the Annals of the New York Academy of Sciences, Volume 120, Art. 2, pages 807–1027, entitled "Home Medication and the Public Welfare."

The Propietary Association has welcomed the opportunities for participation—financially and otherwise—in the following kinds of undertakings related to prevention of accidental ingestion and to promotion of safety in the use of home medicines:

(a) The 1966 Annual Research and Scientific Development Conference, held on December 8 of that year in New York. This was an all-day program on "Safety in the Use of Home Medicines." It was arranged by the Committee on Scientific Development of The Proprietary Association. It involved presentations by leaders in the field of accident prevention (including accidental ingestion). The published "Proceedings" of this meeting attracted world-wide attention with favorable reviews not only in the *Journal of the American Public Health Association*, but also in medical journals from such distant countries as France and Israel.

(b) The Syracuse Health Department Accident Study directed by Virginia Harris, M.D. In 1966, the Association supported the "Syracuse Study" which was designed to determine the factors leading up to accidents in young children and the means of preventing them, including an assessment of the preventive role of educational efforts. Dr. Harris presented a paper at the Association's 1966 Annual Research and Scientific Development Conference entitled "In Pursuit of More Knowledge About Accidental Poisoning."

(c) Publication of the Proceedings of the 1966 Childhood Accidental Injury Symposium at the University of Virginia School of Medicine, coordinated by Roger J. Meyer, M.D. This two-day symposium was co-sponsored by the Children's Bureau of the Department of Health, Education and Welfare, the University of Virginia School of Medicine, the Virginia State Health Department and the Virginia Academy of Pediatrics.

(d) The New England Regional Conference on Poison Information Services in April, 1967 which was chaired by Joel Alpert, M.D.

(e) Publication of the Proceedings of a symposium in 1968 on "Childhood Injury Research," sponsored by the American Academy of Pediatrics through its Committee on Accident Prevention. It was also coordinated by Dr. Roger Meyer. It is anticipated that this publication will be available soon.

(f) National Planning Council for National Poison Prevention Week. Each year since 1962, the President of the United States, by proclamation, designates the third week of March as Poison Prevention Week. Each year the Association has provided staff and financial support to assist in planning for the distribution of poison prevention materials.

(g) American Association of Poison Control Centers' Committee on Education (chaired by Dr. Irving Sunshine).

(h) Greater New York Safety Council Program on Home Safety, April 17, 1969.

(i) International Conference on Poison Control in New York City on June 3 and 4, 1969. Much staff work went into preparation for the meeting and raising of funds.

These efforts of self-regulation, research, and public education have not been without effect. The September-October 1969 Bulletin of the National Clearing-

house for Poison Control Centers again reports a decline in the number of deaths from aspirin and salicylate poisoning. The report states that "this may be due to the voluntary limitation by the manufacturers in 1967 to a maximum of 36 tablets of 1¼ grain children's aspirin to a bottle. However, public education cannot be discounted since the percentage of all reported aspirin ingestions has dropped 4.1 points in 4 years."

In the foregoing circumstances, we are constrained to say that—as to drug products—it is not time for turning the matter of safe packaging over to legislative disposition.

PERTINENT QUESTIONS

The timeliness—or untimeliness—of the bill, as to drugs, is underscored by uncertainty as to what the bill actually requires.

1. It has been described as an "enabling act." Does this mean that the Congress merely authorizes the Secretary—who, in fact, will be the Commissioner of Food and Drugs—to determine, first, the many products which would be subject to the powers reposed in him by this bill, and then to specify the details of their packaging? If that is what it means, then the bill is lacking in standards or guidelines for his direction and in limitations upon his powers.

2. Will the Secretary prescribe not only container closures but also any other facet of the packaging which he considers appropriate? If so, then here again there are no directions, and limitations are wanting.

3. Would the bill enable the Secretary to prescribe the *labeling* for the multitude of products under his jurisdiction? Labeling is a very important part of packaging. Without directions and limitations the area for the exercise of the Secretary's jurisdiction in this respect would be vast beyond foretelling.

4. Would the bill enable the Secretary to require bottle closures, packaging, and labeling without variation? That is to say, would consumers have any freedom of choice? Would "child-resistant" packages be prescribed for all—adults and children alike? The bill puts its emphasis on "child-resistant" packaging. It is also important to provide for adult consumers, particularly those who are aged or crippled. The dependence of arthritics upon ready access to analgesics requires special consideration.

5. Whatever container or closure ultimately is required must assure the integrity of the product and not permit deterioration of the contents. This is of particular moment with respect to liquid products. Most of the study and discussion on container closures has related to tablets and other dry products.

6. There are substantial economic considerations which should be safeguarded by the bill:

(a) A large proportion of families do not have small children; certainly do not have them at all times. Their convenience is entitled to respect.

(b) Machinery and equipment must be capable of meeting the Secretary's regulations as to the form of packaging required. Manufacturers of drug products would have to make necessary investments.

(c) In the event of changing regulations from time to time, equipment and machinery would have to be adapted and factories sometimes retooled. There should be safeguards against reckless administration.

Here it is appropriate to emphasize a danger inherent in legislation of this sort. Even if described as an "enabling act", it would put the Secretary under stress to promulgate regulations lest he be accused of failing to carry out a statutory duty. At the time when there is no consensus on the acceptability of present safety closures, such stress could lead to premature requirement of unproven packaging. The industry would be discouraged from seeking improved packaging because changes would require further retooling and even greater expense. So, instead of *encouraging* the development of truly adequate safety packaging, the bill could tend to freeze the technology of safety packaging in its present initial stage.

CONCLUSION

If the Secretary is enabled to make the foregoing—and many other pertinent—decisions, is the objective of safe packaging really achieved? Most of the decussion has related to container closures. And to containers for dry products, at that. Apparently, the development of safety closures is in its infancy; in its experimental growth. Will it be to the ultimate good of all concerned to have present imperect closures legally mandated? Will the industries, the

professions, inventors, and container makers consider then that the government has taken over and done the necessary and that they may lessen their own efforts?

It is in these premises that we stated at the outset that we think legislative requirements such as those contemplated by this bill would better come at a later time when studies and experimentation now in progress have advanced further.

Our suggestion is that the technical advisory committee provided for in Section 3(d)(2) of the bill be separated from the bill and enacted as a first step; that such committee be instructed to review and coordinate the work of other committees and groups now going on; that the committee be authorized to hold hearings and to take such other steps as may seem proper to it for the purpose of gathering the necessary scientific and industrial information; and that such committee be instructed to report back at a stated time to this Committee with its recomendations.

APPENDIX I

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.

Subpart B—Drugs for Human Use

Subpart C—Drugs for Veterinary Use

Subpart D—Devices

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 under certain items, but not all medicines, the statement: "Warning—Keep this and all medicines out of children's reach. In case of accidental overdosage, contact a physician immediately," or "Warning—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, and in bold type on clearly contrasting background, 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, 146c.409, 146e.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.

* Cyclizine-containing preparations should include the following:

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. *

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 sympotoms 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 administration 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 external 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 Belladona 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 AMINOSALICYLIC ACID AND ITS SALTS). (See also § 3.509 of this chapter.)

Warning—Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately; or

Warning—Keep out of the reach of children.

If the article is an aspirin preparation, it should bear the first of the above two warning statements. In either case, the above information should appear on the label.

Caution—For children under 3 years of age, consult your physician; or

Caution—For younger children, consult your physician.

One of the two immediately preceding caution statements 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.

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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."

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 kerosine, 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 II

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 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 maunfacturer, 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:

(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 seg.).

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.

Conference on Prevention of Accidental Ingestion of Salicylate Products by Children—Arlington, Va., November 21, 1966

Summary of FDA conference on prevention of accidental ingestion of salicylate products by children

Free, open, and vigorous, but cooperative discussion was entered into by the practicing and teaching representatives of medicine, members from industry, and members of F.D.A. The discussion covered all salicylate-containing products packaged for retail sale to the public.

Only some points were determined after motion and voting and are identified (V). Many points were gained by consensus.

It was understood from the representatives of industry that they could assure 100% cooperation by the packagers and dispensers of aspirin-containing products for over-the-counter sales in implementing decisions made by this group.

The significant decisions were these:

(V) (1) The smaller aspirin tablets, often referred to as "children's aspirin" tablets, shall continue as gr. 1¼ in size.

(V) (2) The group was opposed to prohibiting the flavoring of "children's aspirin."

(3) It was against flavoring 5 grain aspirin tablets ("adult aspirin tablets").

(4) The maximum number of gr. 1¼ tablets permitted for a retail container would be 36.

(5) Manufacturers would not ship out retail packages containing a number more than 36 tablets after June 1, 1967. Dr. Goddard assured all that the present bottle size (to contain less tablets) would be permitted.

(6) It was recognized that an ideal safety closure would be desirable for aspirin and all drugs if possible (O.T.C. and prescription). Previous and continuing efforts in producing safety closures were recognized. A committee was appointed to make a continuing study of improved safety closures for "children's" and "adult" aspirin-containing tablets. Members: Dr. Edward Press, Chairman, Dr. Jay M. Arena, A member from Glass Container Industry, A member from Sterling Drug, Inc., A member from Plough, Inc., A member from Bristol-Myers Co., A member from Drug and Allied Products

Guild, A member from Whitehall Laboratories. A strong feeling was expressed in favor of attention to the safety closure feature of strip packaging.

(7) Agreement was reached for labeling all aspirin-containing products intended for children and for adults. This would include carton and container label and would read (in heavy block type on clearly contrasting background) "Warning, keep this and all medicines out of children's reach." "In case of accidental overdose, contact a physician immediately."

(8) Oil of Wintergreen, methyl salicylate, was recognized as a frequently lethal agent when ingested accidentally. Concern was also expressed about poisoning by phenyl salicylate and other toxic salicylates. FDA agreed to again bring this problem to the attention of the manufacturers of these products.

(9) The F.D.A. was asked and agreed to attempt to obtain a more detailed delineation of which deaths from salicylates were from methyl salicylate or from aspirin intended for adults or children. It was agreed that present data from the National Office of Vital Statistics is insufficient.

(10) Educational programs should point out the dangers of accidental ingestion of "adult" aspirin, "children's" aspirin, and therapeutic overdosage. Industry pointed out that the Council on Family Health would be active in educational programs for the public to point out dangers from misuse of salicylates, other drugs and hazardous substances, as well as accidents in general.

(11) It was agreed that advertising to the public with undue emphasis on flavor, and without warning against accidental ingestion, is undesirable.

(12) It was recommended that this study group or similiar body reconvene in the near future to evaluate the status of O.T.C. salicylates.

(13) It was agreed that the conclusions of this group be widely publicized in the Federal Register and elsewhere.

Respectfully submitted,

HARRY C. SHIRKEY, M.D.,
Chairman.

TITLE 21—FOOD AND DRUGS

ASPIRIN

During hearings in 1966 on H.R. 13886, the Commitee on Interstate and Foreign Commerce of the 89th Congress expressed the view that cretain provisions of the bill with respect to aspirin intended for children should be dealt with by the voluntary conference approach. Consequently, on November 21, 1966, the Commissioner of Food and Drugs convened a Food and Drug Administration-sponsored Conference on Prevention of Accidental Ingestion of Salicylate Products by Children under the Chairmanship of Harry Cameron Shirkey, Director. The Children's Hospital of Birmingham, University of Alabama Medical College. The Conference was attened by representatives of the medical profession, the drug industry, and the Food and Drug Administration. The names of the medical authorities and others attending the Conference, the Conference agenda, and the summary of the Conference prepared by the Chairman are available upon request directed to the Press Relations Staff, Food and Drug Administration, Washington, D.C. 20204.

The main items of the agenda of the Conference were:

I. Limitation of the number of 1¼-grain flavored asprin in a retail package.

II. Safety packaging.

III. Other safety measures to prevent injury or death of children from ingestion of salicylate preparations.

The conclusions and recommendations of the Conference may be summarized as follows:

A. The smaller aspirin tablets, often referred to as "children's aspirin" tablets, should continue as 1¼ grain in size.

B. The flavoring of "children's aspirin" should not be prohibited.

C. The flavoring of 5-grain aspirin tablets, "adult aspirin" tablets, should be discontinued.

D. The maximum number of 1¼-grain aspirin tablets that should be permitted in a retail container is 36.

1. The drug industry representatives attending the Conference agreed that drug manufacturers would not ship retail containers containing more than 36 tablets of 1¼-grain aspirin after June 1, 1967.

2. The Commissioner assured the Conference that use of the present bottle size to contain the fewer tablets would be permitted.

E. An ideal safety closure is desirable for aspirin and all over-the-counter and prescription drugs, if possible. A Committee was appointed to make a continuing study of improved safety closures for "children" and "adult" aspirin tablets. Attention to the safety closure feature of strip packaging was strongly favored.

F. The carton and container labelling of all aspirin intended for children and for adults should include in heavy block type on clearly contrasting background: "Warning—Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately."

G. Oil of wintergreen, methyl salicylate, was recognized as a frequently lethal agent when ingested accidentally. Concern was also expressed about poisoning by phenyl salicylate and other toxic salicylates. The Food and Drug Administration agreed to again bring this problem to the attention of the manufacturers of these products.

H. The Food and Drug Administration agreed to seek a more detailed delineation of which deaths from salicylates were from methyl salicylate or from aspirin intended for adults or children. The Conference agreed present data are insufficient.

I. Educational programs should point out the dangers of "adult" aspirin, "children's" aspirin, and therapeutic overdosage. Industry representatives pointed out that the Council on Family Health, 485 Madison Avenue, New York, N.Y. 10022, would be active in educational programs directed to the public to point out dangers from salicylates.

J. It was agreed that advertising of aspirin tablets to the public with undue emphasis on flavor without warning against accidental ingestion is undesirable.

K. This study group or a similar group should convene in the near future to evaluate the status of all over-the-counter salicylates.

L. The Conference conclusions should be widely publicized by publication in the FEDERAL REGISTER and elsewhere.

In accordance with the conclusions and recommendations of the Conference, the Commissioner orders that the statement of policy on labeling of drugs containing salicylates and the regulations regarding warnings on drugs for over-the-counter sale be amended as set forth below. Therefore, pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 502(f), 701(a), 52 Stat. 1052, 1055; 21 U.S.C. 352(f), 371(a)) and delegated by him to the Commission (21 CFR 2.120), Parts 3 and 131 are amended:

1. By revising § 3.509 (a) and (c) to read as follows:

§3.509 LABELING OF DRUG PREPARATIONS CONTAINING SALICYLATES

(a) The label of any oral drug preparation intended for sale without prescription and which contains any salicylate ingredient (including aspirin, salicylamide, other salicylates, and combinations) must bear a conspicuous warning statement in heavy block type on clearly contrasting background, such as: "Warning—Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately," or "Warning—Keep out of the reach of children," except that if the article is an aspirin preparation, it shall bear the first of these warning statements. Such a warning statement is required for compliance with section 502(f)(2) of the Federal Food, Drug, and Cosmetic Act and is intended to guard against accidental poisonings. Safety closures that prevent access to the drug by young children are also recommended to guard against accidental poisonings.

