

y4
. C 73/2

1041

91-35-16
C 73/2
91/4
46

91-35

KANSAS STATE UNIVERSITY LIBRARIES
FEDERAL HAZARDOUS SUBSTANCE ACT

GOVERNMENT
Storage

HEARINGS
BEFORE THE
CONSUMER SUBCOMMITTEE
OF THE
COMMITTEE ON COMMERCE
UNITED STATES SENATE
NINETY-FIRST CONGRESS

FIRST SESSION
ON
S. 2162

TO AMEND THE FEDERAL HAZARDOUS SUBSTANCE 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

OCTOBER 1 AND 2, 1969

Serial No. 91-35

Printed for the use of the Committee on Commerce



U.S. GOVERNMENT PRINTING OFFICE
WASHINGTON : 1969

36-839

KSU LIBRARIES



A11900 964676 ✓



A11208 814098

94
5/27/5
21-32

COMMITTEE ON COMMERCE

WARREN G. MAGNUSON, Washington, *Chairman*

JOHN O. PASTORE, Rhode Island
VANCE HARTKE, Indiana
PHILIP A. HART, Michigan
HOWARD W. CANNON, Nevada
RUSSELL B. LONG, Louisiana
FRANK E. MOSS, Utah
ERNEST F. HOLLINGS, South Carolina
DANIEL K. INOUE, Hawaii
JOSEPH D. TYDINGS, Maryland
WILLIAM B. SPONG, Jr., Virginia

NORRIS COTTON, New Hampshire
HUGH SCOTT, Pennsylvania
WINSTON PROUTY, Vermont
JAMES B. PEARSON, Kansas
ROBERT P. GRIFFIN, Michigan
HOWARD H. BAKER, Jr., Tennessee
CHARLES E. GOODELL, New York
MARLOW W. COOK, Kentucky

FREDERICK J. LORDAN, *Staff Director*

MICHAEL PERTSCHUK, *Chief Counsel*

JOHN M. CARY, *Staff Counsel*

ARTHUR PANKOPF, Jr., *Minority Staff Director*

J. PAUL MOLLOY, *Minority Staff Counsel*

CONSUMER SUBCOMMITTEE

FRANK E. MOSS, Utah, *Chairman*

PHILIP A. HART, Michigan, *Vice Chairman*

JOHN O. PASTORE, Rhode Island
VANCE HARTKE, Indiana
DANIEL K. INOUE, Hawaii
WILLIAM B. SPONG, Jr., Virginia

JAMES B. PEARSON, Kansas
CHARLES E. GOODELL, New York
NORRIS COTTON, New Hampshire
MARLOW W. COOK, Kentucky

(II)

CONTENTS

	Page
Opening statement of the chairman-----	1
Text of S. 2162-----	2
Agency reports:	
National Commission on Product Safety-----	4
Special Assistant to the President for Consumer Affairs-----	4
Department of the Treasury-----	5
Department of the Army-----	5
Department of State-----	6
Department of Agriculture-----	6

STATEMENTS

OCTOBER 1, 1969

Cheney, Richard L., executive director, Glass Container Manufacturers Institute; accompanied by John D. Northrup, vice president, closure division, Owens-Illinois, Inc.; Gerald L. Roy, manager, plastic and metal packaging research, packaging products division, Kerr Glass Manufacturing Corp.; and Eugene L. Stewart, Lincoln & Stewart, Washington, D.C.-----	36
Meade, Robert L., Director for Legislative Affairs, President's Committee on Consumer Interests-----	29
Snodgrass, Alfred W., Renton, Wash-----	8
Sullivan, Charles C., representing the Committee for Continuing Study of Improved Safety Closures, Malton, Canada-----	64
Wegner, Dr. Glen E., Deputy Assistant Secretary for Legislation, Department of Health, Education, and Welfare; accompanied by Georg S. Maisel, Poison Control Division, Office of Product Safety, Food and Drug Administration; Dale C. Miller, Assistant to the Director, Bureau of Compliance, Food and Drug Administration; and Henry L. Verhulst, Director of the Poison Control Division, Office of Product Safety, Food and Drug Administration-----	17
Wolfstone, Leon L., president, American Trial Lawyers Association, Seattle, Wash.; accompanied by Jerry Finn, chairman, legislative section, American Trial Lawyers Association-----	52

OCTOBER 2, 1969

Arena, Dr. Jay M., professor of pediatrics, Duke University, and president, American Association of Poison Control Centers-----	90
Done, Dr. Alan K., professor of pediatrics, director of the Poison Information and Therapy Center, University of Utah, Salt Lake City, Utah-----	74
Franklin, Dr. Murray J., corporate vice president, Hayes-Albion Corp., Jackson, Mich-----	104
Hoge, James F., on behalf of the Proprietary Association; accompanied by Ralph H. Thomas, director of packaging research, Bristol Myers Co.; Daniel F. O'Keefe, Jr., vice president and secretary, the Proprietary Association; and Carrington Boggan, Rogers, Hoge & Hills-----	212
Meyer, Roger J., M.D., associate professor of pediatrics, Northwestern University School of Medicine, and executive director, Infant Welfare Society of Chicago-----	94
Scherz, Lt. Col. Robert G., chief, pediatric service, Madigan General Hospital, Tacoma, Wash-----	126
Tainter, Dr. Maurice L., vice president, Sterling Drug, Inc.; accompanied by James L. Luther, vice president, legal affairs, Sterling Drug, Inc-----	155
Talbott, John, executive vice president, Safety Packaging Corp., Hanover, N.J.; accompanied by S. Howard Cerny, counsel for Safety Packaging Corp.; Mario A. Bennett, president; Dr. Edward Towns, vice president and inventor of Pop-Lok; William Perkins, vice president, Safety Packaging Corp., Hanover, N.J-----	123

WRITTEN STATEMENTS AND LETTERS

	Page
Apple, William A., American Pharmaceutical Association-----	254
The Chemical Specialties Manufacturers Association, Inc-----	250
Mennen, W. G., the Mennen Co-----	253
Moore, S. Donald, president, Continental Research & Development, Ltd----	248
Oxaal, Leif, executive director, Packaging Machinery Manufacturers Institute-----	260
Peterson, Mrs. Esther-----	102
Shirkey, Harry C., M.D., medical and executive director, Rehabilitation Center of Hawaii, Kauaikeolani Children's Hospital-----	256
Stetler, Joseph C., Pharmaceutical Manufacturers Association-----	256
Sunshine, Irving, Ph. D., technical director, Poison Information Center, Academy of Medicine of Cleveland-----	250
Thielke, John T., vice president, corporate and public affairs, Economics Laboratory, Inc., St. Paul, Minn., and New York City-----	247

**TO AMEND THE FEDERAL HAZARDOUS SUBSTANCE
ACT, TO PROVIDE FOR CHILD-RESISTANT PACK-
AGING TO PROTECT CHILDREN FROM SERIOUS
PERSONAL INJURY OR SERIOUS ILLNESS RE-
SULTING FROM HANDLING, USING, OR INGESTING
ANY HAZARDOUS SUBSTANCE, AND FOR OTHER
PURPOSES**

WEDNESDAY, OCTOBER 1, 1969

**U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE FOR CONSUMERS,
Washington, D.C.**

The subcommittee met at 10 a.m. in room 5110, New Senate Office Building, the Honorable Frank E. Moss (chairman of the subcommittee) presiding.

Present: Senators Moss, Hartke, Cotton, and Pearson.

OPENING STATEMENT OF THE CHAIRMAN

Senator Moss. The hearing will now come to order.

The Subcommittee for Consumers will hear testimony today and tomorrow on a bill of great importance to the Nation and especially to the parents of young children. S. 2162, the Poison Prevention Packaging Act of 1969, would empower the Secretary of Health, Education, and Welfare to set standards for packaging designed to prevent young children from obtaining harmful amounts of hazardous substances found around the home.

The problem is clear. At this very moment some small child is innocently exploring the limited environment of his home. In the process he is poking into the medicine cabinet, reaching into his mother's purse, crawling under the kitchen or bathroom sink, or rummaging in the garden shed and possibly swallowing a potential poison. Poisoning by household substances is the most common medical emergency facing young children. The loss that it imposes—in pain, suffering, and death—is incalculable.

Accidental poisonings are senseless and unnecessary. Their tragic toll of young children can be reduced if we are willing to act.

Two tactics, treatment and education against the hazards of household substances, have predominated in the fight against accidental poisoning. The first tactic is exemplified by the operations of Poison Control Centers where information is collected to speed and improve the treatment of poisoning victims. The second tactic is exemplified

Staff member assigned to this hearing: John M. Cary.

by the familiar warning, "Keep out of the reach of children." These tactics have proved helpful. But they have not solved the problem. Young children cannot read label warnings. Improved treatment does not reduce the pain and suffering from poisoning. Young children continue to die.

S. 2162 would begin strong action on a third tactic—that of prevention. S. 2162 would authorize the Secretary of Health, Education, and Welfare to require packaging that would prevent children from getting into hazardous substances. The possibility of poisoning is reduced at the primary level by keeping children and hazardous substances separated. The accidental nature of poisoning—due to the innocence of the child or to the carelessness of his parent—is circumvented because the preventive measures do not depend primarily on actions taken at home.

The problem that S. 2162 seeks to remedy is not in serious dispute—far too many children are being poisoned today. That remedial action should be taken is also not in dispute. There is even some agreement that a preventive tactic is necessary. The drug industry, in particular, has undertaken preventative measures by limiting the number of tablets in children's aspirin bottles and by experimenting with preventive packaging.