* * * * * * *

(c) Aspirin tablets sold as such and containing no other active ingredients, except tablets which cannot be readily subdivided into a child's dose because of their coating or size, should always bear dosage directions for each age group down to 3 years of age, with a statement such as "For children under 3 years of age, consult your physician." It is recommended that:

(1) Aspirin tablets especially made for pediatric use be produced only in 1¼-grain size to reduce the hazard of errors in dosage;

(2) By June 1, 1967, manufacturers and distributors of 1¼-grain size aspirin tablets discontinue the distribution of such tablets in retail containers containing more than 36 tablets, to reduce the hazard of accidental poisoning;

(3) The flavoring of 5-grain aspirin tablets or other "adult aspirin tablets" be discontinued; and

(4) Labeling giving undue emphasis to the pleasant flavor of flavored aspirin tablets be discontinued.

* * * * * * *

2. By revising §§ 131.9 and 131.10 to read as follows:

§ 131.9 GENERAL WARNINGS RE ACCIDENTAL INGESTION BY CHILDREN

Section 131.15 includes under certain items, but not all medicines, the statement: "Warning—Keep this and all medicines out of children's reach. In case of accidental overdosage, contact a physician immediately," or "Warning—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, and in bold type on clearly contrasting background, 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.

3. By revising in § 131.15 the item "Salicylates, including aspirin * * *" to read as follows:

SECTION 131.15 DRUGS FOR HUMAN USE; RECOMMENDED WARNING AND CAUTION STATEMENTS

* * * * * * *

Salicylates, including aspirin and salicylamide (except methyl salicylate, effervescent salicylate preparations, and preparations of aminosalicylic acid and its salts). (See also § 3.509 of this chapter.)

Warning—Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately; or

Warning—Keep out of the reach of children.

If the article is an aspirin preparation, it should bear the first of the above two warning statements. In either case, the above information should appear on the label.

Caution—For children under 3 years of age, consult your physician; or

Caution—For younger children, consult your physician.

One of the two immediately preceding caution statements 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.

Additionally, in accordance with recommendations of the Conference, the Commissioner requests manufacturers and distributors of drug preparations containing significant proportions of wintergreen oil (methyl salicylate) to label such drugs conspicuously with the warning statements contained in § 3.35 *Labeling of drug preparations containing significant proportions of wintergreen oil* and § 131.15 *Drugs for human use; recommended warning and caution statements*, under the heading "Salicylates: Methyl Salicylate (Wintergreen Oil)," which reads: "*Warning*—Do not use otherwise than as directed. Keep out of the reach of children to avoid accidental poisoning."

The Commissioner warns consumers to observe these label warnings carefully to avoid accidental poisonings of both adults and children.

Effective Date: This order shall become effective 30 days from the date of its publication in the FEDERAL REGISTER.

(Secs. 502(f), 701(a), 52 Stat. 1052, 1055; 21 U.S.C. 352(f), 371(a))

Dated: February 21, 1967.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 67-2326; Filed, Mar. 1, 1967; 8:48 a.m.]

[From the Congressional Record, July 11, 1968]

SAFETY IN THE HOME

Mr. MAGNUSON. Mr. President, more than 20,000,000 accidents a year occur in and about the home, bringing injury and personal tragedy into the lives of American families.

More than 28,000 of these accidents prove fatal. Included in this total are 5,500 children under age 5.

Most of these accidents need not happen. They involve a variety of mishaps resulting from human carelessness and ignorance; accidental ingestion of medicines and household chemicals by adults and children, fires, burns, falls, suffocation, electric shock and drowning, among others.

Congress has enacted legislation in a number of important areas of safety where the consumer needs help. The objective of this legislation is to increase the margin of safety of products when used as directed.

However, no amount of legislation and Government regulation can abolish carelessness and ignorance—the root cause of most accidents.

Education of the public by Government and by private industry offers great promise in the reduction of accidents.

I am happy to report that one sector of private industry has been actively conducting, for more than 2 years, an educational program designed to reduce the accident toll. This industry group, consisting of leading members of the drug industry, sponsors the Council on Family Health as a nonprofit, public service organization to promote home safety and family health. Its president is Howard A. Prentice, Ed. D. of Washington, D.C.

While the primary interest of the council lies in the proper use and storage of medicines, the council's program is operated on a much broader scale, namely, to alert mother to all types of accident hazards in the home and how to prevent them, and to give her simple hints on family health.

The council is reaching mothers by the millions through the newspapers and periodicals they read, the television screens they watch, the radio broadcasts they listen to, the club meetings they attend.

As an example, last fall the council began a campaign entitled "Home Safety Tips From the Stars." The time and talent of well-known personalities of the entertainment world were freely given. Stars who contributed their efforts were Danny Thomas, Donna Reed, Lorne Greene, Connie Francis, Eddie Albert, Greta Thyssen, and Emilia Conde and two clergymen, the Reverend Dr. Frederick L. Long and the Reverend Dana F. Kennedy, whose voices are well-known on the air. This project has resulted in bringing tips on home safety to the public through more than 10,000 radio broadcasts in public service time. This type of endeavor is a most effective way of bringing the message of home safety to the homemaker and to the family.

The council currently is preparing specialized program materials relating to the home hazard problems of youngsters, young adults, and senior citizens.

The Council on Family Health has received an award of merit from the National Committee on Films for Safety for a series of three half-minute color TV spot films on "Safety with Medicines," "Safety With Garden Sprays," and "Safety With Household Chemicals." These films also have been endorsed by the Public Health Service, U.S. Department of Health, Education, and Welfare.

I am glad to say that the Council on Family Health is cooperating with educational programs of the Food and Drug Administration, the Public Health Service, the Department of Agriculture Home Extension Service and many State and local departments of health—in addition to major private organizations.

I am also informed that the council's program is being emulated in other countries. Leading members of the Canadian drug industry have established a

Council on Family Health in Canada. Interest in the idea has been expressed in the United Kingdom, Europe, and Australia.

I have been a supporter of programs which pick up where legislation leaves off. I applaud the council's efforts. I for one will always encourage the private sector in helping to educate the public and in developing additional approaches to bring the safety story to every home in America.

Members of the board of directors of the Council on Family Health are: William F. Laporte, chairman and president, American Home Products Corp.; William M. Bristol III, senior vice president, Bristol-Myers Co.; Charles T. Silloway, president, Ciba Pharmaceutical Co.; Ivan D. Combe, president, Combe Chemical, Inc.; Peter Godfrey, president, Menley & James Laboratories; Walter R. Beardsley, chairman of the board, Miles Laboratories, Inc.; Hermon A. High, senior vice president, Richardson-Merrell, Inc.; Alfred E. Driscoll, honorary chairman, Warner-Lambert Pharmaceutical Co.; J. Mark Hiebert, M.D., chairman of the board, Sterling Drug, Inc.; Austin Smith, M.D., chairman of the board, Parke, Davis & Co., and Howard A. Prentice, Ed. D., president of the Council on Family Health.

Mr. Moss. Thank you.

Mr. Keith.

Mr. KEITH. Do you happen to know what other nations are doing in this?

Mr. HOGE. No, sir; I do not.

Mr. KEITH. I would think it would be valuable to have some kind of an interparliamentary discussion of this, or an international proprietary drugs association discussion.

Mr. HOGE. Mr. Keith, if it had not been for your hearings, I would be in New York today with a group that has just been organized; the World Federation of Proprietary Medicine Manufacturers. It was founded by the Canadian, European, and United States Proprietary Association. This bill was not on the agenda, but after hearing you, I would put it on.

Mr. KEITH. I would think it would be a very proper subject for discussion. It might have been one of the reasons for their getting together, and additional raison d'etre. I take it French is the language of that group.

Mr. HOGE. I think it is English and French.

Mr. KEITH. Is Mr. Prentice up there today representing your interests?

Mr. HOGE. No, Mr. Prentice is here; in Washington, that is; not in this room.

Thank you for your suggestion.

Mr. KEITH. Thank you, Mr. Chairman.

Mr. Moss. Mr. Eckhardt.

Mr. ECKHARDT. Thank you, Mr. Chairman.

Mr. Hoge, I note there are a good number of ameliatory phrases in this language which would seem to me not to require the Secretary to cover the entire field but also to restrict him with respect to those matters that are not presently technically feasible.

For instance, in section 3 he is not actually required to establish regulations or standards in any area. It simply says he may.

Mr. HOGE. You are quite right.

Mr. ECKHARDT. It says that these must be technically feasible, practical, and appropriate. In making them, he shall consider the reasonableness, the available scientific, medical, and engineering data. He can even consider the manufacturing practices of industries.

As a matter of fact, he is called on to do it. Under a section on page 4, subtitle (e), "He can, on his own initiative, exempt whole categories that he doesn't find necessary." For instance, I note you handle milk of magnesia, your people do, and I am familiar with that salubrious but repugnant, ill-tasting medicine.

I would immediately exempt that if I were the Secretary, having taken so much of it as a child. I think I can speak with a certain expertise on the fact that children will not take too much of it.

It seems to me there are many ameliorating provisions here that you folks ought to be able to live with.

Mr. HOGE. Mr. Eckhardt, I quite agree with you as to there being the provisions. Whether we can live with them or not may be part of our concern. Let me say this in compliment to Senator Moss and his committee, that much of what you just referred to came into this bill under Senator Moss' and his staff's consideration.

I would like to say that maybe we had a little something to do with that, too, because Senator Moss was very good about letting us talk to him and his staff. You are quite right, Mr. Eckhardt, of course. The bill has been described in the past as an enabling act; that it would enable the Secretary to make regulations. It does not compel him to do it. I know that.

The language is very clear. I think it is fair for me to say, however, as representing people who will be subject to it, that where you impose a responsibility upon an administrative bureau such as the FDA, the inclination to act is pretty great. You won't misunderstand me, I am sure, if I say that sometimes committees on this Hill put a little pressure on bureaus to get out and get busy, and sometimes to go a little further than they would like to go so they won't be criticized here or by the executive or others.

Mr. Moss. Would the gentleman yield for a moment?

Mr. ECKHARDT. I yield.

Mr. Moss. I wish with all my heart that the statement you just made was true, because I have sat on this committee for 15 years and I have watched us direct, not merely authorize, agencies to promulgate standards.

I spent the weekend reading a very interesting report which set forth in considerable detail the failure of those agencies to pay any heed to the direction of the Congress.

If you know of some motivating force that we might employ, I would be most interested in learning about it. There are a couple of agencies with which I am gravely concerned and muchly out of patience.

Mr. HOGE. I think you might also say, Mr. Chairman, that they frequently do things that you never dreamed of when you passed legislation. There is where a great deal of our concern comes from. They do these things which you never intended.

Mr. Moss. But inaction in recent years has caused me greater concern that their action.

Mr. HOGE. I have been reading some of the same material. I haven't seen this report you are talking about. I know it is out and that is part of the "must" reading for me in days to come.

Mr. Moss. It will be very interesting and very enlightening.

Mr. HOGE. I am more encouraged to read it now after talking with you.

Mr. Moss. Thank you.

Mr. ECKHARDT. I think there is a deep cleavage between perhaps the committee's view and the witness' view with respect to the ardentness with which the agencies address their task.

I would like to ask you about your comments concerning section 4 on page 4 and page 5 relating to the exception. I rather agree with you that to try to tightly establish standards, for instance, of a single size and other specific standards may be a little bit too specific for legislation of this type.

What would you think of altering section 4 to make it quite short, to read—reading from the language of section 4 through line 22 identically as it is written—"for the purpose of making a household substance for which a standard has been established pursuant to this act readily available to elderly or handicapped persons who may be unable to use special packaging, the Secretary may provide that such household substance may be packaged in packages not complying with such standards with such limitations annd such conditions as the Secretary shall prescribe?"

And then striking all of the material on page 5.

Mr. HOGE. Mr. Eckhardt, I am not surprised at your question. As I have studied the bill during these months I have wondered if something like that wouldn't be asked, and you are now asking it. It is a very logical and fair question.

Naturally, we would rather have some assurance in the statute, itself. I think that is understandable. If we can read it in the statute, we take it as a command to the Secretary rather than leaving it entirely to his discretion. There may be cleavage at times, and I am sure there is, between regulation and the industrial wish.

It is not unnatural—I think you would agree—that we would prefer to have every assurance we can in the statute. We know today, sir, that we can't have it always in the complications of this modern time.

There have to be regulations, we know that. But wherever we can get assurance from the statute, itself, that is what we would prefer and what we would like for you to do, if we can in some way get language to you that you will accept and agree to.

Mr. ECKHARDT. I had thought, for instance, that (e) almost does all of this because that permits him to exempt in whole or in part any category or product containing any product subject to regulation where he finds that such regulation applied to that category of product is not necessary to protect children, and so forth.

But the addition of where he finds it is not necessary to protect children and it would remove this from such a broad exception area, so I suppose you do need an additional provision by which the Secretary can exempt products under certain protection for this specific purpose.

It would seem to me that it would be logical to put it in as another exemption by the Secretary, though, perhaps as an (f), rather than as a separate section.

Frankly, I don't see any point in absolutely prescribing the manner in which he makes an exception, as is done on lines 1 through 12 on page 5.

In other words, what I am suggesting is one thing that would perhaps make it a little tighter with respect to your industry, or a little more adverse. That is leaving it to the Secretary to make the decision, but, on the other hand, I am suggesting something that might make it a little more lenient with respect to your industry in giving a wider discretion with respect to single size and with respect to some of the prescribed bounds of the exception.

I don't know how you would feel about that kind of tradeout. It is partically favorable to you and partically restrictive.

Mr. HOGE. We would certainly like to work with you, sir, and with your staff, to see if something could be done. I see that you understand what is in my mind, and I think understand what is in yours about it.

This exemption that you see here at (e) was put in, I think, for a number of reasons, but one very real reason was that there may be an article which consists of several ingredients and one of the ingredients may be one which, when sold as a single ingredient or sold in certain proportions, would require special packaging for safety, and yet when intermingled with other ingredients and in smaller proportions the Secretary might very properly, as this would permit him to do, say for that product or that line of products we don't need safety packaging.

Mr. ECKHARDT. Let me suggest two things: No. 1, even with the language contained in section 4, if the Secretary does, in fact, want to make a provision extremely restrictive, he can deny you much relief, I think, under the substantial evidence rule with respect to his activity, anyway.

But it would seem to me that there are areas where the Secretary ought to have considerable scope in dealing with different kinds of products. I can think of situations where the product is so dangerous to children and it would be so easy, for instance, for the druggist to open the package for the elderly person, that there should be no exemption at all, that you should simply package it in the manner that other medicines are packaged under the rule and simply depend on the arthritic, for instance, to ask the druggist to open it when he buys a package.

On the other hand, I can see situations in which there really should be a rather broad exemption and there should be the opportunity to buy either a large or a small package.

For instance, a person might be an occasional user of a particular drug, or he might desire to have a rather large quantity which might be necessary under the particular medical measurement that is applied to him.

But it seems to me that to try to anticipate all the limitations with respect to this exception is a little more than we ought to attempt to do in the statute.

Mr. HOGE. I understand your point. Let me go back to something of a moment ago. You spoke of the arthritic. That is the one we almost always think of. Large quantities have to be bought because it is aspirin. That is the drug for the arthritic. Maybe the druggist could open it for him. But if he took it home and opened it and left it open, then what trouble will we have on the open bottle that the child gets to?

Let me swing you to another drug that comes to mind, a drug for angina pectoris. There you have to have nitroglycerine or some comparable drug. You have to have it fast, and fast wherever you happen to be. The patient has to have it in his pocket so he can get to it quickly.

I had a personal experience with that. At church I found a gentleman in distress and that was his trouble, he couldn't get to his medicine. It was in his overcoat which was hanging up across the hall. Somebody had to go quickly and get the little vial and bring it to him. As soon as he got it and rested a few moments, he was off again.

There may be others. I thought of the two: the arthritic, which goes to one extreme as to quantity, and the heart patient which goes to the other but has need of quick action.

Mr. ECKHARDT. That is what I am thinking of. For instance, one way to protect against the use of this drug by small children, when you are using the exception, would be to require, the Secretary to require, only extremely small quantities.

But this is not necessarily the solution to other questions. I am simply suggesting that the language give more discretion to the Secretary but be initiated only on the Secretary's insistence.

Mr. HOGE. I have enjoyed so much this dialogue with you, Mr. Eckhardt. You won't mind if I say I think it rather reinforces the concern which manufacturers of drugs have, that in making regulations for packaging—which are going to be applicable to firecrackers, firelighters, glue, and all the other things—that we remember that these same regulations are going to apply to things as delicate as we are talking about; the drugs used in sensitive areas. That is a part of the difficulty in framing a piece of legislation like this. It is a part of your great responsibility, and it is a part of our great concern.

Mr. ECKHARDT. That is all I have, Mr. Chairman; thank you.

Mr. MOSS. I have no questions. I want to thank you and your associates for appearing here today.

Our next witnesses is Mr. Robert L. Ackerly, in behalf of the Chemical Specialties Manufacturers Association.

STATEMENT OF ROBERT L. ACKERLY, COUNSEL, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

Mr. ACKERLY. Mr. Chairman, I apologize for not having a prepared statement this morning. I wasn't sure until yesterday that the hearings were going to be held yesterday and today. So, I have not had an opportunity.

I will prepare written comments, if you desire.

The Chemical Specialties Manufacturers Association is a trade association of over 500 companies engaged in the manufacture and distribution of household chemical specialty products. This includes automotive chemicals, disinfectants, germicides, insecticides, waxes and polishes, and the aerosol industry.

This association, Mr. Chairman, in 1960, supported the Federal Hazardous Substances Act before this committee and the Senate Commerce Committee. We supported the Child Protection Amendments of 1966. We were responsible for a portion of the Child Protection Act of 1969, that section which relates to combustibility. We

support the aims of this bill. We always have. We are aware of the statistics of accidents with children 5 years of age and under.

While we support the principles, we have serious misgivings about some of the standards in this bill or, if you will, the lack of standards, the rather broad guidelines and the rather broad definitions. If this bill is passed, I assure the chairman and this committee that our association will cooperate with the Food and Drug Administration. We will work with them to try to make this bill work.

I was in a pediatrician's office this morning and there was a poster hanging on the wall. It said, "For every child who is poisoned there is a responsible adult." Then it posed the rhetorical question, "Are you a responsible adult?"

I think perhaps the poster might have said, "For every child who is poisoned there is an irresponsible adult."

We had great hopes for improved precautionary labeling. It has had some impact, but not enough. I don't think for one minute that changing the packaging is going to solve all of our problems. I think one of the dangers here is that we will enact legislation which will now relate to packaging and think that we have solved the problem.

It has been our feeling all along, and it is still our feeling, that the way to solve this is to get at the human factors in childhood poisoning.

Dr. Robert Meyer of Chicago testified before Senator Moss' committee. His testimony is very interesting. I am sorry he is not before this committee.

We feel that we have never marshalled all of the Federal resources to meet this problem. Everybody who testifies before a committee or everyone I have met who has had a child injured by a household product has repeatedly said, "If I had only known. I never knew this would happen. I never knew this product could hurt a child."

It is spelled out on the label but obviously people don't read labels. It is spelled out on poison control center posters and people pay little attention to them. Some day, Mr. Chairman, I think we will get a message to every pediatrician in this country, every obstetrician, every Public Health nurse, every obstetrical ward, every parent, so that we can get the message to them, "While your children are young you must handle household products carefully."

There was a witness before Senator Moss' committee who said after a child was injured everything was put on a higher shelf. Had they known there would be this risk, even though it was on the label, they would have handled it more carefully.

We hope this committee in your report will emphasize the need for continued education of the public and suggest ways to the Public Health Service and the Department of Health, Education, and Welfare as to how this can be done, by personal contact, through the Red Cross and through Public Health Service.

We have only two specific comments to make with respect to the bill, Mr. Chairman. First of all, the bill includes economic poisons subject to the Federal Insecticide Act. We do not feel that these products should be covered by this bill. They are regulated under the Federal Insecticide Act, which was passed in 1947, by the U.S. Department of Agriculture.

To the extent that there are packaging problems with pesticides that have not been dealt with, I think they can be dealt with under

existing law. If they cannot be dealt with under existing law, we would support an amendment to the Federal Insecticide Act to make clear that the Secretary of Agriculture can deal with the packaging as well as the labeling and safety of the product.

I know from personal experience that ant traps that we used to use around the house that have little holes in them were always subjected to testing by the Department of Agriculture before they were registered. Every economic poison is subject to pre-sale registration by the Department of Agriculture. Before the product is registered, it is subject to review of the U.S. Department of Health, Education, and Welfare, and the U.S. Department of Interior.

If there is a difference of opinion among these three agencies it is referred to a conference committee with two representatives of each of the agencies. If there is still disagreement after that review, the product is reviewed by a special subcommittee of the President's Council on the Environment.

That Cabinet committee then makes the decision and gives the direction to the Department of Agriculture as to what action is to be taken. We feel that packaging is already regulated and if it is not we would support an amendment to that law.

If you put economic poisons in this bill you are going to have this situation: The Department of Health, Education, and Welfare will be adopting a standard for a pesticide, but the product is not registered by the Department of Health, Education, and Welfare; it is registered by the Department of Agriculture.

So, the Department of Agriculture will be reviewing the HEW regulations and applying them to the package. Then when the product is sent over to HEW for review, they, in turn, will be determining what their regulation means or what their interpretation means.

We can get into conflicts solely on the package of the product. We do not feel the packaging of pesticides is a significant factor in childhood poisoning. The most popular package for pesticides around the household now is the aerosol and it is practically impossible for a child or anyone else to collect the contents of an aerosol and consume it. If you hold the spray up to your face to try to get it into your mouth the spray pattern will cover your face and get into your eyes.

Secondly, if you get it close enough it gets extremely cold at the valve. If you try to collect it in a paper cup it comes out under pressure and it will hit the cup and bounce out. We would prefer to see economic poisons remain where they are, subject to the Federal Insecticide Act.

Our second concern with this bill, Mr. Chairman, is the concept of preemption. In 1960 when the basic law was passed, it was passed principally, and the House report and Senate report both establish this, to establish uniformity in the regulation of household substances, hazardous household substances.

At that time, a half dozen States, including Texas, as I recall, Indiana, and one or two others, had passed laws starting in 1955 dealing with the regulation of hazardous household products. The Congress enacted a Federal law to insure uniformity of regulation. Uniformity is important, of course, for the manufacturer. But it is also important for the consumer. It is important that the consumer

know that the word "toxic" or "flammable" or "combustible" has the same meaning in New York as it does in California, because the hazards are the same.

As you know, we could not manufacture a different package for every State because it would be prohibitive economically. The legislative history being replete with statements as to the need for uniformity, most States went along and adopted uniform laws, uniform to the Federal act.

We have, I think, some 25 States with their own laws. But there were one or two States that were really not willing to go along with uniformity, and not only States, but cities.

In New York City, the fire department, believe it or not, insisted upon its own labeling on these same products. So, we had a situation where we were faced with possibly two precautionary statements on the same product, in different words, in different language, plus, for New York City, a statement in rather large letters saying, "NYCFD-C of A number." When you block up the number with that, you reduce the available labeling space for the precautionary message that the Food and Drug Administration has determined to be necessary.

When you put too much language on a label no one will read it. We had a choice then of litigating or coming back to the Congress. We came back to the Congress in 1966 and Congress added a preemption statement to the Federal act.

It preempted the precautionary labeling of all of these products, including exemptions in accordance with the regulations and the interpretations of the Secretary.

At that time, the law only dealt with precautionary labeling, and everybody seemed satisfied. The law now deals with banning. The Secretary under the amendments of 1966 has authority to ban products from interstate commerce. It now deals with toys and electrical hazards. It now deals with the combustible category for liquids and aerosols.

We feel that the preemption of this Federal act should be all inclusive to the extent of regulation within the framework of this act, including packaging, labeling, banning, and every other regulatory power the Secretary has.

The city of New York is still insisting that the New York C of A number appear on the label in large letters. The city of Chicago has under consideration at the present time a new flammability code which differs from New York City and differs from Food and Drug. The New York City regulations differ from the Food and Drug regulations, yet the hazard is the same.

We feel there is more expertise available at the Federal level, and we feel that there is no different hazard in New York City than in Los Angeles, Detroit, or Chicago. If New York City is entitled to have these things on the label, why shouldn't Chicago and Los Angeles and San Francisco, so that you get a whole panel of an aerosol or another product labeled with a series of registration numbers.

The bill as passed by the Senate has a preemption section in it. It takes the language from the National Motor Vehicle Safety Act of 1966. It provides that whenever a standard is established by the Secretary under this act no State or political subdivision shall have any authority to establish or continue in effect any standard for the special

packaging or labeling of such substance which is not identical to the standard established under section 3.

That immediately raises the question as to what happens when the Secretary exempts a product under section 3. If the Secretary determines that a product should be exempt and not subject to special packaging under the language of the Senate version of the bill, it is my judgment that every State is then free to go in and adopt their own regulations, in which case, we would be faced with a nightmare.

We would have been better off, I think, Mr. Chairman, if we had not come to the Congress in 1966, because under the Supreme Court decisions the statements as to the need for uniformity in the legislative history clearly established preemption under the law.

We thought it would be better to have it clarified by the Congress rather than to litigate.

Now, we are faced with what I think is too narrow a statement of preemption in the Senate bill. The States are as free as any member of the public or the industry to petition Food and Drug to establish a standard. If the State of California, or the city of New York, feels that a standard should be different, they can petition Food and Drug to change the standard. Under two decisions of the United States Court of Appeals for the District of Columbia on May 27, 1970, the Secretary must act or if he does not, if he refuses to entertain a petition or act on it, it is subject to immediate judicial review.

The language in section 7, whenever a standard is established, was litigated under the National Motor Vehicle Safety Act in the First Circuit and Second Circuit Court of Appeals last year.

I am familiar with these three cases because I tried them myself, both in the trial court and in the court of appeals.

There a lighting standard had been issued by the Department of Transportation, and the States of Vermont, New Hampshire, and New York, only three out of 50, decided they didn't like a particular lighting feature that Chrysler had on one of its Dodge automobiles and they refused to permit it to be sold in the State.

It was satisfactory under the Federal standard. We took the position that the Federal standard had preempted State authority. But the First Circuit and Second Circuit Court of Appeals pointed out that the language of the preemption section was not broad enough, was not all inclusive.

The States went through the standard and said, "See, you didn't regulate this, and you didn't regulate this. Therefore, we are free to do what we want."

We feel that everybody should go to one forum, the States, the industry, the public. We should make that forum the Department of Health, Education, and Welfare, and their decision, subject to administrative hearings, subject to judicial review, should be the final authority on how these packages are going to be prepared, regulated, and labeled throughout the United States.

We think this is important for the consumer because consumer education is difficult, and we want them to see the same words. At one time the New York City Fire Department wanted nonflammable when Food and Drug wanted flammable. We finally persuaded them that flammable was a better word and they dropped the "non".

So, we would like to see an improvement in section 7 and a clear statement in the committee report that this committee intends by this legislation to preempt the regulation of these products throughout the 50 States and the District of Columbia. We feel that it is important for the consumer, essential for the industry, and we assure the chairman and this committee of our full and complete cooperation in making this law work, in achieving the maximum benefit from this law, but I remind the chairman that this is not a cure-all. This doesn't contain all the answers to the problem we are facing.

We would like the committee report to stress again the need for extensive education, the need for personal contact, to get this message home to the housewife. I don't think there is a human being who, knowing something can harm his child, wouldn't protect that child from it if it could. The fact is apparently people don't know.

Mr. Moss. Mr. Ackerly, in 22 years of legislating I have learned that the perfect law has yet to be written. I would not anticipate that this law would solve everything, or that any law proposed in this session of the Congress or any session of the Congress would solve all the problems it is aimed at solving.

We are subject to a great deal of imperfection in drafting language, and then we have to try to anticipate administrative problems. All the way down the line it is just not possible.

We would not be under any illusion at all as to the effectiveness of the law and the need for continuing education. I think I clearly speak the consensus of the committee on that.

Mr. ACKERLY. That completes my statement, Mr. Chairman.

Mr. Moss. I have just one observation at the moment. During the time of the auto safety legislation I was one of those who worked to exempt my State from certain provisions because we had stronger requirements, particularly in the area of emission standards. I recall in the discussion there that I pointed out that if you take the State of California and break it out as a separate economy, a separate unit, it comes up with the fifth largest gross national product of any nation on earth.

It is a very attractive market because it has spent over the years a great deal of attention upon requiring, as a rule, more stringent protection than many other States. If it can feasibly develop standards which are more stringent than those of the Federal Government and afford greater protection to the citizens of the State, we should not preclude that possibility.

The market certainly is large enough to attract any manufacturer, to cause him to specially package, if necessary, to enter that market.

Mr. ACKERLY. Let me assure the chairman that in this field we have had absolutely no difficulty with California. As a matter of fact California has taken the leadership in some of these areas and Food and Drug has followed. We have complete uniformity between the Federal requirements and the California requirements.

The State of California has a fine department of public health and department of agriculture. I have worked with them for about 15 years. We have absolutely no problem with the State of California in labeling and handling these products. But when you use the words "more stringent," Mr. Chairman, this then becomes a judgment.

Mr. Moss. Let us say more effective.

Mr. ACKERLY. Then it is a matter also of judgment.

Mr. Moss. You have just indicated that the Federal Government has followed in many cases the work of the State of California. They would not be able to do that with total preemption.

Mr. ACKERLY. Yes; they would. As a matter of fact, the State of California has taken the leadership in petitioning the Federal Government to act. They petitioned the Federal Government in several areas dealing with pesticides. They did this by filing a petition with the Department of Health, Education, and Welfare, and then with the Department of Agriculture.

There were hearings. After the hearings, with the State of California being represented, a rule was issued, and we all live with it. It has usually worked out the State of California was right because they do an excellent job. You have a very, very fine State government in the State of California. Not every State has such a fine group of people and facilities as the State of California.

But I feel that every State should have the opportunity to petition Food and Drug. If the State of Indiana wants something in green when Food and Drug says red, or if New York City wants its own number on the label and the city of Chicago wants its own number on the label, we will be defeating one of the principal purposes of this act.

One of the principal purposes is to make labeling legible, make it stand out by color contrast, and using large enough type size so that the housewife can't miss it if she will look. At the bottom you will see, on the household products, "Caution, harmful if swallowed" or "flammable." We have put it on the front and we have put it on the back. The more individual requirements we have to meet, the less room we are going to have.

If we have an arbiter in the Food and Drug Administration or the Department of Health, Education, and Welfare, subject to judicial review, I believe, Mr. Chairman, we can all live under one set of rules. That is really all I am asking.

Mr. Moss. You have more confidence than I do.

Mr. Eckhardt?

Mr. ECKHARDT. Suppose we left out section 7 altogether, Mr. Ackerly, and the agency then makes a rule in which it purports to fully occupy the field. Would this satisfy you?

Mr. ACKERLY. I don't believe so for two reasons: One, it is the Congress that exercises the preemptive power and not the agency. I don't think the courts would accord preemption to a Federal regulatory statement.