The issue with which we will be primarily concerned is the specific form of preventive action to take. Our witnesses, from Government, industry, and the professions, will bring out for our consideration the recent developments in poison prevention packaging. We must determine whether or not S. 2162 will hasten the advent of significant preventive action by requiring use of safety packages.

Since several of our witnesses are from the State of Washington, I would be remiss not to point out the interest of Senator Magnuson in poison prevention. S. 2162 builds upon the foundation laid by Senator Magnuson with his Safe Packaging Act introduced in the last Congress. I am pleased to say that Senator Magnuson is a co-sponsor of S. 2162, as are several members of this subcommittee. Senator Magnuson had hoped to attend these hearings, but the press of official duties have kept him away. At this time I will insert the bill and any agency comments into the record.

[S. 2162, 91st Cong., first sess.]

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 proffered 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.

NATIONAL COMMISSION ON PRODUCT SAFETY,
Washington, D.C., May 27, 1969.

HON. WARREN G. MAGNUSON,
Chairman, Committee on Commerce,
New Senate Office Building,
Washington, D.C.

DEAR SENATOR MAGNUSON: This is in response to your request dated May 15, 1960 for the Commission's comments on the amendments to the Federal Hazardous Substances Act introduced by Senator Moss as S. 2162.

As you know, the Commission is of the opinion that the Federal Hazardous Substance Act is inadequate in several respects, especially in its protection afforded children. It was with this in mind that we recently recommended enactment of the Child Protection Act (Toy Safety Act) of 1969 (S. 1689).

The Department of Health, Education, and Welfare make the following estimates of the numbers of poisonings annually caused by household products: medicines and cosmetics—600,000; laundry and cleaning products—150,000; and pesticides—75,000. Although an exact count of such poisonings would be impossible, it is readily apparent from these estimates that some regulation of the packaging of hazardous substances is needed. The fact that the great majority of these poisonings occur to small children who cannot be protected by warnings, creates additional urgency for such regulation.

The proposed Poison Prevention Packaging Act of 1969 (S. 2162) would afford this additional protection. We are therefore of the opinion this amendment would strengthen the Federal Hazardous Substances Act and recommend its adoption. However, we wish also to reiterate our belief that a piecemeal approach to the problem of hazardous products has obvious shortcomings and that a comprehensive treatment of the entire subject should be considered.

It should also be noted that our copy of the proposed S. 2162 apparently includes a misprint in Section 4(c). The 13th line should probably read . . . "The manufacture of any mibranded hazardous substance, banned hazardous substance, or 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."

Thank you for this opportunity to comment on these matters.

Sincerely yours,

ARNOLD B. ELKIND, *Chairman.*

THE WHITE HOUSE,
Washington, October 2, 1969.

HON. WARREN G. MAGNUSON,
Chairman, Senate Commerce Committee,
U.S. Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: These are our comments on S. 2162, the Poison Prevention Packaging Act of 1969. We recommend that the bill be passed.

Legislation of this type is necessary for the adequate protection of children from accidental poisoning. Despite existing labeling laws, many thousands of young children each year are victims of accidental ingestions of solids and liquids that are injurious to their health. In most instances, the toxic substances involved are packaged in containers easily opened by children.

Educational programs designed to inform adults of the potential dangers to children are helpful, but relative ineffective. Children are naturally curious and unable to comprehend the seriousness of the hazards involved.

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 that can be opened without difficulty by adults, but that will be resistant to being opened by children. In that way, instances of childhood poisoning can be markedly reduced.

The bill provides that the Secretary of Health, Education and Welfare may, by regulation, establish standards for child-resistant packaging of any hazardous substance, as defined in the bill. Such standards may be established only after consultation with a technical advisory committee composed of not more than 15 members who are equally representative of the Department of HEW, manufacturers of household consumer products, and widely recognized independent packaging consultants.

We submit that the language of Section 2(A)(2), defining hazardous substance, is ambiguous and that it be changed to make it 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; and fuel stored in containers and used in the heating, cooking, or refrigerator tion system of a house, are within such definition for purposes of child-resistant packaging. It may be preferable from the standpoint of practical administration that the child-resistant packaging of economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act be covered by that Act, rather than an amendment to the Federal Hazardous Substance Act.

We further believe that the technical advisory committee should contain some outside consumer representatives with some expertise in the packaging area. This will ensure that the Secretary of Health, Education and Welfare receives advice from sources outside his own agency or the industry involved.

While it might optimally be preferable to adopt a comprehensive approach to the whole field of product safety rather than attacking only one aspect of the problem, we believe that a bill of this nature is needed now for the protection of millions of small children.

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

Sincerely,

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

THE GENERAL COUNSEL OF THE TREASURY,
Washington, D.C., October 6, 1959.

HON. WARREN G. MAGNUSON,
*Chairman, Committee on Commerce,
U.S. Senate,
Washington, D.C.*

DEAR MR. CHAIRMAN: Reference is made to your request for the views of this Department on S. 2162, "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 proposed legislation would authorize the Secretary of Health, Education, and Welfare to establish, by regulation, standards for the child-resistant packaging of hazardous substances, if he finds that 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 of such hazardous substances.

Prior to issuing such regulations, the Secretary would be required to appoint a technical advisory committee consisting of representatives of the Department of Health, Education, and Welfare, manufacturers of household consumer products, and widely recognized packaging consultants, to assist in the development of appropriate packaging standards, and to consult with the members of this committee before finally establishing any standards.

The proposed legislation is not of primary interest to this Department and the Department has no comment to make as to its general merits. The Department, however, anticipates that the customs workload, chargeable to enforcement participation at ports of entry on imports, will increase somewhat, particularly involving customs demands for redelivery of nonconforming shipments, assessments under customs entry bonds against noncomplying entrants; and from disposal of shipments in violation.

The Department has been advised by the Bureau of the Budget that there is no objection from the standpoint of the Administration's program to the submission of this report to your Committee.

Sincerely yours,

PAUL W. EGGERS, *General Counsel.*

DEPARTMENT OF THE ARMY,
Washington, D.C., October 7, 1959.

HON. WARREN G. MAGNUSON,
*Chairman, Committee on Commerce,
U.S. Senate,*

DEAR MR. CHAIRMAN: Reference is made to your request to the Secretary of Defense for the views of the Department of Defense on S. 2162, 91st Congress, 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 Department of the Army has been assigned responsibility for expressing the views of the Department of Defense on this bill.

The title of the bill states its purpose.

The Department of the Army, on behalf of the Department of Defense, favors the bill in principle and interposes no objection to its enactment. The bill expands the Federal Hazardous Substances Act to include child-resistant packaging and provides for a technical advisory committee to be established by the Department of Health, and Welfare to advise the Secretary in promulgating standards under this Act. The bill will not directly benefit the Department of Defense; however, indirect benefits would accrue to the dependent children of Department of Defense personnel. Inasmuch as the Department of Defense is a large purchaser of packaged products, has a large dependent children population, and has technical expertise in this area, it would be desirable to have Department of Defense representation on the technical advisory committee if it is created. We take no position on the need for a technical advisory committee for the purpose of this legislation; however, if it is included in this legislation it is recommended that line 5, page 4 be changed to read as follows: "cation, and welfare, other interested agencies, manufacturers of household consumer." For the foregoing reasons, the Department of the Army, on behalf of the Department of Defense, interposes no objections to the bill.

The enactment of this legislation will cause no apparent increase in budgetary requirements of the Department of Defense.

This report has been coordinated with the Department of Defense in accordance with procedures prescribed by the Secretary of Defense.

The Bureau of the Budget advises that, from the standpoint of the administration's program, there is no objection to the presentation of this report for the consideration of the Committee.

Sincerely,

STANLEY R. RESOR,
Secretary of the Army.

DEPARTMENT OF STATE,
Washington, D.C., October 7, 1969.

HON. WARREN G. MAGNUSON,
Chairman, Committee on Commerce,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: The Secretary has asked me to reply to your request for the views of the Department of State on S. 2162, 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 bill would provide for the establishment of standards for the child-resistant packaging of hazardous substances where the objective of protecting the health and safety of children so requires.

The Department of State has examined S. 2162 from the standpoint of foreign economic policy and has no objection to the bill as it is presently drafted.

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

Sincerely,

H. G. TORBERT, Jr.,
Acting Assistant Secretary for Congressional Relations.

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, D.C., October 11, 1969.

HON. WARREN G. MAGNUSON,
Chairman, Committee on Commerce,
U.S. Senate.

DEAR MR. CHAIRMAN: This is in reply to your request of September 24, 1969 for a report on S. 2162. 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 hazardous 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 S. 2162 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.

Enclosure.

EXPLANATION OF USDA POSITION ON S. 2162

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 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, 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 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 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 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.

Senator Moss. Before I call our first witness, I might say I am very happy to have Senator Pearson of Kansas sitting here this morning as the ranking Republican member of the subcommittee. I would ask you if you have any opening comments, Senator Pearson?

Senator PEARSON. No, thank you, Mr. Chairman.

Senator Moss. We are pleased to have as our first witness Mr. Alfred W. Snodgrass from the State of Washington. Mr. Snodgrass' young son swallowed electric dishwasher detergent. His testimony will focus our attention on the kind of tragedy that S. 2162 could prevent.

Mr. Snodgrass, we appreciate very much your willingness to recount this painful experience and perhaps your testimony will help other parents avoid the same experience. If you would come to the table, please, Mr. Snodgrass, we would be pleased to hear from you now.

STATEMENT OF ALFRED W. SNODGRASS, RENTON, WASH.

Mr. SNODGRASS. Senator Moss, members of the committee:

I want to thank you for providing me with this opportunity to present my family's personal experience as it relates to the bill that you are here to consider this morning.