Mr. ECKHARDT. Do you feel that the leaving out of section 7 would deny to the Secretary of Health, Education and Welfare the right to make a rule in which it purports to make the sole rule covering, for instance, the nature of the package, the nature of the closure?

Mr. ACKERLY. I do, for two reasons. One is because the law now has a pre-emption section in it and it is limited to precautionary labeling. When that section was adopted the law only dealt with precautionary labeling.

Now, we are getting into other areas. So a court, I think, would read the present——

Mr. ECKHARDT. I see what you mean. The present preemption section dealing with the specific.

Mr. ACKERLY. That is correct.

Mr. ECKHARDT. So, you would like to see section 7, but I would like to see it written more strongly, is that the point?

Mr. ACKERLY. Broader, I would say.

Mr. ECKHARDT. Have you any language that you would suggest?

Mr. ACKERLY. Yes and I can submit it to the committee. (See p. 118).

The language that I suggest is very consistent with section 17 of the act as it now stands. "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 regulation of any substance or article intended or suitable for household use which is not identical to the requirements or exemptions of this Act."

Mr. ECKHARDT. Of course, the Secretary could do absolutely nothing under this act and still conform with it, could he not, since the language is generally that he may establish in accordance with the provisions of the act rules with respect to various items.

Mr. ACKERLY. That is true.

Mr. ECKHARDT. If he did nothing, he would still pre-empt the field under your language, wouldn't he?

Mr. ACKERLY. He would. But in the status we are in now in administive law, our court of appeals held here on May 27, when a group of people petitioned the Department of Health, Education, and Welfare to establish a zero tolerance on DDT and the Secretary refused to propose it because he said it wasn't practical, the group took that to the U.S. court of appeals and they reversed the Secretary and directed the Secretary to publish the proposal and institute hearings.

I believe we have judicial review of the Secretary's action or failing to act, if we feel he is failing to act arbitrarily.

Mr. ECKHARDT. How could the court demand a closure that was considered safe from children if the Secretary didn't act? As a practical matter, the court couldn't make a nationwide requirement with respect to standards with respect to closure, could he?

Mr. ACKERLY. The way I envision this is if the Secretary doesn't act, as you suggest, and a group of concerned parents petition him to require a closure on a certain product and he doesn't act on that, they can get judicial review of his failure to act.

Mr. ECKHARDT. Do you feel they would have standing?

Mr. ACKERLY. Yes, sir.

Mr. ECHARDT. Do you have any authority on this? Would you suggest a case?

Mr. ACKERLY. It is the environmental defense fund versus Hardin, both decided by the U.S. Court of Appeals for the District of Columbia on May 27, 1970. They cite the *Associated Data* case in the Supreme Court. I believe that the Secretary, though the language is "may," if he refused to act arbitrarily, could be forced to take action by concerned citizens, and they would have standing.

Mr. ECKHARDT. Do you also have the three cases that you referred to with respect to the preemption cases?

Mr. ACKERLY. I don't have the citations with me. Chrysler Corp. was one party, and it was decided in the first circuit in June 1969 and in the second circuit in the fall of 1969, in about October.

Mr. ROBERTS. The New York case was *Chrysler* v. *Tofany*. The Vermont case was *Chrysler* v. *Malloy*. The New Hampshire case was *Chrysler* v. *Rhodes*.

Mr. Moss. Let the record show the answer was given by former Congressman Roberts.

Mr. ACKERLY. The Congressman has a much better memory than I.

Mr. ECKHARDT. Thank you very much.

(The following letter was received for the record:)

SELLERS, CONNOR & CUNEO,
Washington, D.C., June 10, 1970.

Re: S. 2162.

Hon. JOHN E. MOSS,
Chairman, Subcommittee on Commerce and Finance, House Committee on Interstate and Foreign Commerce, Rayburn House Office Building, Washington, D.C.

DEAR MR. MOSS: At the conclusion of yesterday's hearing on S. 2162, you stated that the record would remain open for ten days. Since my remarks on preemption may have left you not entirely persuaded, I submit these further comments to you.

This law cannot and should not be equated with the National Traffic and Motor Vehicle Safety Act of 1966. My reference was merely to point out the similarity of language in that preemption clause and Section 7 of S. 2162 and how the former had led not to clarity, but litigation. Yet, each act must be considered separately.

The Federal Hazardous Substances Act was passed in 1960 principally to achieve uniformity.

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. . . . 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. Rep. No. 1861, 86th Cong., 2d Sess., p. 3]

The Senate Commerce Committee said:

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. Rep. No. 1158, 86th Cong., 2d Sess., p. 3]

The American Medical Association also stressed the need for uniformity. [S. Rep. No. 1158, 86th Cong., 2d Sess.]

The 1960 Act achieved uniformity everywhere but with the New York City Fire Department and, in one minor instance, readily resolved, the State of Indiana. California's regulations dovetail perfectly with the Federal Regulations. Now we are faced with a proposed fire code for Chicago which may differ from New York City and the Federal Regulations.

Since New York City alone refused to accept preemptive effect of the 1960 Act, it seemed preferable to return to Congress rather than to litigate the issue.

This Committee, in approving a preemption section in 1966, said:

In 1960 this committee and the Senate committee emphasized the importance of *uniform regulation* of household products at which the act is aimed, which are sold nationally and across State lines. It is impractical, unnecessary, and undesirable for each side product to be labeled specially for those States and cities which have developed their own standards for requiring warnings and their own special forms of warnings over the years during which there was no Federal law. . . . On the other hand, if the hazard involved is of a kind not dealt[h] with by the Federal act, e.g., the hazards involved in power lawnmowers, the States

and localities would continue to be free to impose warning requirements though there is no such Federal requirement. [H. Rep. No. 2166, 89th Cong., 2d Sess., p. 3 (1966)]

The Department of Health, Education, and Welfare supported preemptive language in the law not only to achieve uniformity but to improve efficiency of enforcement and avoid duplication of cost and 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. [H. Rep. No. 2166, 89th Cong., 2d Sess., p. 13 (1966)]

The preemption was limited to precautionary labeling, then the only authority delegated in the Act though the committees stressed uniformity of regulation.

The Act has been amended in 1969 in addition to 1966, and now will be amended in 1970. Congress is responsive to changes needed in this law. But we request preemption of only the extent of regulation delegated under this law.

The Senate Bill, S. 2162, couches preemption in terms of *packaging* and *labeling* and only when a standard is in effect. Thus, a preemptive judgment of the Secretary for an exemption will not have a preemptive effect. Yet, there will always be preemption, if not by Federal law, then by the most severe, not always the best, law or regulation of all states and cities. Industry must meet not the most strict but many times the most ludicrous local ordinance. In ten years of administration of this law, the only major problem is raised by the New York City Fire Department. This is eloquent testimony that preemption under this law is successful and reasonable.

Crowding the label with all sorts of local requirements renders the Federal warning less legible and noticeable and defeats the main effort of this Act.

We urge you to adopt the language enclosed in lieu of Section 7 of the bill.

Very truly yours,

ROBERT L. ACKERLY.

SUGGESTION OF CHEMICAL SPECIALTIES MANUFACTURING ASSOCIATION FOR SECTION 7 OF S. 2162

(b) 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 regulation of any substance or article intended or suitable for household use which is not identical to 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 requirement shall be null and void.

Present Section 17(b) of the Act reads as follows:

(b) 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 sections 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.

S. 2162 attempts to amend this Section piecemeal, which will create only confusion. The law has been amended three times in the last four years and the established preemptive effect of the law should be as broad as the delegated authority.

Mr. Moss. At this point, I would like unanimous consent to insert into the record a communication addressed to the Honorable John Jarman, from the Department of the Army, together with certain exhibits and enclosures.

If there is no objection, it will be received for the record.

(The letter and exhibits referred to follow:)

DEPARTMENT OF DEFENSE,
DEPARTMENT OF THE ARMY,
MADIGAN GENERAL HOSPITAL,
Tacoma, Wash., May 25, 1970.

Re: Child resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting hazardous substances.

Hon. JOHN JARMAN,
Member, Interstate and Foreign Commerce Committee,
U.S. House of Representatives, Washington, D.C.

DEAR MR. JARMAN: As you know, accidental childhood poisoning is a national problem that affects up to 3,000,000 children each year in the United States. Only a small fraction of the poisonings are actually reported. However, of those reported to the National Clearinghouse for Poison Control Centers, over 90% of the poisonings of children under the age of 5 years fall into one of four categories:

1. Medicines—about 54%.
2. Household products—about 20%.
3. Petroleum products—about 10%.
4. Pesticides—about 6%.

A characteristic common to these four categories, is that the products are in *containers* easily accessible to small children.

In tests at our hospital, we have dispensed over 900,000 prescriptions in safety containers from 1 May 1967 to 22 May 1970. We have more experience in the clinical use of safety closures at Madigan General Hospital than any other hospital in the world.

Through the use of safety closures, there has been a consistent marked decrease in accidental poisoning of young children. It is our belief that the general use of safety closures for all hazardous consumer substances will greatly diminish the number of accidental poisonings that occur in the United States by 80%—just with this passive protection program.

Educational programs have just not done the job. What is needed in my opinion is legislation at the national level to protect our young children.

I've enclosed, for your interest, some recent reports from our hospital on the subject, and I would be happy to appear at house hearings if it would be helpful to you. (I made a statement at a hearing before the Consumer Subcommittee of the Committee on Commerce, United States Senate, on behalf of S. 2162, on 2 October 1969.)

Sincerely,

ROBERT G. SCHERZ,
Lieutenant Colonel, MC, Chief, Pediatric Service.

3 Enclosures:

1. Child-resistant Containers Can Prevent Poisoning, Pediatrics, January 1969.
2. Prevention of Childhood Aspirin Poisoning, Mil. Med., December 1969.
3. Prevention of Childhood Poisoning—A Community Project, to be published in Pediatric Clinics of North America, August 1970.

CHILD-RESISTANT CONTAINERS CAN PREVENT POISONING

Robert G. Scherz, LT COL, MC, George H. Latham, CAPT, MC, and Carl E. Stracener, LT COL, MC

Pediatric Service, Madigan General Hospital, Tacoma, Washington

ABSTRACT. During the period May 1, 1967, to April 30, 1968, prescription tablet and capsule medications from the pharmacies of Madigan General Hospital and McChord Air Force Base were dispensed in 270,000 child-resistant containers. Poisonings from all prescription medications decreased from 15.8 to 8.2 poisonings per 10,000 pediatric outpatient visits. The most significant change was a 90% decrease in poisonings due to prescription tablets and capsules dispensed in plastic vials originating from Madigan and McChord Air Force Base pharmacies during the test period.

The study suggests that widespread use of the test container would produce a significant reduction in accidental childhood poisonings due to prescription tablets and capsules. *Pediatrics*, 43:84, 1969, POISONING, CHILD-RESISTANT CONTAINERS, MEDICATIONS—PACKAGING OF, ACCIDENT PREVENTION.

In large surveys medications, particularly tablets and capsules, account for over one half of the poisonings due to ingestions.[1] Effective preventive programs are needed to reduce the annual toll. One approach would be the use of child-resistant containers for consumer medications. The purpose of this paper is to evaluate the effectiveness of a child-resistant prescription container in a clinical setting.

MATERIALS AND METHODS

In a previous report we demonstrated that a practical, inexpensive, child-resistant prescription container was markedly superior as a barrier to the small child when compared to the standard plastic snap-top containers in current use by our pharmacies to dispense tablet and capsule medications.[2] To test the effectiveness of the container in a clinical setting, a large study was devised, utilizing the medical facilities and a mixed population of 100,000 servicemen, retirees, and their dependents in a large Army-Air Force complex.*

During the period May 1, 1967, through April 30, 1968, all suitable prescription tablet and capsule medications were dispensed in child-resistant containers. The childhood poisoning experience was compared to the prior year. The pediatric work load at this medical installation is a function of the total child population. Therefore, visits to the Madigan pediatric outpatient clinic were used as a basis for comparing experience during the two time periods (Table I).

RESULTS

The accidental childhood poisoning rates per 10,000 pediatric outpatient visits during the two 1-year periods are summarized in Table II. There was an overall decrease of 37% in poisoning rates from all causes. However, the largest decrease, 47%, was in the category of prescription items, with a 70% decrease in poisonings from tablets and capsules (Table III). The sources of the prescription containers could be divided in three simple categories (Table IV). The plastic snap-top containers containing tablets and capsules involved in childhood poisonings came from prescriptions dispensed before the test period or from other civilian and military pharmacies. During the test period 270,000 child-resistant containers were used to dispense tablets and capsules.

* Fort Lewis-McChord Air Force Base, Tacoma, Washington.

(Submitted May 20; revision accepted for publication July 14, 1968.)

ADDRESS FOR REPRINTS: (R.G.S.) Madigan General Hospital, Tacoma, Washington 98431.

There were five poisonings from the child-resistant containers (Table V).

CAUSES OF FAILURE OF CHILD-RESISTANT CONTAINERS

Brief case histories of the failures were as follows:

Case 1

A 4-year-old girl was taking candy coated imipramine hydrochloride tablets (Tofranil) nightly for enuresis. The mother would routinely open the container in front of the child and give her a tablet just before bedtime. The child took 11 tablets while the parents were sleeping. She was hospitalized for 24 hours for signs and symptoms of drowsiness and disorientation. She easily opened a child-resistant container when she recovered.

Case 2

A 7-year-old, confirmed "children's aspirin eater" obtained a child-resistant container of flavored aspirin from an unlocked medicine cabinet. He read the directions, opened the container, and took an unknown quantity. To divert blame, he gave the uneaten portion to his 2-year-old brother. He then reported to the mother that the sibling had "gotten into" the aspirin. Neither child became toxic or was hospitalized.

Case 3

A 2-year-old boy climbed to a high shelf to get the "rattle" that his father had put there moments before. Fifteen minutes later the father found the open container and 58 diazepam tablets (Valium) scattered over the kitchen floor. The vomitus contained no recognizable tablets or parts of tablets.

The child was given a test container and observed for 1 hour, but he did not open the container. Significantly, he banged it, cap side down, on the floor, on repeated occasions during his play. On another occasion we observed a 1-year-old child use a banging motion on a rug surface. With a coordinated bang, cap side down, flat on the rug, and a slight counterclockwise twist, the cap came off. This random but precisely coordinated action most likely explains what happened with our Case 3.

Case 4

A mother was in the habit of leaving the tops off of her medicine containers and storing them on a high shelf in the kitchen. Her 2-year-old son was found playing with Dexamyl tablets on the kitchen floor. Actual ingestion was suspected but not proven.

Case 5

A mother had three propoxyphene hydrochloride tablets (Darvon) left from a prescription. She dumped them in her purse for convenience. Her 2-year-old son was found rummaging through her purse; one of the tablets was missing.

Based on the previous year's experience, the "expected" number of childhood poisonings due to capsules and tablets dispensed in plastic snap-top containers by Madigan General Hospital and McChord Air Force Base during the test period was 49. The actual number represented by the failures was at the most five, with a very liberal interpretation of poisoning. This apparent reduction of 90% is extremely encouraging.

COMMENT

There appears to have been a significant decrease in childhood poisonings in the population studied, due directly to the use of child-resistant containers to dispense pre-

TABLE I

MADIGAN GENERAL HOSPITAL, PEDIATRIC SERVICE WORK LOAD, MAY 1, 1966 TO APRIL 30, 1968

Data	*1966–1967*	*1967–1968*	*% Change*
Deliveries	1,947	2,113	(+) 8.5
Outpatient visits	58,884	63,670	(+) 8
Hospital admissions	1,681	1,537	(−) 9

TABLE II

ACCIDENTAL CHILDHOOD POISONINGS—RATES PER 10,000 PEDIATRIC OUTPATIENT VISITS FROM MAY 1, 1966, TO APRIL 30, 1968

Data	*1966–1967*	*1967–1968*	*Change*	*% Change*
Total poisonings	64.8	40.8	24.0	(−) 37
Total medications	42.6	27.6	15.0	(−) 35
Prescriptions	15.8	8.2	7.6	(−) 47
Aspirin	18.6	13.2	5.4	(−) 29
All other medications	8.2	6.3	1.9	(−) 23

TABLE III

ACCIDENTAL CHILDHOOD POISONINGS—RATES PER 10,000 PEDIATRIC OUTPATIENT VISITS, MAY 1, 1966 TO APRIL 30, 1968

Data	*1966–1967*	*1967–1968*	*Change*	*% Change*
Prescription containers—total	15.8	8.2	7.6	(−) 47
Plastic snap-top	11.4	3.6	7.8	(−) 70
Screw cap	3.6	2.5	1.1	(−) 31

TABLE IV

CHILDHOOD POISONINGS DUE TO PRESCRIPTION MEDICATIONS, MAY 1, 1967, TO APRIL 30, 1968: ANALYSIS OF CONTAINERS BY SOURCE AND TYPE

Container Type	*Madigan Pharmacies*		*Other Civilian and Military Pharmacies*	*Totals*
	Dispensed Before May 1	*Dispensed During Test Period*		
Plastic snap-top	11	0	12	23
Screw cap	0	10	6	16
Packet	1	6	1	8
Child resistant	0	5	0	5
Totals	12	21	19	52

TABLE V

ACCIDENTAL CHILDHOOD POISONINGS DUE TO PRESCRIPTION TABLETS AND CAPSULES DISPENSED IN 270,000 CHILD-RESISTANT CONTAINERS, MAY 1, 1967, TO APRIL 30, 1968

Cause of Failure	*Number*	*Age (yr)*	*Sex*
Child opened container			
Trained visually	1	4	F
Read instructions	1	7	M
Random trial and error	1	2*	M
Container top left off	1	2*	M
Contents of container transferred to unsafe container	1	2	M

* Ingestion suspected, not proven.

scription tablets and capsules. Of the five "failures," only one developed toxic signs and required hospitalization (Case 1). Two additional children were included who were circumstantially implicated; however, ingestion was not proven (Cases 3 and 4). Overall, the effectiveness of the child-resistant container was quite high. There was also an overall decrease in childhood poisonings in all other categories. The overall decrease in childhood poisonings of 37% could not be explained on the basis of population shifts, the pediatric outpatient work load, or changes in policy for management of poisonings. The overall decrease in childhood poisonings may be an indirect effect of the child-resistant containers—a reminder to an adult each time a child-resistant container is opened, that accidental childhood poisonings are an ever present threat.

IMPLICATIONS

The test containers are effective deterrents chiefly to children under the age of 5 years. It is this young age group that is most likely to ingest toxic solid and liquid substances. It should seem reasonable, based on our favorable experiences with child-resistant containers and medications, to look for ways to adapt effective child-resistant closures to household products, petroleum products, pesticides, and medications of all types. In 1967 to 1968, substances in these four categories accounted for 95.2% of all accidental childhood poisonings treated in our hospital. With the general use and acceptance of effective child-resistant containers for consumer items potentially toxic to children, we should expect significant decreases in childhood poisonings and mortality rates.

It is our conclusion that the widespread use of the test child-resistant containers to dispense prescription tablets and capsules, will markedly lower the incidence and death rates from accidental childhood poisoning.

SUMMARY

During a 12-month period, 270,000 child-resistant containers were used to dispense prescription tablets and capsules to a population of 100,000. The results of the

study demonstrate three important points. (1) Inexpensive child-resistant containers can be used in large quantities to dispense prescription tablets and capsules. (2) There was a significant decrease in childhood poisonings from prescription tablets and capsules due directly to the use of child-resistant containers. (3) There was an overall decrease in childhood poisonings which may be an indirect effect of the containers—a reminder each time a child-resistant container is opened, that accidental childhood poisonings are an ever present threat.

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Prevention of Childhood Aspirin Poisoning

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ACCIDENTAL childhood poisoning due to aspirin is a very common problem. The purpose of these studies was to evaluate the relative effectiveness of child-resistant containers to prevent ingestions of orange flavored 1¼ grain aspirin which is the aspirin form most frequently implicated in reported aspirin poisonings.

There were two aspects of the study:

1. A laboratory study of the comparative ability of 200 children under the age of five years to open three different types of closures.

2. A clinical study to evaluate the most effective container in the comparative study.

Historical Background

Year after year, poison control centers, child poisoning surveys, and pediatric clinics report aspirin as the most common medication involved in accidental childhood poisoning. From 1963-1967 accidental ingestions of aspirin among children under five years of age reported to the National Clearinghouse for Poison Control Centers ranged from 23.0 per cent to 25.8 per cent of all ingestions. In 1966, 40 per cent of all reported accidental ingestions among three year old children was aspirin. Each year since 1956, salicylate has been reported the primary substance producing death in children from ingestion. In 1965, of 379 deaths due to accidental poisoning of children under five years by liquids and solids, 113 were reported due to aspirin and salicylates.

This heavy toll from aspirin continues, despite local and national efforts by a variety of safety conscious groups to meet the problem with mass education techniques. Literally thousands of TV and radio messages and millions of pamphlets regarding prevention of aspirin poisoning have been disseminated throughout the United States, with little real effect in reducing the number of ingestions due to aspirin. The young children involved usually cannot read, and are only vaguely aware, if at all, of the consequences of ingesting aspirin.

The overwhelming majority of aspirin ingestions are 1¼ grain flavored aspirin tablets. However, the more serious poisonings from accidental ingestions are frequently five grain unflavored aspirin.

Since greater numbers of children consistently ingest flavored aspirin, this group seemed the most amenable to study. The principles learned from study of this group should be applicable to a great extent to all forms of aspirin poisoning by accidental ingestion.

Education Techniques

Education techniques may ultimately solve the problem of accidental poisoning for children amenable to learning. However, young children, as a group, are less able to understand or comprehend the seriousness of impulsive ingestions. Children need a maximum amount of passive protection during the preschool years.

It would seem that educational programs aimed at the parents, which emphasize the hazards of aspirin and the importance of careful storage, would be effective. However, two well-conceived studies demonstrate that this

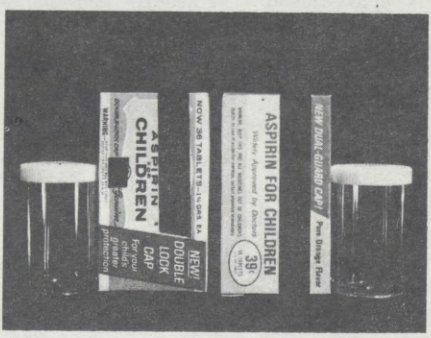

Fig. 1. Test containers taped to 9,505 boxes of commercial aspirin sold in Fort Lewis-McChord Air Force Base Post Exchanges, 1 Feb. 1968-31 Jan. 1969.

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approach has limitations.[2-3] In both of these studies, storage habits of the test and control groups were not significantly different. Children still find a way to get at usual containers of aspirin. Few, if any, shelves in the home are inaccessible to an active, climbing three year old child. Locked cabinets have a way of being unlocked at the wrong time.

Since the parents have difficulty keeping containers away from small children, another approach to the problem has been to make containers less vulnerable.

Safety Closures

In 1958, Arena[4] reported the results of a study conducted over a three year period with over 14 different types of safety closures, as well as the screw cap closure in common use at that time. The most effective closure was a close fitting polyethylene cap, with a ridge on the inner surface (press-lug) that gripped a tapered bottle neck and provided a very tight seal. A wide glass bead on the neck of the bottle was meant to discourage the child from biting it off. This closure has been used with modifications to package St. Joseph aspirin. Similar closure designs, utilizing the principle of a friction cap closure, have been used by a host of aspirin manufacturers. Although the friction cap closure was more of an effective barrier than the screw cap closure, it is breached too easily by small children using their teeth.

Comparative Study in a Laboratory Setting

In a previous report, a child-resistant container was found to be markedly superior to plastic snap-top prescription containers as a barrier to young children.[5] A subsequent clinical test demonstrated a significant reduction in accidental poisonings, due to prescription tablets and capsules,[6] when the test container was used in a large-scale study involving a semi-closed population of 105,000 Servicemen and their dependents. The same population was used for studies described in this manuscript. The purpose of this comparative study was to evaluate the relative effectiveness of three closures on medicine containers as barriers to 200 children under the age of five years in a laboratory setting. The technique for evaluation has been reported.[5] The study is described and summarized in Table I.

Results

Although better than the screw cap closure, infants as young as 12 months were able to open the friction cap closure without help. With visual demonstrations to simulate a common home situation, that is, the child imitating the parent opening a container, over 50 per cent of the two year old and 100 per cent of the four year old children opened the friction cap closure. Sixty-three of 131 successful children used their teeth. On the other hand, the same 200 children had great difficulty opening the press-lug closure. Only one child opened the closure within three minutes without help. An additional seven children opened the press-lug closure after visual demonstrations.

Evaluation in a Clinical Setting

To evaluate the effectiveness of the press-lug closure in a clinical setting, a second study was designed as follows: Between 1 February 1968 and 31 January 1969, a test container was taped to boxes of commercial 1¼ grain orange flavored aspirin, with newer versions of the friction cap closures, sold in the local Post Exchanges at Fort Lewis and McChord Air Force Base (Fig. 1). On the same shelves were boxes of aspirin without attached test containers. A simple sign on the shelf of aspirin encouraged the patron to transfer the children's aspirin from the original to the "safer" container. No other stimulus or instructions were given to encourage transfer.

Results of the Clinical Test

The data from the clinical test are summarized in Table II. During 1967-68, there were 58 childhood ingestions of aspirin sold by the local Post Exchanges and subsequently treated at Madigan General Hospital. The local Post Exchanges sold approximately 12,800 boxes of aspirin. Thus, during 1967-68, we had one aspirin ingestion for each 220 bottles of aspirin sold. During 1968-69, poisonings from aspirin sold by the local Post Exchanges decreased to 11.

A very close monitoring of aspirin sold with

TABLE I

MADIGAN GENERAL HOSPITAL COMPARATIVE ABILITY OF 200 CHILDREN TO OPEN THREE TYPES OF CONTAINERS

Age	No. studied	Opened Successfully								
		Screw cap*			Friction cap**			Press cap†		
		No Dem	1 Dem	2 Dem	No Dem	1 Dem	2 Dem	No Dem	1 Dem	2 Dem
12–23 mo.	50	11	11	8	4	3	6	0	0	0
24–35 mo.	50	34	12	1	7	13	8	0	0	1
36–47 mo.	50	49	0	0	15	21	4	0	1	1
48–60 mo.	50	50	0	0	32	16	2	1	1	3
	200	144	23	9	58	53	20	1	2	5
			176			131 (63 opened with the aid of the teeth)			8 (5 opened with aid of the teeth)	

* Two oz glass bottle with standard screw cap.

** New Bayer of St. Joseph pink plastic friction cap on 36 tablet bottle of 1¼ grain orange flavored aspirin.

† Palm-N'-Turn plastic press-lug cap on seven dram plastic container.

Trial: Three minutes *or* give up by the child despite encouragement, whichever occurred first. Inducement of candy inside of the container as a reward. Each child attempted each container in random order. If the child failed, he was given one or two demonstrations *visually*. The child was shown that he *could* use his teeth. Study terminated when:

1. Child was successful in opening the container after no demonstration, one demonstration, or two demonstrations.
2. Child was unsuccessful after three minutes with no demonstration, three minutes after both the first and second demonstrations.

Conclusions: 1. The press-cap closure is superior to the screw-cap and friction cap closures as a barrier to children under age five years.

2. The screw caps and friction caps tested should not be considered "child-resistant."

3. In the future, the one age group (48–60 months) should provide an adequate sample to determine whether or not a container is child-resistant.

and without an attached test container was done throughout 1968-69, by a monthly inventory of the sales by each Exchange outlet. During 1968-69, 9,505 boxes of aspirin were sold with an attached test container, and 3,887 boxes without this container.

Eight of the 11 poisonings were from aspirin sold without a test container (one per 485 boxes sold). Three were from aspirin sold with an attached test container (one per 3,168 boxes sold). On further questioning, two of the three ingestions were from the original container, because the parents had not made the transfer to the test container. Only one of the ingestions was due to a child opening the test container. This was a 19 month old female, who opened the container with a random motion and took five to six aspirin. During a subsequent one hour interview in my office, this child was unable to coordinate her movements and repeat opening the test container, despite encouragement and four visual demonstrations.

During the 1968-69 period, the local civilian physicians' Poison Control Center, County Poison Prevention Committee and hospitals caring for children were alerted to the existence of this clinical study. There was no increase in numbers of military dependent children seeking medical care for poisoning in the community. Specifically, there were no poisonings reported which involved a test container. In broader context, the total number of ingestions of "baby aspirin" treated during the

TABLE II

ACCIDENTAL CHILDHOOD POISONINGS FROM 1¼ GRAIN ORANGE FLAVORED ASPIRIN SOLD BY THE NORTHWEST AREA EXCHANGE BRANCHES AT FORT LEWIS AND McCHORD AIR FORCE BASE
1 February 1967–31 January 1969

	1967–68	1968–69
Total ingestions	58	11
Total sales	12,800*	13,392
Sales with attached test container	0	9,505
Sales without attached test container	12,800	3,887
Ingestions		
Units without test container	58	8
Ratio ingestions/sales	1/220	1/485
Ingestions		
Units with attached test container	—	3
a. Aspirin transferred	—	1**
b. Aspirin not transferred	—	2
Ratio ingestions/sales		1/3,168
Per cent change in ratios of ingestions/sales without test container 1967–68 compared to ingestions/sales with test container 1968–69	↓ 93 Per Cent	

* Estimated to nearest 100.

** 19 m.o. female opened container with random motion and took six aspirin.

1967-68 period was 91. Thirty-three of these were from aspirin obtained from other sources. During 1968-69, there were 51 children treated for ingestion. Forty were from aspirin obtained from other sources. Ingestions from aspirin obtained from other sources were not significantly different during the two time periods.

Comment

There was a marked reduction in ingestion rate which can be best explained by the use of an effective child-resistant container. It is apparent from this study that children's aspirin should be originally packaged in a more effective container. Relying on parents to consistently transfer aspirin to a safer container will lead to unnecessary poisonings when they fail to do so.

There was also a decrease in poisoning rates from aspirin sold in 1968-69 without a test container (1/485 compared to 1/220 in 1967-68). This decrease may be related in some way to the test container program. By conjecture, some of the parents may have purchased one or more boxes of aspirin without a test container and re-used a test container from an earlier purchase. This occurred in several specific instances; however, the extent of the practice could not be determined.

It would appear from the results of this study that effective child-resistant containers, used universally to package aspirin, will be accompanied by a significant decrease in the number of aspirin ingestions and subsequent poisonings of children under age five years.