Before I get into it, I would like to make a comment that is not in my prepared statement. I notice on your agenda of speakers, that you list my company affiliation, Lockheed Aircraft Corp. I am here as a private citizen, and represent my company in no way. My testimony is strictly about myself and my family.

Senator Moss. Thank you for making that clear for the record.

Mr. SNODGRASS. First of all, let me give you a little family background. My wife, June, and I have six children ranging from age 16 down to age 2½ years. Our oldest boy, Wayne, Jr., is 16, Mark is 14, Steven just turned 12, Kimberly is now 9, Robin is 6, and Michael, our youngest, will be 3 in January.

My story here today will pertain primarily to Michael, who was seriously injured in an accident on July 26, 1968. One cannot, however, adequately describe the impact of such a tragedy without relating to you some of its effect on the other members of the family and the family's future.

I have here with me today a box of Finish dishwashing detergent. I'm not taking a poke at this particular product. It is typical. I saw six or seven others like it when I picked it up in the store yesterday. This

particular detergent is the one my boy got into. Note how attractive the package is, particularly to a small, inquisitive child. This particular package has not yet been opened, so let's see just how difficult a job that is. As you can see, it wasn't much of a task.

My boy, Mike, was just 18 months old the morning of July 26, 1968, when he got into the kitchen alone. The rest of the family were in other rooms of the house. It was about 7:30 in the morning, and I had already left for work. Evidently Mike, in his usual 18-month-old curiosity, opened up the cupboard beneath the kitchen sink, alongside our automatic dishwasher, and took out the box of Finish detergent. It had already been opened and was kept there for convenience relative to the dishwashing machine.

Yes, the label on the package says, "Precaution, harmful to swallow," et cetera. As parents, we know more than anyone that we were negligent in placing it there. The fact remains that most families don't look that closely at the label, and it was there.

We now believe that Mike looked at this spout on the side of the box and related it to the spout on his little training cup from which we were teaching him to drink. Based upon the amount of detergent he had back in his throat immediately following the accident, it seems that he must have tipped the box up, tilted his head back, and poured the powder into his mouth.

My oldest son, Wayne, was in the next room and heard Mike gagging and choking. He ran into the kitchen and when he saw what had happened, screamed for his mother to come running. Luckily my wife had previous training as a nurse and also had the experience of raising five other small children. So she didn't panic. She put him over the kitchen sink and rinsed his mouth out. We called the Poison Center and found they were not very well versed on household detergents, so they said they thought she had done what was correct; we should go to the family doctor.

A neighbor, Mrs. Matt Jeffrey, helped my wife get to the doctor's office. My regular pediatrician, Dr. Vincent, didn't happen to be in at the time and another member of the staff, Dr. Thomas Cock, handled Mike's visit. He carefully examined Mike's throat, and told my wife that she should keep Mike at home under close observation.

The key point here is neither was the pediatrician aware of the seriousness of the accident at the time.

She took him home. By noon his fever had gone up. We got very concerned and contacted the doctor. He told me to bring him back. He took X-rays, but before the X-rays could be developed it became obvious Mike was getting worse by the minute. So we rushed him to Children Orthopedic Hospital, about 7 or 8 miles away.

By that time, Mike could hardly get his breath. Dr. Cock had phoned ahead to the hospital and made arrangements for Dr. Lester R. Sauvage, a pediatric cardiovascular surgical specialist, to meet us at the hospital. They took him directly to the emergency operating room. They had to give him oxygen on the way out. Mike was in surgery until early evening, 6 or 7 hours.

The doctor told us Mike was serious. He had to put a tube in his throat so he could breathe and a tube into his stomach so he could receive nourishment. He told us he had almost lost Mike once or twice on the operating table, and he wasn't sure how successful he would

be in restoring Mike's esophagus without major surgery. He said we should look forward to several months of Mike's being in the hospital, and several years of tender loving care thereafter.

Attached to this paper is a copy of the news article about Mike that appeared in the Seattle Times on July 30, 1968. Also attached is a statement that I obtained for insurance purposes from our pediatrician on July 11, 1969. I won't take time to go over these two documents in detail; you can review them at your leisure.

Senator Moss. They will appear in the record attached to your statement.

Mr. SNODGRASS. Thank you.

Mike stayed in intensive care at Children's Orthopedic Hospital for several months thereafter. Then, almost miraculously, he began to recuperate, almost overnight. We had a problem—we kept restraints on his arms for several months, but several times he pulled the tubes out of his throat and stomach, and we had a panic to get it back into him. We were able, in October 1968, to finally remove the trach out of the throat and the gastrostomy tubes from his stomach.

Everyone was amazed. In fact a Dr. Bill, who is a partner of Dr. Sauvage, had been corresponding with several children's hospitals in Australia and they just couldn't believe Mike had recovered that fast.

We were able to take Mike home in October. Within 5 weeks Mike began to show signs of difficulty in swallowing and also had some difficulty in breathing. By early November, he had almost completely lost the capability to swallow. He was readmitted to Children's Hospital for exploratory activities by Dr. Sauvage. This attempt to establish communication between Mike's mouth and his stomach was unsuccessful. At this time, Mike had his trach and gastrostomy tubes reinstalled so that he could breathe and be fed. Dr. Sauvage became concerned that he might inadvertently penetrate the membrane of Mike's throat, and called in Dr. Alvin Novak, a prominent Seattle pediatric ear, nose, and throat specialist.

Dr. Novak assumed primary responsibility for Mike's case and also, unsuccessfully, attempted to reestablish communication to Mike's stomach several times in the following week. He finally advised us that he saw no other alternative but to go in through open neck surgical procedures and perform a skin graft in Mike's throat.

Dr. Sauvage would assist him in obtaining sufficient membrane from intestines for the throat skin graft and any open chest surgery that would be necessary to gain access to the esophagus.

Dr. Novak told us that the operation was very delicate and serious and had slightly better than a 50 percent chance of being successful. The body oftentimes rejects tissue from a skin grafting procedure. Should this happen, the only other course of action left open would be further open neck surgical operations.

It seemed that, at that time, we had no other alternative, so Mike's neck surgery was scheduled late in November, approximately 4 months after his accident.

The night before the surgery Dr. Novak said he spent a very restless night. During his mental review of the next morning's procedures, he got the idea that perhaps Mike had had scar tissue form over the

opening to his esophagus. If so, he might reestablish communication to the stomach by probing under the lip of the scar tissue.

The next morning he told us what he planned to do. He would first spend 45 minutes once more attempting to reestablish communication before starting the operation. Thank God, it was successful.

Dr. Novak found that Mike's esophagus was twisted to one side by a lip of scar tissue healing over the top of the opening. He was able to get a monofilament line under the scar tissue, down through the esophagus, into the stomach, and out through the gastrostomy tube. This monofilament was to be used for inserting dilating devices for future treatment.

In the weeks that followed, Dr. Novak lysed, or made small cuts and notches, in the edge of the scar tissue and found that, once freed, the esophagus fell readily back into place. He then diagnosed that he might be able to pull Mike through without the drastic neck surgery. It would be, however, a long, drawn out process of lysing and dilatation.

We were able to take Mike home for Christmas. He still had his trach and gastrostomy tubes. Again, we were thankful for my wife's previous training as a nurse. We had to purchase a mechanical aspirator so that my wife could suction Mike's trach every few hours, even throughout the night. We had to keep a vaporizer running constantly in his room, and listen closely through the night for sounds of needed suctioning.

Mike was returned to the hospital on each Wednesday for surgical treatment and then brought back home on Saturday.

This went on until March 1969, 9 months after the accident. Several weekends prior to March, we were unable to bring Mike home at all due to bronchial congestion and other complications.

Mike pulled his trach and gastrostomy tubes out several times during his stays at home, each time causing a panic to get him back to the hospital to the emergency room to have them reinserted. Fortunately, each time we were able to get to the hospital before it required additional surgical procedures. By March, however, Mike was doing well enough so that his trach and gastrostomy tubes were permanently removed.

From March 1969 until July 1969, Mike progressed rapidly. We were only required to take him into the hospital for treatment every 2 to 3 weeks, depending upon his progress.

In July, further difficulties were encountered. This time Mike's excellent throat growth progress caused the problem. His throat opening was enlarging the way we wanted it to, but much more rapidly than the scar tissue itself. Again we had to return to a weekly hospitalization schedule, so that the scar tissue could be dilated and lysed, as required, to keep up with the rapid improvement.

Now between these treatments Mike is able to eat table foods with the rest of the family with little or no difficulty. We have had some problem with him aspirating and getting food particles into his lungs. In fact, he has had pneumonia twice in the last 2 months and has been required to be hospitalized for approximately 1 week's duration each of these times.

Mike is now doing quite well again. We take him in each week, Wednesday evening, and he spends the night in the hospital. The next

morning, he goes up to surgery for his weekly dilatation. I pick him up from the hospital on my way home from work each Thursday evening. A note of encouragement was received this past week from Dr. Novak. He says that if Mike does as well this week as he has the past couple of weeks, it looks like we can again start extending the time between treatments.

What does the future hold? We don't really know for sure. All we can do is hope and pray that Mike is again on his way to recovery. The only thing that Dr. Novak can tell us now, is that he thinks that Mike will one day be normal again, at least by the time he's 5 years old and ready to start school. That will be about $3\frac{1}{2}$ years after the accident.

I would like to make a brief statement about the financial impact on a family of a case such as Mike's. Mike spent almost 5 months in intensive care at Children's Orthopedic Hospital in Seattle. The basic rate of intensive care is \$90 per day, plus incidental expenses. I guess it is well worth it when you consider the care received there relative to other normal hospital rates.