Summary

A child-resistant container, evaluated in both a laboratory and clinical setting, was found to be more effective than the common friction cap "safety" closures in preventing accidental childhood poisoning due to 1¼ grain flavored aspirin. The clinical use of the test containers during a 12 month study period, was accompanied by a 93 per cent decrease in poisoning rates due to flavored aspirin.

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Prevention of Childhood Poisoning—A Community Project

(By Robert G. Scherz, Colonel, M.C., U.S.A.)

They that are healthy have no need for a physician.

—Luke 5:31.

Most of the practice of medicine today deals with effect, not cause, for without a disease state in the human body, there would be no need for the traditional physician. The preceding chapters in this symposium dealt primarly with what to do with a child who has been poisoned. Each day physicians and poison control centers in the United States and Canada receive *thousands* of inquiries from parents in their communities regarding accidental childhood ingestions. These parents are asking for help—for an acute problem. We should be giving them help—*and* seeking specific programs to prevent recurrence of similar or identical phone calls in the future. As long as communications remain open, parents will continue to call to remind us that the community is *not* solving the problem of cause, by dealing only with effect.

Accidental poisonings should be considered preventable. Not in some vague way such as a general edict to parents to protect their children from poisoning, but with community programs directed with precision toward specific problems, much like preparing a specific vaccine for a specific infectious disease.

Health workers in the community who direct their attention toward prevention of a poisoning perform a task that is of greater value to society than the many hours and days of time and resources needed to imperfectly repair the damage from a single case of lye ingestion. The publicity and honor go to those who deal with the dramatic effect. Effects of poisoning can be *seen*. Those poisonings that have been *prevented* are much more difficult to identify. Yet careful gathering of pertinent data can reveal how successful a community program really is. This chapter will examine the factors that should be considered in developing community programs, outline an organization of health resources for community action, give several examples of successful community programs, in the United States and Canada, and suggest a method for evaluating success of the programs developed.

The poisoning event

Accidental poisoning of a child is a complex interaction between the child, a hazardous substance, and certain environmental situations. These three factors must be kept in mind when developing community programs. The characteristics of each can be summarized as follows.

The child

The young preschool child is most susceptible to accidental poisoning. In all societies where statistics have been gathered, the two and three year old children account for over one-half of all reported poisonings, with 80–90% of the children under the age of five years. (5), (10), (14), (15), (17), (24)

Characteristically those children who are poisoned are more likely to be impulsive, overactive, and discipline problems for the parents. Not infrequently the parent-child relationship is disturbed. Children are particularly prone to accidental poisoning when usual family patterns are interrupted, during such episodes as moving, pregnancy, illness, death, marital problems, or visiting another home. Too frequently the recognition of family stress occurs *after* the first accident or poisoning. Since approximately 10% of the children are repeaters, the children and the circumstances around the initial poisoning should be evaluated carefully to uncover factors that may be important in preventing subsequent poisonings. (18)

More than one-half of the time, the child ingests a toxic agent that is in clear view of the child. A child tends to react to his environment impulsively, seeking what he wants when he wants it. A toddler may not be innocent or ignorant when he secretively gobbles down a bottle of flavored children's aspirin or samples granules of caustic lye, however, he is certainly naive to the consequences.

In many instances the possibility of poisoning is related to the developmental patterns of the child. The six month old child will put *anything* in his mouth. A one to two year old child will empty cupboards, particularly low ones, and experimentally taste most things. Kerosene stored in a familiar soft drink bottle may be ingested completely by a two year old child with no fussing or crying. By the time he is 2½-3 years old, the child is adventurous and has virtual access to any unlocked drawer or cupboard in the home. All challenges are accepted in

impulsive or ingenious ways. Toward the end of the third year of life and by the age of four, the numbers of accidental ingestion are starting to decline despite an increase in motor ability. The four year old child tends to be more selective in what he ingests, preferring those things that taste good; including flavored children's aspirin, vitamins, and candy coated tablets.

To prevent poisoning, programs must be developed that will completely protect the child from age three and under. When he is approaching age four he will, if he is taught, understand simple safety rules and have enough good sense not to eat or sample everything that he comes across in the home. From the age of four on, self-control through education is the primary deterrent to poisoning.

Parents should strive for complete and instant obedience to rules of safety early in the child's life. Rules of obedience offer a form of guidance that a child must have to grow up free from serious injury. It is much better to go through life with a questionably scarred ego than a very real scarred esophagus which will requre a lifetime of repeated dilatations.

The hazardous substance

In any poisoning there must be at least two components—the child and the hazardous substance. Unless both are together, a poisoning cannot take place. Most poisonings in the United States are from the ingestion of toxic substances in the home stored in accessible places in the original container with the top closed. In industrialized societies, the most common substances reported in accidental poisonings are medications. They account for one-third to over one-half of the reported poisonings in Germany, France, Italy, United States, England, and Canada. In one survey, the average home contained 30 containers of medications.(20) Each year an estimated 400 containers of toxic or potentially toxic substances enter the homes of families of four in the United States. This pool consists primarily of medicines, household products, including cosmetics, petroleum products, including turpentine and paints, and pesticides. Poisonings from these containerized products have been implicated in at least 90% of the reported poisonings to the National Clearinghouse for Poison Control Centers during the last five years.(16) (Table I) This plethora of potential toxins in homes is a ready source of material for ingestion by young children.

In lesser developed countries, the substances ingested reflect the toxic substances in the home. In India, kerosene used for heating is a principle toxin. In one study it accounted for 60% of all poisonings.(5) Indian children under the age of six months are poisoned frequently by opium given to them by mothers to control diarrhea and excessive crying. In New Zealand, agricultural chemicals are a prominent cause of accidental poisoning.(15)

The emphasis in most reported accidental childhood poisonings is on the ingestion of solids and liquids. However, inhalation of poisonous gas, fumes, and smoke also produce poisonings and death.(6) The most common offender is carbon monoxide which may arise from a defective auto exhaust system or a smoldering fire in a confined area. In one case a month old infant living in a house trailer had several unexplained illnesses and eventually became severely ill. Carbon monoxide poisoning from gas escaping from a propane-heated oven was the source of the poisoning.

More than one child allowed to sleep on the back seat of an automobile or worse yet on the floor, has been poisoned from carbon monoxide seeping into a running automobile from a defective muffler. Parents should be alerted to the dangers of carbon monoxide poisoning.

Environmental factors

There are a number of environmental factors that interrelate with the child and the hazardous substance, to end in poisoning. They include such things as time of day, relationship to meals, whether the product is in or out of sight, recent experience with the substance, family stress, and parent attitudes toward the toxin. There is a general understanding among the laity and professionals that careless storage is a major factor in the cause of accidental poisoning, yet there is no clear cut evidence that this is true. In a study reported by Sobel, (22) of 400 families (122 families with a history of a poisoning and 278 controls) no significance was found:

1. In the degree of hazard in poisoned VS non-poisoned homes.
2. In storage habits between poisoned and non-poisoned groups.
3. In storage habits one year later even though there may have been a poisoning in the interim.

How careful are physicians with young children with storage of medications in their own homes? One would think that pediatricians in particular would be quite sensitive to safe storage practices. However, a surprise survey of medications in the homes of twelve pediatricians with young children (Table II) disclosed that only one pediatrician had all of his medications securely locked up. A second pediatrician had 23 of his medications locked in a steel file box, however, he had 12 other medications in three other accessible sites in the home. In this sample there was a common disregard in the homes of practicing pediatricians of a basic principle of poison prevention extolled to their patients: "Keep all medications out of reach of children". Yet, it would seem pure heresy to recommend that parents disregard safe storage principles.

In a similar study of 52 poisoned and 52 control families, Baltimore et al found no significant differences in the poisoned and control groups in storage habits or the mother's knowledge re toxicity. (2)

In the studies reported thus far, the vast majority of toxic substances in the home associated with accidental poisonings were accessible and packaged in containers easily opened by young children. In this hostile home environment, the child must develop self-control early if he is to survive. However, we are far from achieving the goal of establishing self-control in early childhood for all children. The alternative is to increase our protective efforts through elimination of useless toxins in the home, safer packaging, and parent education while attempting to find better methods to control undesirable childhood impulses. (7)

Health resources in developing community accidental poison prevention programs

The approach toward the prevention of accidental poisoning should be a community one which includes a close interaction between the poison control center, the local health department, communication media, public schools, physicians, pharmacists, Public Health nurses, social workers, and family units. Although ultimately it is the parents' responsibility to protect the child, health workers can provide assistance which will result in lowering accidental childhood poisoning rates.

Poison control centers

Approximately 600 poison control centers are scattered across the United States and Canada. In the past, they have assumed the role of information centers for the physician and community, to help in the recognition and early management of accidental poisonings. With few exceptions, they have *not* been engaged in successful *prevention* programs. They all should be. These centers can be a source of vital information regarding the types of poisonings that are occurring, to whom, and how frequently. Cooperating hospitals and physicians should report all poisoning cases to the local center, to add to the inquiries received by them from other sources. With a more complete reporting system, a truer incidence of poisonings in the community could be realized. Monthly reports should be sent to individuals in the community, who are in a position to participate actively in prevention programs. The effectiveness of a particular program could be judged by evaluating the changes in reported poisoning rates.

Health workers

Specifically, what can the professional health workers do? How can the preventive program be organized?

The physician

The physician is the center of the poison prevention team. He is the one who has contact with the patient's acute problems and provides care to reduce disabi'ity and the possibility of death. The physician who cares for a poisoned child should be aware of the increased risk from repeating and specifically caution the parents. (25) With a chronically disorganized family, a referral to a social service worker or Public Health worker may be helpful particularly if they can make a home visit and offer specific practical advice. (11)

Physicians should insist that in most instances their prescriptions are properly labeled with the name and strength of the drug. The patient has a right to know about his illness and the medications prescribed. Also, in emergency situations such as accidental poisoinng or overdosage, the product can be immediately identified and appropriate treatment initiated without delay. Proper labeling may or may not prevent many poisonings but it can *reduce* the morbidity. It also reduces the chances of mix-up of medications taken by different members of the family. The Council on Drugs favors labeling of prescriptions as a general prac-

tice, and furthermore, it is recommended that prescription pads contain a yes-no box on whether to label. (12) The physician should also insist that his prescriptions be packaged in child-resistant containers (CRC's) whenever possible.

The physician should be the impetus for guiding others in the community in poison prevention programs. He can be the matrix to hold together a prevention program, and the ferment to keep it moving. He cannot, however, do it alone. He needs help from other interested health workers in the community. Since over one-half of all childhood poisonings involve medications, it is *essential* that the professional pharmacist become intimately involved.

The pharmacist

The practicing pharmacist should establish a working relationship with the nearest poison information center. He will become familiar with the problem and be in a better position to advise and discuss accidental poisoning with other professionals in the community. He is in an enviable position to *prevent* many childhood poisonings by:

1. Using CRC's to dispense prescriptions whenever possible.
2. Encouraging manufacturers of over-the-counter medications to package medications in CRC's, and favoring those medicines so packaged.
3. Supporting legislation requiring safe packaging.
4. Encouraging labeling of prescriptions.
5. Affixing "Keep Out of Reach of Children" stickers to all medicines both prescription and over-the-counter.
6. Communicating the dangers of overdosage of medicine to parents of young children.
7. Providing "Syrup of Ipecac" at cost to families with preschool children throughout the year.
8. Distributing poison prevention literature.
9. Serving as a member of a speakers bureau made up of professionals including nurses, physicians, pharmacists, social workers, and educators who would be available to speak to community groups on poison control. Slide talks can be obtained from the American Pharmaceutical Association and the American Association of Poison Control Centers.
10. Serving as an advisor to the local poison information center.

The Public Health oriented nurse and social worker can be of immense help in the community in prevention programs through their support and active participation. Through home visitations and counseling, they can become extensions of the physician and provide insight into the variables important in producing an accidental poisoning. Nurses can be particularly effective in the organization and management of the local poison control center and in conducting prevention programs centering on educational talks to lay audiences. School nurses should insist that instruction in prevention of accidents and poisoning be part of the school health curriculum.

Community programs for poison prevention—Mass educational programs

In the past, most poison prevention programs have been directed toward utilizing various communication media in mass public education programs. In September 1961 the Congress by joint resolution, authorized the President to issue annually a proclamation designating the third week in March as National Poison Prevention Week. The purpose of the observance was to ". . . aid in bringing to the American people the dangers of accidental poisoning." Mass educational programs originating from a national headquarters, are particularly prominent in March of each year. Regrettably the continuing high rate of poisonings of young children in the United States leads to the conclusion that however well intentioned mass education programs have been, they have fallen short of controlling this major childhood problem. Over the years, the reported numbers and percentages of substances ingested by young children seem monotonously similar. (16)

How helpful are concentrating and continued mass educational programs in reducing accidental poisoning? That question is difficult to answer. Ideally base lines should be the number of children who ingest toxic substances. This base line has not been established in any extensive study to date. To be valid it would have to include those children who received no medical attention. Two surveys evaluating a project in Charleston County, South Carolina, disclosed a decline in hospitalizations of children under five years of 23–29% during the period 1962–1964. (13)

The surveys also disclosed that despite a great deal of community effort, there was still a lack of awareness by adults pertaining to:

1. The potential hazard of commonly used household products.
2. The mobility, ingenuity and agility of children as they progress in their growth and development.

In the two surveys of 1733 families, newspapers, television, radio, school, friend or relative, and group meetings were principal sources of information regarding accidental childhood poisonings. It's not clear why there was a decrease in hospitalizations for there was no clear cut difference after the educational campaign in storage habits, concept of accessibility of children to toxic substances, or changes in parents' plans of action after poisoning. All educational programs aimed at parents must be translated by them to their children. That parents are eventually successful in transmitting safety concepts to children is evidenced by the decreasing rates of accidental poisoning by children before they reach school age. However, it is during the ages of highest risk of poisoning, particularly under age 5 years, that parents need additional help in protecting their children. Specific programs should relate to the immature, naive psyche of the young child and his particular inability to realize the potential harm of his impulsiveness.

Educational programs aimed at parents should *not* be discontinued. Although it is difficult to prove how effective they are, it may be that current programs reflect a relatively low saturation point with increasingly massive programs capable of producing only a limited increase in effectiveness.

National organizations such as the American Medical Association, American Association of Poison Control Centers, American Public Health Association, National Clearinghouse for Poison Control Centers, National Planning Council for Poison Prevention Week, National Safety Council, the American Pharmaceutical Association, and the American Academy of Pediatrics have abundant amounts of prepared material that can be useful for parent education. They can also provide information regarding other sources of material useful for local community action.

Educational programs directed toward children

Children are particularly susceptible during the early school years to educational programs stressing accidental poisoning. By the time the child reaches school age he has passed the age of greatest risk to himself. Educational programs for him must be considered primarily informational. They will produce secondary changes in poisoning rates as a function of how much the school child can transmit to his parents and preschool siblings.

One could say that conditions might be worse if there were no mass educational campaigns. Conversely, the measurements of real success has been elusive. The practical limitations of mass educational programs should be realized and other methods utilized to reduce the opportunity for young children to ingest toxic substances.

Some specific poison prevention programs

Several community programs for prevention of accidental childhood poisoning have been developed that have practical application for the control of specific poisoning problems.

Prevention of lead poisoning

The prevention of lead poisoning in children is at once a simple and a complicated problem. Poisoning results mostly from ingestion of lead containing paint in old, dilapidated housing. Prevention of lead poisoning is to prevent children from eating the paint. Prevention starts with recognition by health workers in the community that the problem does in fact exist. Once it is recognized that there are within the community dwellings which have leaded paint in interiors, the following steps are essential:

1. All occupants should be warned. Parents and other adults in the home can do much to keep the younger children from eating paint and chewing the surfaces if they know that they are dangerous.
2. Remove leaded paint or cover it. One city (Baltimore) reports good results from covering walls to a height of four feet with wall board.
3. Keep child suspected of eating lead from further exposure. This may mean removal from the home until the home can be made safer.
4. Alert health workers and those who come in contact with children from hazardous dwellings, to early signs of lead poisoning (lethargy, irritability, stomach pains, vomiting). Have suspects tested for plumbism. Most reliable are blood lead levels. However, in low risk communities, urine screening tests are adequate.

5. When a case is found, check other children in the home.

6. Treatment should start immediately after diagnosis of lead intoxication to prevent further damage.

For further details on successful community programs for prevention of lead poisoning, consult the listed references. (1), (9)

Prevention of poisoning from prescription medications

Two separate studies in Canada and the United States have demonstrated that widespread community use of child-resistant containers (CRC's) to package solid prescription medications can reduce significantly the numbers of accidental childhood poisoning. (3), (4), (20), (21) In both studies there were in addition to the direct reduction of poisonings by safety packaging, unexpected reductions in poisonings by other non-related toxins. These studies suggest that safety packaging acts as a primary deterrent and as an educational device. Each time an adult opens a CRC to obtain medication, he is reminded of the ever potential threat to children by other toxic substances in the environment, and subsequently transmits this reminder into action that results in fewer childhood poisonings. (2)

The experience in accidental poisonings at Madigan General Hospital from May 1966 to February 1970 is summarized in Table III.

Since May 1967, all suitable tablet and capsule medications have been dispensed from the Madigan General Hospital and McChord Air Force Base pharmacies in child-resistant containers (CRC's). To date (1 Feb 1970) 750,000 CRC's have been dispensed. During the same period there were only 17 CRC's involved in accidental poisonings. (Table IV) In six instances the child actually opened the container. The average age was 4 years, 3 months. In the other 11 instances, an adult, usually a parent, violated the safety principle of the CRC in some way. The average age of the children poisoned was 2 years, 1 month. This average age was indistinguishable from the average age of children poisoned from all causes under age 12 years. Twelve of the 27 unsafe plastic snap-top containers involved in accidental poisonings in 1967–68, and all of them in 68–69, 69–70 were from medications dispensed by civilian and other military pharmacies.

During a one year period prior to use of the CRC's we could expect one poisoning treated in our hospital for each 5,100 prescriptions dispensed in unsafe plastic snap-top vials. The *expected* number of poisonings from 750,000 CRC's would have been 149. The actual number was 17, and ⅔ of these were from improper use of the CRC! Thus, despite adult errors, there was a marked and significant reduction in accidental poisonings from solid prescription drugs with the use of CRC's. During the test period, the local poison information center, local civilian hospitals, and pediatricians were monitored for reports of accidental childhood poisonings of military dependent children from prescriptions, as well as other causes of accidental poisoning. There was no general shift of patients to these facilities for medical care. To date there has not been a single reported accidental childhood poisoning in the surrounding civilian community from a medication originating from Madigan General Hospital in a CRC.

In Essex County, Ontario, Canada, under the direction of Henri Breault, Director of the Ontario Association for the Control of Accidental Poisoning, the pediatricians and pharmacists in the community have with joint cooperation, has been dispensing tablet and capsule prescriptions in CRC's since January 1967. During the first three years of use, they dispensed over 2,250,000 CRC's. There were 47 containers involved in poisonings. Of these 47 poisonings, 10 children with an average age of four years opened the closures and took medication. In 37 instances the CRC's were improperly used. The average age of the children was two years. (4)

The clinical studies at Madigan and in Essex County, representing over 3,000,000 CRC's used to dispense solid pharmaceuticals, clearly demonstrate that community-wide use of CRC's to dispense prescription medications will produce significant decreases in accidental poisonings from prescriptions. To extend the thought a bit further, the use of CRC's for *all* potentially harmful consumer substances that enter the home including medicines, household products, petroleum products, and pesticides will reduce significantly the problem of accidental poisoning by young children. Safety closures can be developed for harmful consumer products. However, it will require a unified community action to put them to use. For some products, legislation may be required to ensure safer packaging.

The U.S. Federal Government has recognized the value of CRC's to prevent accidental childhood poisonings for several years. CRC's are in general use throughout the Army, Navy, Air Force, and Public Health pharmacies through-

out the world—wherever there are dependent children at risk. (23) This has been done on a voluntary basis. Several civilian community programs are now established in the United States and Canada. Wherever there has been a careful analysis of the effectiveness of CRC's, the direction of poisoning rates has been consistently down.

Prevention of aspirin poisoning

In advanced societies drugs are ubiquitous and tend to be over-used. Aspirin is an outstanding example of this. It is constantly on hand in nearly every home in this country. Since this is so, it is often thought of as being as innocuous as over-the-counter antacid mints by many, and accidental childhood ingestion considered of no great consequence. Aspirin continues to lead the list as the substance most frequently mentioned in childhood poisonings. Orange flavored 1¼ grain children's aspirin is the most common aspirin form ingested.

Little information is available that would relate ingestions of children's aspirin to sales. One such study disclosed that one accidental childhood ingestion of children's aspirin required medical attention on a large military base for each 220 units sold by local post exchanges, over a study period of one year. (21) Over a two year period CRC's were taped to 21,053 units of aspirin sold by the same post exchanges. A small sign over the sales area instructed the purchaser to transfer the commercial aspirin from the original unsafe container to the CRC. The results are summarized in Table V. The overall effect was strikingly successful. The expected number of poisonings from sales of 21,053 units of aspirin based on one year's previous experience was 96. The actual experience was five. In three of the five poisonings, the parent had not transferred the aspirin as suggested. These three children obtained aspirin from the original container. In only two instances did the child actually open the container. This study again demonstrates the favorable downward effect of safety packaging on poisoning rates. Although the greatest numbers of accidental poisonings from aspirin are from flavored aspirin, the most serious poisonings are from adult 5 grain aspirin. Currently, only a very small amount of this higher dosage form is packaged safely.

Safer packaging—now and in the future

Safer packaging is an *effective* approach to the problem of accidental poisoning by young children. Strip packaging's weakest point is that a child can obtain the first tablet easily. (8) Whether or not he will continue to open the strips and obtain a toxic dose before he loses interest is still a matter of conjecture. There are no published clinical studies that clarify this point. The chief weakness of CRC's in current use, is the accessibility of the entire contents of the vial to the child once it is opened. The theoretical ideal of an inexpensive practical CRC that dispenses small quantities of medicine is yet to be developed, tested, and distributed commercially. It would seem that such a container would be particularly valuable for over-the-counter pre-packaged medications, where size, shape, and other physical characteristics of the drug form are predictable; items such as aspirin, birth control tablets, antacids, laxatives, and vitamins. The dispensing of prescription drugs in an endless procession of sizes and forms would require a number of different dispensers for the pharmacist to choose from. For the practicing pharmacist the easiest transition would be to a CRC that resembles the unsafe containers he now uses. The present generation of CRC's in general use should reduce accidental poisonings from prescription drugs about 90%. If adult education programs are successful in promoting proper use of the CRC's, then based on experience with 3,000,000 CRC's dispensed in two clinical studies, the number of accidental poisonings could be reduced to 3% of the previous poisoning rates.

Safer packaging is another way of making hazardous toxins secure in the home. They are not a substitute for parental vigilance, child guidance, or safe storage principles. They offer an additional measure of safety, at little or no additional expenditure of thought or effort by the parent. Safer packaging can be applied to common household products, petroleum products including paints, and consumer pesticides.

If safety packaging will protect preschool children from accidental poisoning, why isn't everything potentially toxic that comes into the home in safer containers? Who controls safety packaging? In the final analysis, the general public does. If they want it *bad* enough, then it can and will be produced. Yet the consumer, through apathy, disinterest, lack of knowledge or a sense of involvement, may not express a clear desire for safety packaging to the manufacturers. There is no question that demand can be encouraged by informational and educa-

tional programs. Advertising *safety* will produce a demand, especially if safety can be offered with little or no change in price or inconvenience to the user.

Certainly it is speculation. However, if:

1. Closures with 90% clinical reliability despite parental misuse could be devised for all toxic consumer items that enter the home, and

2. Ninety percent of the poisonings of children under five years of age are poisoned by medicines, household products, petroleum products, including paints, and pesticides.

then: such protective devices could prevent 1,600,000 of the 2,000,000 childhood poisonings that occur each year in the United States. Federal legislation may be needed to establish general use of safety packaging. (19) With full implementation of safe packaging of toxic or potentially toxic consumer products in the United States, as many as 20–30,000,000,000 containers could be affected annually. However, we need not wait for legislation to start local programs for poison prevention.

In summary

Every community with preschool children has a problem of accidental poisoning. Look around your community—what are the poisoning problems: Do you have an *effective* poison control committee with effective programs? Are medications being dispensed in CRC's? Is Syrup of Ipecac in the homes of preschool children? Is poison prevention part of the school curriculum? Does your community have a particular poisoning problem requiring specific action? With careful thought translated into community action, accidental poisoning can be prevented.

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TABLE I.—ACCIDENTAL INGESTIONS AMONG CHILDREN UNDER 5 YEARS OF AGE REPORTED BY POISON CONTROL CENTERS IN THE UNITED STATES, 1965–68

Type of substance	Percent of total ingestions per year			
	1968	1967	1966	1965
Medicines	53.6	52.8	53.6	54.4
Household products [1]	20.4	20.7	20.4	19.9
Petroleum products [2]	10.5	9.6	10.0	9.8
Pesticides	5.5	5.6	5.8	6.1
Total	90.0	88.7	89.8	90.2

[1] Cleaning, polishing, cosmetics.
[2] Including turpentine, paint.

TABLE II.—MEDICATION SURVEY IN HOMES OF 12 PEDIATRICIANS, FEBRUARY 1970

	Total	Range	Average number
Medications	701	6–155	58.0
Medications with aspirin	48	1–10	4.0
Storage sites	46	1–7	3.9
Locked	2	0–1	0.2
Unlocked	44	0–7	3.7
Number of children under age 5 years	12	0–2	1.0

TABLE III.—MADIGAN GENERAL HOSPITAL SUMMARY OF ACCIDENTAL CHILDHOOD POISONINGS, MAY 1, 1966–FEB. 1, 1970

	1966–67	1967–68 [1]	1968–69	1969–70
Total poisonings	382	259	162	156
Total poisonings from medications	251	175	108	88
Total poisonings from aspirin	119	89	63	29
A. 1¼ grain flavored aspirin	109	82	49	26
Purchase source:				
(a) Post exchange	([3])	46	13	4
(b) Other	([3])	36	36	21
B. 5 grain unflavored and APC	93	49	26	27
Total poisonings from prescription drugs:				
Prescription containers:				
Plastic snap top	67	27	7	7
Screw cap	21	10	8	7
Box or packet	3	7	6	5
Tube	2	0	0	0
Child resistant		5	4	8
Household products	62	30	26	34
Petroleum products	28	22	19	16
Pesticides	11	7	1	7
Plants and berries	19	13	6	12
Miscellaneous	9	6	0	7
Hospitalizations	48	20	21	20

[1] (1) Test containers used to dispense prescription tablets and capsules May 1, 1967, to date. (2) Test containers attached to boxes of commercial aspirin sold in local post exchanges Feb. 1 to date.
[2] May 1, 1967 to Feb. 1, 1970 (9 months).
[3] Unknown.

TABLE IV.—MADIGAN GENERAL HOSPITAL: 17 ACCIDENTAL CHILDHOOD POISONINGS FROM PRESCRIPTION MEDICATIONS DISPENSED IN 750,000 CRC'S

Reason for failure	Medication	Sex	Age of child
1. Child opened container:			
(a) Trained unintentionally by mother	Tofranil	Female	[1] 7
(b) Read instructions	1¼ grain flavored aspirin.	Male	7
(c) Random trial and error	Valium	do	[2] 2
(d) Used teeth to pry off cap	Dexamyl	do	[2] 4
(e) Used teeth	Penicillin	Female	4
(f) Used teeth	Valium	Male	5
2. Violation of safety factor:			
(a) Medication stored without top	Dexamyl	do	2
(b) Medication loose in purse	Darvon	do	2
(c) Open container in trash can	Phenobarbital	Female	3
(d) Top loose	Ornade	do	2
(e) Spilled on floor	Tofranil	do	[2] 4
(f) Top loose	Reserpine	Male	2
(g) Top loose	Ferrous sulphate	do	[1] 2
(h) Top off	Darvon	Female	2
(i) Top loose	Multivitamins	Male	2
(j) Top loose	Ferrous sulfate	do	[1] 1
(k) Top loose	do	do	2

[1] Hospitalized for 24 hours.
[2] Ingestion suspected, but not proven.

TABLE V

MADIGAN GENERAL HOSPITAL, TACOMA, WASH.

Childhood aspirin ingestions, 1¼ grain flavored aspirin sold by local post exchanges, Feb. 1, 1968–Jan. 31, 1970 (24 months)

Sales:	
A. With test containers [1]	21,053
B. Without test container	5,744
Total sales	26,797
Ingestions:	
A. From sales with test container	5
1. Parent transferred aspirin	2 [2]
2. Parent did *not* transfer aspirin	3
Ingestion/sales ratio—1:4,210.	
B. From sales without test container	17
Ingestion/sales ratio—1:335.	
Total ingestions	22
Ingestion/sales ratio before use of test container 1967–68 (58:12,800) 1:220.	
Percent change in ingestion/sales ratio, 1967–68 versus 1968–70 with use of test container	95

[1] 7 dram plastic Palm-N-Turn(R) vial.
[2] (1) 19 m.o. female—opened test container with random motion; (2) 7 y.o. male—twisted top off of test container, broke the vial.

Mr. Moss. At this point, I would like unanimous consent to insert into the record a statement from Mrs. Esther Peterson, former Special Assistant to the President for Consumer Affairs. Mrs. Peterson is presently the legislative representative of the Amalgamated Clothing Workers of America.

(The statement referred to follows:)

STATEMENT OF MRS. ESTHER PETERSON, LEGISLATIVE REPRESENTATIVE, AMALGAMATED CLOTHING WORKERS OF AMERICA

I am Esther Peterson, presently legislative representaive for the Amalgamated Clothing Workers of America. I am testifying today on my own behalf.

The matter that is before the subcommittee today came visibly to my attention when I was serving as the first Special Assistant to the

President on Consumer Affairs. At that time I had many letters and conversations with people detailing tragic stories of children being poisoned, burned, or whose vision had been impaired because substances were too easily "get-attable." I commend the chairman, Congressman Moss, and his cosponsors for introducing this bill, the Federal Hazardous Substances Act of 1969.

If the subcommittee had had this issue under consideration in 1966 and the Congress had passed the measure and put it into effect, it is possible that 83,704 accidental poisonings might have been avoided in 1967. And bear in mind that horrifying figure—83,704—represents only the number of accidental poisonings documented by the National Clearinghouse for Poison Control. If we projected these reported cases into the number treated at home or otherwise unreported, it would unquestionably run into hundreds of thousands. The report for 1967 further states that children are the principal victims of accidental poisonings. Industries which package goods of a poisonous nature argue that you cannot legislate human nature or, in the case of a child, the human instinct of curiosity. Of course, children tend to explore and experiment; to experience new sensations of touch and taste, but this is an argument obviously dictated by self-interest.