Mike has now been admitted to the hospital 28 separate times—today will be 29—for a total of 114 days since his accident.

As I previously mentioned, we've had three different doctors involved constantly in Mike's case: Dr. L. Sauvage, a pediatric cardiovascular surgeon, Dr. A. Novak, a pediatric ear, nose, and throat surgical specialist, and Dr. T. Cook and L. Vincent, our family pediatricians.

Hospital bills to date now amount to approximately \$13,000. The doctors' fees to date are approximately \$4,100. The anesthesiologists have added another \$1,400. This comes to a total of approximately \$18,500 to date. How much more to go? We just don't know. We've been very fortunate that the company I work for has a very good group insurance program with a major medical expense coverage included. Even with this, our family expenses over and above the insurance, amount to approximately \$3,000.

One of our major concerns now is that there is a dollar limit on the group insurance major medical expense coverage. If it should work out that Mike is not well by the time that this point is reached, we will have serious financial problems to face, as a young family with many children. We're hoping that by the time Mike will be old enough to at least be in a nursery school so that my wife can return to work. Otherwise we may have to ask for financial assistance from other members of the family or the local community.

Now that you have heard Mike's story, you might be wondering what impact all this has had on my family. My wife asked that I leave out the impact on her and me.

For one thing, our values have changed considerably. Some of the material things that meant so much to us before are now relatively unimportant. In fact, if there ever is a "reason" for this type of thing happening, perhaps this was why it happened to Mike.

We are undoubtedly a closer knit family than we were before. Our older boys have matured more rapidly than their neighborhood chums. They were required to care for the rest of the family while my wife and I spent long hours at the hospital. My two little girls are very protective about Mike now. In fact, they spoil him rotten, because he

gets anything he wants from various members of the family. I'm sure that each of us will remember this past year forever. We consider ourselves fortunate that Mike has done as well as he has, considering the circumstances. We are also very fortunate that this particular incident has not yet meant financial disaster for our family.

In closing, I would like to make just one other point. Please don't think that our story is an isolated case. During the past 15 months, my wife and I have seen many other children at the hospital with problems similar to Mike's. In fact, just this past week, I was talking with one mother who had a child who swallowed oven cleaner in March of 1968. They are still undergoing surgical operations with an uncertain future.

Anything that we can do to make containers for these types of substances more difficult for a child to open, or anything that we can do to force the product manufacturers to more clearly label and identify their products as dangerous, will help the Nation's children to grow up in a safer environment.

Thank you.

(The attachments follow:)

[From the Seattle Times, July 31, 1968]

BOY, 18 MONTHS, LIVES; DETERGENT ALMOST KILLED HIM

(By Al Dieffenbach, Medical Editor, the Times)

Michael Snodgrass, 18 months, is in Children's Orthopedic Hospital today, a wide-eyed, blond example of the damage that can be done by the caustic substances in some dishwasher detergents.

Michael's esophagus (food pipe) and windpipe are burned nearly closed. His mouth and lips are blistered. He breathes through a tube in a hole in his throat. He will be fed through a tube sticking out of his abdomen.

About every six weeks for the next two years, Michael will have a tube put down his scarred esophagus to stretch it back to serviceable size.

Michael's parents, Mr. and Mrs. Alfred W. Snodgrass, of 12509 72nd Ave. SE, Renton, joined the hospital in another effort to warn others of the danger.

"I had no idea that the dishwasher detergent was dangerous," Mrs. Snodgrass said. "All the other soaps and things are in a cupboard out of the reach of children."

Mrs. Snodgrass, the mother of six children, said Michael recently found the box of detergent and gulped a mouthful before anyone realized what he was doing.

She said she immediately washed his mouth and face with water, had one of her older children call the Poison Control Center and summoned a neighbor who is a registered nurse.

All of the actions were proper, a doctor said, except that the caustic in the dishwasher detergent usually does its painful work in 30 seconds.

After treatment by a doctor, Michael was sent home, but began running a fever and showed signs of lung congestion.

He was taken to Children's Orthopedic Hospital and was sent immediately to surgery, where a doctor said, "We nearly lost him."

Several brands of dishwasher detergent carry no warning about their danger. Others use small type. "All of them should be kept out of the reach of children, if not out of the house altogether," a doctor added.

PEDIATRIC ASSOCIATES,
Bellevue, Wash., July 11, 1969.

Re Michael James Snodgrass.

To Whom It May Concern:

This child ingested a quantity of dishwasher powder called Finish on 7-26-68, which produced severe oral, pharyngeal, and esophageal corrosion and burning. The child was hospitalized at Children's Orthopedic Hospital on that day and for some time following that.

His care was a mutual project between the general surgeon and the pediatrician. The function of the surgeon in such care is to take care of the placement of gastrostomy, tracheostomy, and to lyse adhesions and work with the mechanical problems. The function of the pediatrician is to regulate fluid and electrolyte balance, to correct problems in these areas, to monitor for and treat infections, and to care for the emotional and psychiatric problems which invariably follow severe crippling injuries in children.

The child has subsequently been cared for during the convalescent period by an otolaryngologist, Dr. Alvin Novack, with regard to the mechanical aspect of his oropharyngeal problems.

The speech development has been slow, due to the prolonged need for a tracheostomy, but this has begun to show rather remarkable improvement and at this point the overall adjustment of the child is excellent considering the severity of the damage and the prolonged hospitalization which was initially required. He will continue to require considerable care over the next few years, primarily directed at the scar problems which occurred from the burning, but also with regard to the rehabilitative portions of his care.

If any further information is needed about this patient, please contact me directly.

Sincerely,

LEE S. VINCENT, M.D.

Senator Moss. Thank you very much, Mr. Snodgrass, for a poignant and moving discussion of the very serious accident that occurred in your home, and your summary, saying anything we can do that is effective to protect young children from similar accidents certainly is worthy of our attention and our immediate consideration.

I was interested to see you just pop that box of cleaner open and pour the powder out there. And I guess every one of us is familiar with that type of package. That's the usual thing for a detergent cleaner in an automatic washer. It is not necessarily that brand alone; as far as I know, all of them come in that type of package.

Mr. SNODGRASS. As a matter of fact, and I won't mention the product's name, I bought this specifically, because this is what Mike got into. There's another product, a bright green package. It says, "New, easy-open spout." I saw it right on the shelf, day before yesterday.

Senator Moss. Well, we don't have any small children in our home now, but we keep our cleaner the same as you do, down under the sink close to the dishwasher.

Mr. SNODGRASS. The article I attached to my statement in the paper, it's amazing—every place we go, whether it be church or school—in fact work—the people have asked, "Was that your son?" They made the statement that until they saw that article in the newspaper they were doing the same thing.

So it really is a lack of awareness, even though they are good conscientious parents, to the danger involved here.

Senator Moss. As you also pointed out when you exhibited the package, even though it carries a warning on it, the warning is meaningless to a child, and is probably not seen very well by a parent buying the product. They just don't think about it.

Maybe it's a little bit like the warning on the cigarette package. We found the warning on there didn't deter very many people. They didn't see it after the first impact of putting it on.

Now, since Mike's accident what have you done about placement of your detergents?

Mr. SNODGRASS. It is now in the high cupboard in the back. Like most families, we make our children help with the dishes and so forth,

and they are pretty well trained now. They know the detergent goes up out of reach of the small ones.

Senator Moss. Of course you've had this terribly traumatic experience.

Mr. SNODGRASS. Yes. We are much more conscious, not only on household detergents, but with any liquid or substance now. But most people aren't.

Senator Moss. Before hearing about this bill and this hearing, have you done anything to try to get the idea out that there ought to be safe packaging for substances that are dangerous to children?

Mr. SNODGRASS. I'm sorry to say that I have not. I think this is another factor. My wife and I talked about it before I came here. I think most people who have an unfortunate accident like this are so embroiled in their own personal problems that they don't think of the good of the community, and what should be done for others. This is the very reason I'm here today, at my own expense, as a private citizen. We would like to think that should the bill pass, we are hoping it does, that in Mike's future, looking back, he can feel he had a small part to play in this legislation.

But no, we have done nothing, and I think this is probably true, as I talked to most of the people I've met in the hospital, they are so tied up in their own problems and their family difficulties and financial difficulties, that they don't think about going forth and doing something about it as a private citizen.

Senator Moss. Well, I can understand your feeling of urgency on this matter. I want to commend you very highly for coming here, clear across the continent at your own expense, to tell this story which is certainly one of the most dramatic and devastating stories that you can have on this child injury matter. In just listening to it, I am rejoicing that Mike is getting along so well. I feel like I know him now.

I think this sets the picture against which we are going to have the hearing. If there is a reasonable way to lessen that chance of injury or prevent it entirely, I think all of us agree we ought to do it.

Just one final question from me, and then Senator Pearson may have some questions.

There has been talk about having some common symbol on all dangerous substances, something like the skull and crossed bones that you have come to see on some poison packages. Do you think that that would serve the purpose to warn a family in advance not to keep the detergent close to children, if it had this one symbol on it?

Mr. SNODGRASS. I think it would help. Again, I think you still have the problem of, as you mentioned earlier, small children can't read. This is a personal opinion, I've noticed on most of the packages, and we are quite conscious of this now, that the danger sign is always very small. It is at the back of the package, at the bottom of all of the other stuff that most people don't read. Yet, on the fronts of the packages, that faces out of the counter, when you go to buy it off the shelf, we have a big sales approach, "Special formula for water in this area," and so forth.

It would seem to me if such a label were applied, it should be on the front of the package as well as the back.

Senator Moss. You have furnished a good warning to me, personally. I said we had no small children in our own home now, but

grandchildren are coming along and they will be crawling around. I think maybe we will be a little more careful where we put the detergent now.

Senator Pearson?

Senator PEARSON. Thank you, Mr. Chairman.

Mr. Snodgrass, first, I commend you for your testimony. I think it would be the natural course for one to keep a personal experience to themselves, and your testimony here today is a contribution to these hearings.

I assume that after this accident that Mrs. Snodgrass and you made a very close examination of the other products within your home. How many did you find which are the normal and usual products that are required in a house for housekeeping that did represent some danger?

For example, ammonia in a bottle or oven cleaner.

Mr. SNODGRASS. I can't give you a number, but I could mention a few from memory. You mentioned oven cleaner, ammonia. Even though most clothes washing soaps aren't labeled, and we don't know for sure whether they are caustic, we take no chances with that. We put those up in the laundry room now. We have become much more conscious of medications, too; I guess the common household aspirin, et cetera. I can't give you an exact number. If there is any doubt in our mind whatsoever, it goes up.

I must admit it probably wouldn't have happened if it hadn't been for Mike's accident.

Senator PEARSON. I notice the warning is in small print. You are a consumer, and a common denominator of the shopper. What do you suppose would be required? The child can't read, but the adult can. What do you think would really be required to command the attention and to require a response and caution?

Mr. SNODGRASS. My personal opinion is it should be a uniform labeling of all products, if possible. And that if it would show on the face of the package, which is the show side on the shelf, I think most people, at least in my own case, I don't read all of the small print on the back. My wife says get a box of dishwashing detergent, and usually she doesn't tell me what kind. Once it's in the house, I know how a dishwashing detergent works, and I use it. I don't read the small print.

I think it has to be on the front of the package, and has to be a common label across all packaging. I do not think that will do the job in my personal opinion. We get careless as parents. I think something has to be done—personal opinion again—to the container itself, to make it where it is a combination of opening features, something a small child can't get at readily if his parents are negligent, or in some cases perhaps, just don't care.

Senator PEARSON. Maybe these hearings and the press stories might help too.

Mr. SNODGRASS. I hope so.

Senator PEARSON. Thank you.

Senator MOSS. Thank you very much, Mr. Snodgrass. We are grateful for your testimony. May we add that we hope that Mike continues to improve and becomes a normal, healthy individual.

Mr. SNODGRASS. Thank you, Senator.

Senator MOSS. Our next witness will be Dr. Glen E. Wegner, Dep-

uty Assistant Secretary for Legislation, Department of Health, Education, and Welfare. I believe he will be accompanied by Henry L. Verhulst and Mr. Georg Maisel, Office of Product Safety, Food and Drug Administration.

We are glad to have you gentlemen here, all of you.

STATEMENT OF DR. GLEN E. WEGNER, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY GEORG S. MAISEL, POISON CONTROL DIVISION, OFFICE OF PRODUCT SAFETY, FOOD AND DRUG ADMINISTRATION; DALE C. MILLER, ASSISTANT TO THE DIRECTOR, BUREAU OF COMPLIANCE, FOOD AND DRUG ADMINISTRATION; AND HENRY L. VERHULST, DIRECTOR OF THE POISON CONTROL DIVISION, OFFICE OF PRODUCT SAFETY, FOOD AND DRUG ADMINISTRATION

Dr. WEGNER. Thank you, Mr. Chairman, I am Glen Wegner and I have on my extreme left Mr. Georg Maisel, who is with the Poison Control Division; on my immediate left, Mr. Dale Miller, Assistant to the Director, Bureau of Compliance, Food and Drug Administration; and on my right, Henry L. Verhulst, who is the Director of the Poison Control Division in the Office of Product Safety in the Food and Drug Administration.

Senator MOSS. Thank you. You are all welcome, gentlemen.

Dr. WEGNER. Mr. Chairman, I would like to have my complete statement submitted for the record with your permission and go through that statement and then my colleagues and I will be happy to attempt to answer your questions.

Senator MOSS. Thank you. It will be printed in full in the record after you summarize it, or handle it in any way you wish.

Dr. WEGNER. I think we have some pertinent facts for deliberation before your committee and I will go through the statement as it is printed.

I am pleased to be here today to discuss with you S. 2162, the Poison Prevention Packaging Act of 1969.

This bill would amend the Federal Hazardous Substances Act to authorize the Secretary of Health, Education, and Welfare to require safe packaging of hazardous substances. The bill provides that the Secretary shall establish standards for child-resistant packaging when he finds that the degree of hazard from a household substance requires such action for the protection of public health and safety of children. The Secretary is directed to appoint a technical advisory committee of not more than 15 members to assist in developing these standards. The committee is to represent equally the Department of Health, Education, and Welfare, household consumer products manufacturers, and widely recognized independent packaging consultants. Consultation with the committee is required prior to the final establishment of any standards authorized by this bill. The bill would require child-resistant packaging for foods, drugs, cosmetics, pesticides, and other household products which are currently exempt from requirements of the Federal Hazardous Substances Act.

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 speciality 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 effort 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 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.

Thus, 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 articles such as imported flammable dolls, do-it-yourself bomb and fireworks kits, and flammable fabric-covered play tunnels. Seizure actions have also removed from the market an extremely flammable waterproofing masonry paint (now banned) and necklaces made of the poisonous jequirity bean.

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 persist, 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 complete mortality data are available.

In 1968, 420 poison control centers reported over 105,000 ingestions of drugs and potentially toxic household products. Children under 5 years of age were involved in 71,563 of these ingestions, and 4,129 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, pesticides, turpentine and related paint products, petroleum products, and plants followed in descending frequency in the accidental ingestions reported in 1968.

At first glance, the total of 325 child deaths from accidental poisoning reported for 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. Morbidity relates to those children who survive the injury resulting from the accident.

Some chemicals cause serious illness requiring lengthy hospitalization, as Mr. Snodgrass has revealed to you this morning, 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. I think you will see from this data, Mr. Chairman, that the case history revealed to you this morning by Mr. Snodgrass is not an atypical situation. As a practicing pediatrician, prior to my coming to work with this Administration, I have treated many such cases in the Children's Orthopedic Hospital in Seattle, in the Johns Hopkins Hospital in Baltimore, and in Boston and other places.

I would like to commend this man, as you have, for the case history he has revealed, and relate to you professionally that it is not an atypical story.

Senator Moss. Thank you.

Dr. WEGNER. 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 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 8 in both 1966 and 1967. Six such deaths have been recorded for 1968, although the mortality data for that year are not yet complete.

Merely reading of these statistics, I emphasize again, does not communicate the underlying tragedy; this can be appreciated only by those who have visited or treated these hospitalized children including the parents.

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 consist, 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 has 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 sulphuric 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 not have presented 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 S. 2162. 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 1 $\frac{1}{4}$ -grain flavored aspirin to 36 tablets per retail container. This 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 S. 2162.

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. This is very important, Mr. Chairman, because 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, we believe the administration procedures provided for in S. 2162 are generally satisfactory. However, we would like to suggest a few changes which we believe will strengthen this legislation.

Section 2(b) of the bill defines "package" as a container or wrapping for personal care items and items for performance of services ordinarily rendered within or about the household. We suggest this defi-

nition be broadened to include items used or stored within or about the household. A large number of chemical specialty items, such as antifreeze, carburetor cleaners, brake fluid, and other automotive care products that contain hazardous ingredients, are not used for services rendered within or about a household, but they are frequently stored in the household. Such items have been responsible for poisonings and fatalities of children; thus, they should not be exempt from the proposed safe packaging requirements. Other typical products in this category include boat maintenance items, hobby items such as model airplane fuels, and ammunition. The issue has been raised on occasion with the Food and Drug Administration as to whether such items—not intended for ultimate use within or about the household per se—are subject to labeling under the Federal Hazardous Substances Act. We believe this change in the bill will clarify the matter.

We believe that the provision for a statutory advisory committee in section 3 is unnecessary. We would, of course, in any event consult with experts in the field and interested groups in the administration of this legislation. However, should the committee consider a statutory advisory group to be essential, we believe that the bill should be clarified regarding the selection of "packaging consultants" to serve as members of the technical advisory committee. The present language of the section calling for selection of "widely recognized independent packaging consultants" may be unduly restrictive with respect to selection of professors, members of scientific bodies such as the National Academy of Sciences, and others, who are not professionally dependent upon the packaging industry. Without the option of appointing committee members from the academic scientific community, the intended balance of the advisory committee may not be achieved. We would further point out the need for medical as well as product technology experts to serve on the advisory committee to assure an objective appraisal of the child-resistant packaging standards proposed for adoption under the act.

Section 4 of the bill amends certain of the prohibited acts of existing law to include a reference to a "hazardous substance in a package which fails to comply with standards established pursuant to section 3(d)." We believe the bill also amends sections 4(b), 6(a), and 14(a) of the present act to require firms or individuals repackaging or packaging articles received in bulk after interstate shipment, or importing articles subject to the act, to also use "child-resistant packaging" for their distribution of these articles, and to make the judicial seizure provisions applicable to violative products.

We understand that the Department of Agriculture is suggesting to your committee that the bill be amended so as to continue the present exemption, from the Federal Hazardous Substances Act, for articles covered by the Federal Insecticide, Fungicide, and Rodenticide Act instead of making the exemption inapplicable to the new safe-packaging provisions. We understand, further, that the Department of Agriculture believes that it already has authority under the FIFR act to safeguard against unsafe packaging of pesticides, but that it is considering a legislative proposal to strengthen its present authority in that respect. We would not object to the Agriculture Department's proposed amendment to S. 2162, and would in any event work with that Department to achieve the objectives of this bill.