Virtually every package with inherently or potentially poisonous contents bears a warning to the effect, "Keep out of the reach of children." If we could place our faith in such magic, we would not be faced with the tragic—the tragic hundreds of thousands of children scarred, maimed, blinded—and yes, some even killed—by packaged poisons each year.

During my years as Special Assistant on Consumer Affairs, a good deal of information was collected and many discussions took place, which I like to believe contributed to the formation of the National Commission on Product Safety. In these discussions fear was expressed that any legislative course aimed at correcting the difficulties might tread on the toes of big business, whose representatives argued that as many as 24 billion cans, boxes, cartons, and other containers might fall under its provisions, with the attendant redesign, restructuring and resetting of packaging machinery.

Re this and re that—they take into consideration all the re's, excepting one that is pronounced a bit differently—in re: the health, safety and very life of hundreds of thousands of our greatest asset—the children of America.

It is my firm belief that the Poison Prevention Packaging Act of 1969, offered by Senator Moss as an amendment to the Federal Hazardous Substances Act, represents one of the most important and desirable pieces of legislation to be brought into committee in a long, long time.

Another argument put forth by those opposed to this measure and their spokesmen against legislation of this nature is the specious one that if it were passed, parents would feel such a degree of safety that they would relax their vigilance and even more children would be poisoned. And still another is that a safety device or closure that would demand more strength to open than a child has, would present problems for the elderly, the weak or the arthritic.

This is just not true. I have found myself using the term "get-attable" to describe poorly packaged poisonous substances. If a

technological community that can put men on the moon cannot design packaging that would make toxic contents un-get-attable for children and get-attable for any adult, we ought to take their drawing boards away. But that is not necessary. I have seen closures that would meet basic safety requirements, a number of which are on display before this committee. These safety closures have already been designed, already been patented, are already in production. One that has been brought to my attention is on display before the committee and is manufactured by Stem Industries, Inc., of New York, and I'm sure there are many others.

On an aerosol can, for instance, the one brought to my attention looks like the conventional type with which we are all familiar. But, if you try to open it in the same way that you open an ordinary aerosol cap, nothing happens. The top simply spins, and cannot be removed unless the rim of the two-piece cap is held by the thumb and finger. Simple? Yes, if you can read the instructions, which no infant can. Difficult? I'm no Hercules, and if it required gargantuan effort, I couldn't do it. For arthritic hands? Easy. Safe? One of the safest closure devices I have seen.

But the question of expense is, understandably, a major factor since it affects pricing, sales and profits. Hence, a natural resistance on the part of the business community collectively is to be expected.

It is nice to be able to report, therefore, that some of these safety closures, despite their seeming complexity, add something in the vicinity of a penny to the cost of the product to which they are applied. I don't think there is a parent who would not pay a penny to safeguard the well-being of a precious child.

I really believe that if consumers were informed of a device like this it would increase the volume of sales to the point where it would be virtually self-liquidating. I know that if I saw two competitive products next to each other on a supermarket or drugstore shelf and both were priced the same, I would unquestionably select the one that protected my loved ones. And if the one that was protectively packaged were priced at a penny or two more, I would still make it my choice.

That is only the beginning. Once having seen that a safety closure is a workable reality, I believe that consumers would expect it—indeed, would demand it, on every can or bottle of household cleanser, insecticide, deodorant, spray paint, furniture polish, germicide—in effect every potentially dangerous product that might conceivably be get-attable for children.

Earlier, I mentioned 83,704 reported—I emphasize reported accidental poisonings—87 per cent of them involving children 5 years of age or less—in 1967. How many such incidents have occurred in 1968, 1969, and in the years to come? This problem was recognized years ago. The Food and Drug Administration has had a Safety Closure Committee working since 1966. But it is underfinanced, undermanned. In almost 4 years it has barely completed the first phase of research, investigative efforts and recommendations for child-deterrent safety closures.

It is within the power of this committee to take a giant step forward in this vitally important area. The Poison Prevention Packaging Act of 1969 is a lifesaver, literally. If favorable action is taken here and

continues through to the passing of the bill, untold thousands of children will owe their lives to you. Additional untold thousands will have avoided lives of misery due to scarring, maiming, and blindness.

Gentlemen, I'm sure it is far easier for you to vote favorably on this measure than it is for a child to open the aerosol or any of the other safety closures before you today.

Thank you.

Mr. Moss. I would like to announce at this time that the hearing record will be held for 10 days for the filing of statements or supplementary views.

We have no requests pending for witnesses tomorrow. I believe we have notified everyone on record with the committee as being interested. Therefore, we will adjourn the hearings, subject to possible recall, but with the understanding that the record will be open for the 10-day period.

(The following letters were received for the record:)

CONTINENTAL RESEARCH & DEVELOPMENT LTD.,[1]
Toronto, Canada, June 9, 1970.

Re bills H.R. 16541, H.R. 16884, S. 2162 and related bills; special packaging to protect children.

Representative HARLEY O. STAGGERS,
Chairman, Subcommittee on Commerce and Finance, Committee on Interstate and Foreign Commerce, Rayburn House Office Building, Washington, D.C.

DEAR REPRESENTATIVE STAGGERS: This written statement is submitted for the Public Hearing record on the above-referenced House of Representatives Bills concerning the proprietary child-resistant safety closure developed through our firm for United States marketing requirements. The Senate files now contain certain technical and general information concerning our development while we have submitted under separate cover commercial samples illustrating our operating principle to your Committee.

In the past, the domestic drug and household chemical industries have opposed child-resistant, safety-type closures on their packaging for several reasons; their cost was substantially higher than that of existing closures (higher percentage-wise—but only fractions of pennies); few safety closures inherently combined ease of operation by adults while foiling the attempts by children in opening the packaging; and, technically, it has been particularly difficult to obtain a liquid-tight seal to serve the very large field of packaging in potentially dangerous liquid household drugs and chemicals.

The criteria that a truly practical and economic child-resistant safety closure must meet may be summarized as follows:

1. The closure must be simple for adults to operate.
2. The closure must be difficult for children to open.
3. The closure must be low in cost (which, practically speaking, requires a plastic unit which can be mass produced with simple production tooling and the unit must be of single piece construction requiring no assembly or other handling during manufacture).
4. The closure must be liquid-tight (therefore, the unit must operate through a flexible or moving cap rim or related means, while the closure top itself remains firm, solid and non-moveable).
5. The closure must be adaptable to all packaging materials and to all container types (plastic, glass and composition containers and metal cans).

Hundreds of so-called "safety" closures have been patented over the years. Practically without exception, such safety closures have been of multiunit construction requiring costly handling and assembly—or the closures have been technically very difficult to produce at a low unit cost by conventional production tools and machinery. Additionally, they have been generally impossible to operate in darkness or by persons with poor eyesight (by requiring the alignment of slots or numerical combinations, utilizing "trick" hinges, etc.)

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[1] *U.S. Operations*, Continental-Paragon Corp., 420 West Street, Port Chester, N.Y.; *Subsidiary*, Faynee Industries Inc., 476 Broome Street, New York, N.Y.

Probably the most important operating criteria not generally met by most, if not all, safety closures is the provision of a liquid-tight seal, inherently impossible in most safety closure designs.

With increasing affluence, many more American households are now consuming potentially dangerous household drugs and chemicals. Packaging has become more colorful and sophisticated in design—ideal children's "toys." With television, a visual medium, younger children have become much more sophisticated and successful at an early age in efforts to imitate adults by locating colorful containers among household cupboards and opening them for their "play" use, as visually instructed on television screens.

Continental Research & Development Ltd. holds world rights to United States Patent #3,435,975, issued April 1, 1969, and designated the *"Tamper-Proof" Child-Resistant Safcty Closure.* This development is also patented in Canada, West Germany, the United Kingdom, France and Italy, with other patents pending.

The basic operating principle of our "Tamper-Proof" closure is advantageously adaptable to the full line of consumer gods packaging—for plastic containers, particularly drug prescription ware—for glass and plastic bottles and containers utilized in packaging aspirin, medicinal syrups, household disinfectants, detergents, germicides, insecticides, ammonia, chlorine bleaches, etc.—and for metal cans where the conventional pouring spout and captive cap can utilize our "Tamper-Proof" design for use in packaging floor cleaners and waxes, lemon oil furniture polish, lyes and caustics, charcoal lighter fluids and solvents, etc.

The samples being provided your Committee prove that they meet the basic, essential economic and operating criteria listed above in this letter. We will provide additional samples for distribution to all interested Government Departments and offices, medical, nursing and consumer groups, consumer goods manufacturers, packaging manufacturing firms and other interested associations and agencies in Government and industry.

Our safety closures have been fully perfected for all commercial applications in the plastic and glass container fields and for metal can assemblies. We have available and can provide working production samples of each basic model for each consumer package.

We are available for your further consultation on request and can provide additional technical information that your Committee or the general House membership may require.

Yours very truly,

S. DONALD MOORE,
President.

PLOUGH, INC.,
Memphis, Tenn., June 15, 1970.

Re S. 2162.

Hon. DAN KUYKENDALL,
U.S. House of Representatives,
House Office Building, Washington, D.C.

DEAR DAN: Subject Bill which is known as the "Poison Prevention Packaging Act of 1970" is now before the Subcommitte on Commerce and Finance of the House Interstate and Foreign Commerce Committee. Our Company has a very vital interest in this Bill since our people, over the past ten to twelve years, have worked at great lengths on this problem of safety closures for drug packages.

This has entailed many, many hours of time and many thousands of dollars in engineering; the purchase of patents; clinical and market testing and the like. One of our people headed the special committee appointed by Dr. Goddard of FDA to set standards for safety closures. We adopted the first version of a safety closure applied on a package of medicine. This was in 1954, and an improved safety closure was put into use about six months ago on St. Joseph Aspirin for Children.

With this background of experience, we are writing not to object to the Bill—but to endorse one suggestion, which has already been brought before the Subcommittee. That suggestion is that it is a serious mistake for the Congress, when seeking to enact legislation for experts to establish standards in a highly complicated field, to write into the bill one of "the standards" to be set. We refer to the specification defining "special packaging" as packaging designed to be significantly difficult for children *under six* years of age to open. All evidence in

Poison Control Centers and in the various federal bureaus clearly point out that this problem of accidental poisoning of children clearly lies in the age bracket of four and under. Available data on the physical dexterity of children over five also clearly reflects that this "under six" portion of the definition will greatly and unnecessarily complicate the problem of those who are honestly seeking to solve it.

It would appear that if the objective of the Congress is to have experts set standards that the Bill would be written to enable the experts to set the standards without being restricted by the Bill itself. If, however, the Congress feels it necessary to specify an age limitation, certainly *"under five"* years of age would be more appropriate to the factual evidence on the subject.

You may feel that this is a "hair-line argument" but the data clearly reflects that the problem is to have a closure that the average Mother *can* open without too much difficulty but that the four-year-old and under *cannot* open (all records clearly reflect this to be the critical age bracket); and available data reflects that there is a great deal of physical dexterity difference in the under-six and under-five age brackets. For this reason, the Bill as written is going to make it extremely difficult (if not in fact almost impossible) for an FDA appointee to achieve the desired objective.

Why not let the experts who will have the very difficult responsibility of setting the standards do so without a restrictive guideline written into the Bill?

Respectfully,

H. B. SOLMSON,
Executive Vice President.

PAPERBOARD PACKAGING COUNCIL,
Washington, D.C., June 16, 1970.

Hon. JOHN E. MOSS,
Chairman, Subcommittee on Commerce and Finance, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Washington, D.C.

DEAR CONGRESSMAN MOSS: This letter is submitted on behalf of the Paperboard Packaging Council for inclusion in the record of the hearings before your Subcommittee on Commerce and Finance on S. 2162 and related bills dealing with the subject of child-resistant packaging. The Paperboard Packaging Council represents approximately 130 member companies that produce folding paper cartons, primarily for consumer products. Last year, industry sales exceeded 1.2 billion dollars.

Since the bills in question deal with "packaging," the Council has been active, both in soliciting the opinions of its members and in making those opinions known to the Congressional committees considering the legislation.

Initially, let me note that the Paperboard Packaging Council is in full agreement with the commendable purpose of the proposed legislation; i.e., protecting young children from serious personal injury or illness. As a safety-conscious industry, we favor all reasonable efforts aimed at reducing accidents in the home or on the job.

Having reviewed S. 2162 with our members, we would like to direct our comments to three provisions in the bill, which we feel are of particular importance.

Section 5(a) of the bill provides that all standard-setting activities will be conducted in accordance with the full procedural safeguards of Section 701 (e), (f), and (g) of the Federal Food, Drug & Cosmetic Act. We strongly endorse this provision and urge its retention in this legislation. Although some have suggested that the full administrative process guaranteed under Section 701(e), (f) and (g) can be time consuming, this slight drawback is more than outweighed by the positive procedures which have been successfully used under the Food, Drug & Cosmetic Act for many years. These procedures have also been incorporated into the Fair Packaging and Labeling Act and the Federal Hazardous Substances Act and have worked well in actual practice under those acts.

The 701(e), (f) and (g) procedures require a full-scale administrative hearing only when there is a disputed question of fact, which is significant and clearly relevant to the Secretary's decision in adopting or revising regulations. Since special packaging regulations will have a profound economic impact and since many important and complex issues of safety will be under consideration, the administrative safeguards provided by the Section 701(e), (f) and (g)

procedures are both necessary and desirable to insure the maximum effectiveness of this legislation.

The Council is also in full accord with Section 7 of S. 2162, which provides for full Federal preemption in the field of child-resistant packaging standards. As a national organization of packaging manufacturers, we have consistently urged uniformity of packaging and labeling requirements. Adoption of Section 7 would do much in that regard and would prevent needless interstate conflicts.

Our single cause for concern with the bill is Section 4. That section, as you know, would limit non-complying packaging to a single size once a standard for special packaging is adopted by the Secretary of Health, Education and Welfare. We believe that Section 4, in its present form, is unduly restrictive and unnecessarily limits the consumer's freedom of choice. It is our firm conviction that the goal of child protection can be achieved without the severe packaging limitations that would result from the adoption of Section 4.

Therefore, we recommend that the language of Section 4(1) be revised to read as follows:

"(1) such substance is (i) packaged in noncomplying packaging which bears conspicuous labeling stating: 'This product is also available in protective packaging designed for use in households with young children,' and (ii) available in complying packaging of not less than two popular sizes, or"

Alternatively, we feel that the approach suggested by Congressman Bob Eckhardt during the June 9 hearings before your Subcommittee, would be preferable to the present language of Section 4(1). Congressman Eckhardt suggested that the Secretary of Health, Education and Welfare be granted discretionary authority to establish the number of package sizes composed of traditional packaging material that would be available once a special packaging standard has been adopted. As he noted during the hearings, there are many products where more than one size of non-complying packaging might be allowed by the Secretary; there are also a few where only special packaging might be allowed. We favor a flexible approach of this type as a highly acceptable substitute for the single-size restriction now contained in Section 4(1).

The Paperboard Packaging Council greatly appreciates the opportunity to offer comments on this most important consumer protection legislation and stands ready to provide you and your Subcommittee any information regarding our industry that may prove helpful during your deliberations.

Very truly yours,

ROBERT R. LOVELACE,
Director, Government Relations, Public Information.

(Whereupon, at 12:10 p.m., the subcommittee was adjourned.)

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