We believe that this bill can substantially contribute to a reduction in the annual number of accidental injuries and deaths caused by hazardous products found in the home environment. We therefore, recommend enactment of this legislation with the amendments that have been outlined in our statement. We will be pleased to work with the committee staff to develop language which will clarify the provisions we have discussed.

Thank you, Mr. Chairman, for this opportunity to present the Department's views on this legislation. I would be happy at this time to attempt to answer any questions the committee may have.

Senator Moss. We will. Thank you, Dr. Wegner, for a very fine statement. I do appreciate having this for our record as we consider the bill. I am a little startled to read the figures of the number of children that are affected in the immediate past by this ingestion of hazardous substances. As this underlies, of course, the need for further action in this field to try to protect children and others who are able to get hold of these products.

Your report that you have had these voluntary meetings with industry people and have reached some advances is encouraging, but I take it from your endorsement of the purpose of this bill that you recognize that, perhaps, they are not fully effective and that we need, by legislative act, to make some requirements on packaging. Is that correct?

Dr. WEGNER. Mr. Chairman, I think you have stated it very eloquently and about as diplomatically as it can be stated. We are encouraged by the voluntary action that has been taken in many instances. On the other hand, if you look at the total number of voluntary compliance situations versus the hazards that still exist, there is no question but that we must provide some leadership in this area. We look forward to working with you in this regard.

Senator Moss. Do you believe that if this bill became law and we had this standard set for safety packaging that it would tend to freeze the packaging technique and cut out innovation in moving on from there?

Dr. WEGNER. No, I do not think that it would. I think that it could do so. I think there again we have to have a very strong nonpartisan effort to work out the problems. We are not trying to come here and tell this committee that these things can be worked out with no difficulty. We know that industry has some real problems. Advertising itself necessitates attractive packaging and necessitates a difference from one package to another and so forth. I do not think that we are without difficulty here in working out the ultimate solution. But I do think that it is possible through this type of legislation to encourage more in the way of a voluntary effort on the part of industry.

As you know, the administrative difficulties involved in this sort of thing become enormous. The Federal Government, and I certainly speak for the Department at least, has no intention in getting involved in anything that can be done voluntarily. We have a big enough can of worms in other areas that we do not wish to take on any burdens that are not dictated by necessity.

Senator Moss. Apparently your Department has already been giving some consideration to what the factors would be in safe packaging. You spoke of the plastic bottle with a hard cap to take off that tended

to cause it to be squeezed and you had instances of fluid coming out because the bottle had been squeezed. Have you developed some standards or have you already moved along in deciding what would be desirable by way of safe packaging?

Dr. WEGNER. Yes, we have given thought to these things, but it has not moved along as far as any of us would like. I have these program experts here with me and I will ask any of them if they have anything to contribute to that question. I think they have been closer to it than I.

Mr. VERHULST. I think so far the major emphasis has been developing a method for evaluation, so that we can really determine whether a product that is designated as safe packaging is truly effective in preventing the access of the child to the contents of the package. And also so that we might evaluate various types of packaging that could be recommended. In line with the question you previously asked. I think we want some flexibility, so as to not bind industry into any one solid set type of packaging.

Senator Moss. Would you envision this as being a continuing examination so that any packager who came up with an innovation could come and present it to the Department? If it was new and different, but still accomplished the objective, the Department could then approve it. They would not all be just standard?

Mr. VERHULST. Absolutely.

Senator Moss. One thing I noticed from Mr. Snodgrass' testimony, he said that when they called the Poison Prevention Center, they apparently didn't know much about washing detergent. At least, whoever answered said well, you have washed his mouth out, that is probably enough. Does this indicate that we haven't had much trouble with automatic dish washing detergent in the poison centers or not?

Dr. WEGNER. I think it could. I don't have the actual statistics on detergents themselves but will ask Mr. Verhulst to comment. I would like to discuss briefly the general problem, about which I am somewhat familiar. First of all, I trained at the University of Washington Medical School at Seattle. As a medical student I spent time working with the staff physicians and residents at the Childrens' Orthopedic Hospital, which is a very capable pediatric institution and which was one of the early hospitals to develop a poison control center. I think it is recognized even back here on the east coast as being a very capable center. Obviously these things depend on the competence and capabilities of individual physicians and staff.

I am sure, Mr. Chairman, you are aware of the very severe health manpower problems we have in this Nation today. We are constantly trying to beef up all aspects of medical practice, including this very important area of poison control.

In my experience, household detergents, such as the product that was demonstrated here this morning, are not real frequent offenders, at least in terms of morbidity and mortality. Usually the products are very distasteful, like other soaps and are repulsive to the child after a small sample is tasted. Outside of the drug area the most frequent cases that come into the emergency room, I think, are furniture polish ingestions. There are several furniture polishes that every medical student, intern and physician knows well. Because they are so frequent, they may not be reported as physicians learn how to appropriately treat cases and do not request information.

I would like to add that almost anything normally kept under the kitchen sink gets high on the admission list as a possibility for childhood poisoning.

Do you have anything to add to that, Mr. Verhulst?

Mr. VERHULST. We are aware that some of the automatic dishwasher detergents have created problems and the centers have been notified of such. I believe in line with Mr. Snodgrass' statement, that the mother had done pretty well administering the emergency first aid. The Center had not too much more to offer, other than to tell them to see their pediatrician and this is what was done. I believe the Center really gave all of the information they could. The treatment from that point on had to be taken by the physician.

Senator Moss. The bill as it is drawn now gives the Secretary positive power of prescribing safe packaging. Do you think it would be better to put that in the negative, giving him the power to ban packaging that does not meet the standard of safety? It is just a matter of how his power should be exercised. It seems to me it might be better to go around to the negative and leave the ingenuity with the industry, but give him the power to disapprove.

Dr. WEGNER. As we have tried to convey here, the big thing we would like at this stage is to maintain flexibility; hopefully so that we can continue both seizure and banning type operations as well as provide some leadership in terms of the way we think packaging should occur. It is my impression, as it is yours, that it could go either way. I see nothing wrong with a positive approach which will allow the Secretary to offer positive leadership. I look upon this as giving us more flexibility perhaps than using the negative approach.

As I mentioned before, I think we very much realize the problem that industry has with this, but accident and poison prevention is something that is so important, we simply must take a positive aggressive approach. I don't have the recent figures, but accidents and poisoning together are the leading cause of death in the pediatric age group. As a matter of fact, until recently they stacked up more than the next six items together. So I think in spite of the fact that we have these problems, we must do something to cut down the morbidity and mortality related to these areas of medicine.

Mr. Verhulst, do you have anything to add?

Mr. VERHULST. No.

Dr. WEGNER. Mr. Miller?

Mr. MILLER. I would agree with Dr. Wegner that the best way probably would be to have the opportunity to guide in the development of these standards. The banning procedures which were mentioned as an alternative, are extremely cumbersome and time consuming. If we had to follow those, we could end up in an unending series of hearings and administrative procedures.

Senator Moss. And, of course, I appreciated the part of your testimony, Dr. Wegner, where you pointed out that if opening the package is made so severe that it is hard for an adult or a slightly handicapped adult to do it, then he may be tempted to put it into another container, or leave the top open.

Dr. WEGNER. Yes. I think that example points out one of the areas where there is an obvious problem. We must work that out. We have to achieve some balance between a safe package and one that a con-

sumer not only can utilize, but one that will get the job done by protecting all unintended consumers.

Senator Moss. I talked a little with Mr. Snodgrass about this question of having some very distinctive symbol or label. I wondered, first, if you have the power to do that now, and secondly, if you are considering anything of that sort? Do you need legislation? This may not be a warning to a child, but it might be striking enough and common enough in its appearance that it would influence parents to place these items more out of reach of children.

Dr. WEGNER. Well, there again we have some problems. I will speak on the actual authority later. Any time we get into something that might have an economic impact on the product and an industry, we would much prefer to work it out on a voluntary basis, help them in terms of education, and have them explain their problems to us and work this out on a voluntary basis, rather than use the big harsh stick of the Federal Government to again come down on private citizens and on industry.

We feel, as I have just expressed, that this is an area of such importance that if we cannot get voluntary compliance, we predict that consumer pressures will mount and we will probably be encouraging consumer pressures to mount to get something along these lines.

Mr. Verhulst, do you have anything specific on whether or not we have the authority presently?

Mr. VERHULST. No.

Mr. Miller?

Mr. MILLER. We do not feel that we have present authority to require symbols, other than the skull and crossbones. We feel that the overuse of the skull and crossbones on too many products would tend to negate its value. This would mean that a new set of symbols would be necessary, symbols which would probably have no meaning to the average person until such time as they could be educated as to their meaning. There would be some problems there in that education. And also the law presently requires that certain things appear conspicuously on the front panel. I didn't see the package of Electrasol Mr. Snodgrass had, but some time back we initiated some seizure actions against Electrasol and certain other detergents of that type. As a result these firms have now revised their labeling, and words such as "Danger, contact with eyes or mouth may cause burns, harmful if swallowed," will appear on the front panel of the package in large bold type. These will have to be prominent and conspicuous on the front. Admittedly there are some enforcement problems.

There are many products on the market, and all of them are not up to the conspicuousness that we would like to see.

Senator Moss. I recognize that a symbol of some sort might be a bit of a deterrent, perhaps, to the sale of the product and therefore would not be desirable from the point of view of the packager, the seller. And I don't have any particular symbol in mind. But I just think maybe an overlay of a child with a big "X" across the face of the child might become a symbol of telling people that this should be kept out of the reach of children, something like that.

Dr. WEGNER. This sort of a symbol could be useful in terms of an educational device, that parents from a very early age of their child,

could use to teach youngsters about poisonous and hazardous substances.

Senator Moss. Thank you. I wanted to get your consideration on it. What is your situation now as to manpower if this became law? Would it require appreciable increase in the number of personnel you would need to put it into effect?

Dr. WEGNER. Some increase in personnel. We have some very general figures here. Just for 1971, for example, we have seven different positions that would be required at approximate funding cost of around \$375,000, in that general range. This would include people such as medical officer, packaging engineer, chemist and a clerk and a food and drug officer and a program analyst and a clerk, to fit into the activities that are presently in the Food and Drug Administration. I am sure you do appreciate that again this would have to be worked out in terms of the real need that is there to make this legislation work.

Senator Moss. Is there any need to put in this legislation a preemption for State regulation in order to keep it uniform under Federal supervision and regulation?

Mr. MILLER. Well, there is presently a preemption with respect to labeling, and I don't recall the exact wording, whether or not it would cover packaging—I guess it would have to be amended slightly to cover packaging, but for the same reasons that it was felt desirable to put it in for labeling, it would also be desirable with respect to packaging.

Senator Moss. Is there any part of this that you observe that is in conflict with or incompatible with the Food and Drug Act as it exists now, or to be dovetailed in any way we haven't done? Have you studied it to that extent?

Dr. WEGNER. To our knowledge, no, Mr. Chairman.

Senator Moss. I do thank you for a very fine statement and for your answer to a number of questions that we have presented here. I am pleased that you give this endorsement. I want to commend you for the amendments you have suggested. Right offhand all of them seem to me to be very acceptable and desirable. I appreciate that kind of examination of a draft of a bill, because this is what we need, refinements and suggestions coming from the operating agency. I appreciate that.

Dr. WEGNER. Mr. Chairman, after you have reviewed this, your staff has reviewed it, if there are any questions we would be happy to assist the staff.

Senator Moss. I appreciate that, too.

Senator Cotton, do you care to question?

Senator COTTON. No, not at this time, thank you. I regret I didn't get here in time to hear the Dr. Wegner testimony but I will read the statement with interest.

Senator Moss. Senator Hartke?

Senator HARTKE. Do you work with the Product Safety Commission at all?

Mr. VERHULST. Yes, the Poison Control Division has cooperated with the National Commission on Product Safety.

Senator HARTKE. How do you cooperate with them?

Mr. VERHULST. Supplying data and information.

Senator HARTKE. Do you ever get any of their reports?

Mr. VERHULST. I couldn't answer that question right now.

Senator HARTKE. You mean to say they have been in this business all of this time, making these reports, they are holding hearings right now in Washington.

Mr. VERHULST. I am sure they are sent to the Office of Product Safety.

Senator HARTKE. Do you have any recommendations from the Product Safety Commission which you have not replied to or not acted upon?

Dr. WEGNER. At least in terms of the group here before you, no. We would be happy to check.

Senator HARTKE. I wish you would go back and check and find out why you don't act on them, why you don't reply to them.

Dr. WEGNER. We certainly will do that. If you would like us to report on them we shall be happy to do so.

Senator HARTKE. I can't see how you can be vitally concerned as you indicate in your statement, in the same field in which they have given reports on some of these products, which have been especially marked as being dangerous, and no action is being taken by the Department, which probably you might have authority to act now.

Dr. WEGNER. I can assure you I will check on that immediately and find out. I have not had contact with that group myself in the Office of the Secretary. But we will certainly check to determine what that relationship is. It sounds as though there should be a close bond between the groups.

Senator HARTKE. Yes. It was established for that very purpose, to work with the various agencies, especially with Health, Education and Welfare.

Dr. WEGNER. I agree. We will certainly check it out today.

Senator HARTKE. Thank you.

Senator Moss. Well, thank you very much, gentlemen. We appreciate it. We are glad to have you with us.

(The following letter was subsequently received for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
October 22, 1969.

HON. FRANK E. MOSS,
Chairman, Subcommittee on (the) Consumer Committee on Commerce, U.S.
Senate, Washington, D.C.

DEAR SENATOR MOSS: During my appearance on October 1, 1969, before your Subcommittee regarding S. 2162, the "Poison Prevention Packaging Act of 1969", Senator Hartke asked if this Department has received any recommendations from the National Commission on Product Safety which have not been acted on or received attention.

In checking with the Office of Product Safety in the Food and Drug Administration, we find no record of any recommendations having been submitted to the Food and Drug Administration by the Commission. The Office of Product Safety has a professional person assigned full-time to the Commission for liaison activities, including coverage of all hearings the Commission has held. This individual is presently serving in the capacity of Chief of Operations for the Commission. Thus, we are confident of having been apprised of any recommendations that the Commission intended to bring to the attention of the Office of Product Safety.

We respectfully request inclusion of this response to Senator Hartke's question in the hearing record.

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

Sincerely yours,

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

Senator Moss. Our next witness will be Mr. Robert L. Meade, Director for Legislative Affairs, the President's Committee on Consumer Interests.

STATEMENT OF ROBERT L. MEADE, DIRECTOR FOR LEGISLATIVE AFFAIRS, PRESIDENT'S COMMITTEE ON CONSUMER INTERESTS

Senator Moss. We are glad to have you, Mr. Meade. You may proceed.

Mr. MEADE. Thank you, Mr. Chairman. Mr. Chairman and members of the Subcommittee for Consumers, thank you for the opportunity to be here today to testify concerning S. 2162, the Poison Prevention Packaging Act of 1969.

Mrs. Virginia H. Knauer, Special Assistant to the President for Consumer Affairs, is out of town today honoring a long-standing commitment and I am pleased to appear here in her behalf.

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 upward of 300 of these children under 5 years of age die as a result of the poisoning.

These tragic figures are likely to continue in future years unless some drastic action is taken. There will be more and more poisonous substances, not merely the ones commonly thought of as being toxic, but aspirin, vitamins, diet pills, cough medicines, soap, bleaches, and other useful everyday products.

Children get into just about everything around the house. This natural curiosity on their part, psychologists inform me, should be encouraged; it is a part of the educational process. Yet, the curiosity which killed the cat should not be allowed to continue to kill children; they must be protected from themselves.

Ideally, parents would do the job, but this is, unfortunately, an unrealistic notion. Adults are not fully aware of the seriousness of the problem, nor of its extent. They are sometimes careless or otherwise occupied. At any rate, it is well-nigh impossible to watch children in the home every minute.

Adequate labeling of substances would be helpful, but not wholly effective. Adults will still be careless and, of course, the label has no meaning for small children. Furthermore, all products potentially harmful to children cannot realistically be labeled as poisons, and it is difficult for adults to remember that a substance such as aspirin can be dangerous to children.

In that regard, adult education to the problem and hazards involved is also important and presumably has been of some help, but again has not been wholly effective.

Children need physical protection from potential poisons, not merely parental watching.

Many of our States have taken action, for example, in requiring the doors of discarded refrigerators to be removed. Yet far more children swallow hazardous substances than crawl into discarded refrigerators.

We require safety features on many products used by adults to protect them against carelessness, forgetfulness, or chance. How much more so do we need protection for small children?

Our investment in our human resources—children—is too great to permit continued inaction. Children must be protected from themselves; the cost of doing nothing is too high.

I would hope and expect that modern technology could provide safety closures that would not appreciably increase the cost of products. But even if there were a particular increase in cost, it would still be worth it in view of the results that should be achieved. We cannot afford the cost of doing without this protection.

The small special effort required in an adult's opening a safety closure would be a reminder to him of the problem and hopefully would lead to better parental supervision and care.

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

Surely a start can be made quickly on those items that are most commonly accidentally ingested, such as aspirin and salicylates.

As far as the proposed bill is concerned, it should be made clear that the seizure provisions of section 6 of S. 1265 of the Federal Hazardous Substances Act apply to any package not complying with the standards established pursuant to section 3(d) of the bill.

It should also be made clear that imports of hazardous substances not complying with the standards established pursuant to section 3(d) are subject to the provisions regarding imports of hazardous substances generally.

If the committee believes that a technical advisory committee as called for in section 3(2) of the bill is necessary, I would prefer to see some independent consumer representatives with expertise in packaging and medical experts as members of it. In that way, the Secretary of Health, Education, and Welfare would be insured of receiving advice from sources outside his own agency or the industry involved.

Optimally, I believe it might be preferable to adopt a comprehensive approach to the whole field of product safety rather than attacking only one aspect of the problem, but the need is so compelling for legislation of this type to protect millions of small children that I strongly support the bill.

Thank you.

Senator Moss. Thank you very much, Mr. Meade, for your testimony.

I take it that you and Mrs. Knauer consider this bill as a consumer interest bill, something that you should be concerned about because of your interest in the consumer. Is that correct?

MR. MEADE. That is correct, Senator. As the representatives from Health, Education, and Welfare have pointed out, although the numbers of deaths of children under 5 years of age seem to be decreasing slightly in recent years, the figure is still appallingly high, with 325 in 1967, 345 in 1966, 379 in 1965 and 454 back in 1963. So this is a matter of deep concern to a consumer representative.

Senator Moss. One reason I posed that question is that while we have been working on this bill we have heard from drug manufacturers, container manufacturers, physicians, and retailers, but we have heard very little from the consumers.

I think Mr. Snodgrass and Mrs. Esther Peterson have been in touch with us, and that is about all that came from that sector. I wondered

about that, why there wasn't a wider expression of opinion in the formative process.

Mr. MEADE. Well, I would expect it was due to ignorance of the subject matter of the bill. And the lack of awareness of it on the part of consumer groups throughout the country.

Senator Moss. I suppose that the sort of coordination that Senator Hartke was trying to discover in his questioning is something that would appeal to you, representing the consumer interests. The Council apparently hadn't been in touch with Food and Drug, at least they knew very little about its reports.

I wonder if you have any comment on that?

Mr. MEADE. I would hope that some section of Health, Education, and Welfare has been in close touch with the National Commission on Product Safety. I am willing to believe that Food and Drug Administration is such a large operation that perhaps one segment was not in touch, but another was. I hope that has been going on. If it has not, I hope it will commence.

Senator Moss. In this field of packaging, should there be some designation so that the consumer going in to buy a product off the shelf is guided to or attracted to a package that has a safe closure container, one as against another, assuming they won't all be uniform?

I wondered what you envisioned along this line?

Mr. MEADE. I would hope that once the bill becomes effective and minimum standards, at least, are set, that there would be some sort of healthy competition among the producers for safety features, safety closures, and that they would begin advertising this product, that it is safe, stressing safety features rather than perhaps other features which now get stressed more.

Senator Moss. So you feel this could be part of the selling techniques; although all of the closures must meet a certain minimum standard, part of the selling technique would be advertising that this has a special feature for safety?

Mr. MEADE. Yes, "our closure is better than anybody else's." I think that is much preferable to see competition along the lines of health and safety, factors than esthetics or what-have-you.

Senator Moss. Senator Cotton?

Senator COTTON. Mr. Meade, you are director for legislative affairs for the consumer organization; right?

Mr. MEADE. For the President's Committee on Consumer Interests.

Senator COTTON. What are your duties?

Mr. MEADE. My duties are generally to be responsible for preparation of any legislative matters that might be presented through the office, to review all pending legislative proposals up on the Hill that might concern consumer interests, to deal with any matters generally in the office of a legal nature that might result in either new legislation or new legislative power or new regulatory power, to be informed generally about matters that have a broad consumer interest and to serve in that respect as an advisor to Mrs. Knauer, who in turn is the special assistant to the President.

Senator COTTON. Do you have something to do with preparing legislation to be sent up to the Hill?

Mr. MEADE. Yes, I do.

Senator COTTON. Now in the last paragraph of your statement you

say, "Optimally I believe it might be preferable to adopt a comprehensive approach to the whole field of product safety rather than attacking only one aspect of the problem, but the need is so compelling for legislation of this type to protect millions of small children that I strongly support the proposed bill."

I am curious to know what this comprehensive approach to the whole field is. What do you mean by that and how would you proceed on that kind of approach?

Mr. MEADE. Well, this is the approach that I believe the National Commission on Product Safety is taking, Senator. They are looking at the entire field of product safety and, hopefully, at the expiration of the term of that Commission we will have comprehensive legislative proposals covering the entire field, not just child resistant packaging but the whole field of product safety.

They have, however, made interim reports such as the 1966 amendments to the Child Safety Act, on matters that are of immediate concern.

I started that sentence by saying "optimally" this might be done, that if today we could take a comprehensive approach I think it would be preferable. But the Commission of course is not that far along in its studies yet to make such a report and, therefore, an interim report or an interim act of this nature I feel is necessary now.

Senator COTTON. What is the meaning of the word "optimally"? I couldn't find it in the dictionary I have. It is a new term for me.

Mr. MEADE. I would hope it was an adverbial form of "optimum." If I am incorrect, I stand corrected.

Senator COTTON. I am not suggesting to correct you. You are evidently more erudite than I. Frankly, I didn't know the meaning of it. Do you mean "preferably"?

Mr. MEADE. It would mean "in the best of all possible worlds," Senator, this would be the way to do it.

Senator COTTON. Well, that is interesting. You speak of the "entire" field of product safety. In your answers to me you referred to it again and again. But, please give me an example of some of the things that would be encompassed in what you call the entire field that haven't been at least under consideration? We have had all kinds of bills before this committee, all kinds of proposals, and we have passed legislation for various specific products.

Mr. MEADE. I think there are a number of products used around the home, such as power lawn mowers, other tools; the field of automobile safety might well be part of the comprehensive package. It might be related to certain forms of sporting goods equipment that have been considered potentially hazardous.

Senator COTTON. What sporting goods equipment would be hazardous?

Mr. MEADE. Any item of sporting equipment such as a ski pole or something, Senator, that might be potentially dangerous to the user, or that might require some special safety feature in order to make it less of an accident hazard. There are a number of products for agricultural purposes, for example, that have been high in accident frequency. The whole range of products that are in common use that are sold day to day.

Senator COTTON. I was a little startled the other day to read that Mrs. Knauer suggested that either her office or your organization consider the electric power reliability problem—the matter of “black-outs,”—and whether consumers may be endangered in the next few years or sooner with a lack of sufficient electricity.

Were you in on that decision?

Mr. MEADE. No, not really, Senator.

Senator COTTON. Of course that subject already is under consideration by this committee. It reaches into the province of the Federal Power Commission. Some of the other things that you mentioned, I think, may also impinge upon the jurisdiction of other agencies or departments.

At the moment I am somewhat alarmed at your suggestion of a comprehensive approach. If you build up a volume of statutes that cover every conceivable thing—and there is some danger in almost everything one uses—you would need a small army of enforcement officers to follow consumers around the marketplace and to protect them from every conceivable danger.

I also was impressed by a question of the distinguished Senator from Indiana, Senator Hartke, when he wanted to know why HEW didn't know what was being done by the National Commission on Product Safety. This simply is one of the symptoms of becoming involved in so many things. We have it here on the Hill every day. We have committees of mayors, committees from labor, committees from business, committees from somewhere else, and by the end of the day it is hard to assimilate all of this.

It seems to me that if you confine yourself to the real danger points there is some hope of enforcing legislation that is passed by Congress. But this comprehensive approach may only add to existing confusion. For such reasons, I was somewhat astonished, as I said at the idea of your organization getting into the province of the Federal Power Commission and others in dealing with electric power and related areas.

I think you are liable to get too far afield. Have you any comments to make on that?

Mr. MEADE. When I say a comprehensive approach, Senator, I am not suggesting that we are going to be able to protect against all possible hazards and against a person's own negligence necessarily. I also am not suggesting that we so dilute the matter that the real problems are neglected.

But I think that the approach—I used the word “comprehensive” as opposed to piecemeal, patchwork, taking up one problem at a time. I would like to see the whole field of product safety reviewed and, if possible, consolidated, so we don't have fragmentation throughout the Government agencies, they perhaps not speaking to one another.

As far as electric power reliability goes, it is certainly a concern of consumers and presumably anything that is of concern to consumers is of concern to Mrs. Knauer's office, regardless of whether the problem falls specifically under the jurisdiction of some other agency or department of Government or is under consideration by a committee of Congress. It still would remain a matter of some concern to her.

And certainly we hope that something is being done to further electric power reliability. I see no reason why Mrs. Knauer should not be concerned about it.

Senator COTTON. I am not saying Mrs. Knauer should not be concerned. I do wonder, however, just how many activities one group can cover. I also am wondering just how much overlapping and duplication may result. We have enough of that in Government now. I merely used that as an illustration. But to get back to the issue at hand, do you agree that this bill is necessary and essential?

Mr. MEADE. I do, sir.

Senator COTTON. I agree with you.

Now forgetting for the moment your comprehensive approach, what shall we concern ourselves with next. If we are going to approach the problem piecemeal, in your opinion what is the next most vital thing that should be done or should be considered by this committee? What is needed next for the safety of children after this bill, in regard to hazardous substances?

Mr. MEADE. I think the suggestion that Senator Moss made, by implication in the questioning of earlier witnesses, might well be considered; the problem of some uniform designation that would indicate "danger" on certain products. Certainly on highly toxic products; their labeling is now covered by the 1966 amendments as set out in the Child Protection Act.

Senator COTTON. Like what? Give us an example.

Mr. MEADE. Well, the bill provides that a highly toxic product, which would be determined by the Secretary of Health, Education, and Welfare, would have on it the—

Senator COTTON. I understand that. But name me a product that you have in mind when you say "highly toxic." Could you give us an example?

Mr. MEADE. I would suppose any poisonous product, perhaps oil of wintergreen, something like that.

Senator COTTON. I beg your pardon?

Mr. MEADE. Perhaps oil of wintergreen. A friend of mine died from that once.

Senator COTTON. Are you a psychologist?

Mr. MEADE. No, sir.

Senator COTTON. I gather you had been advised by a psychologist. I note you say in your prepared statement children get into just about everything around the house. "This natural curiosity on their part, psychologists inform me, should be encouraged as a part of the educational process." Do you have definite advice from psychologists that such activity is beneficial?

Mr. MEADE. Yes, I spoke to two of them last weekend, Senator.

Senator COTTON. How about children being curious to indulge in their natural curiosity of getting into everything in someone else's house? What do psychologists say about that?

Mr. MEADE. I don't know from a psychology standpoint that they have considered it. I expect they do have this natural tendency and maybe it shouldn't be encouraged in somebody else's house, for other reasons.

Senator COTTON. Wouldn't you agree that neither this committee nor your organization should get into how to bring up children?

Mr. MEADE. Yes, I will agree with that.

Senator COTTON. Thank you.

Senator MOSS. Thank you, Senator. Thank you, Mr. Meade. We appreciate your testimony, and I'm glad that the Consumer's Office has an interest in this matter and you have come to testify before us.

Our testimony schedule now is a little bit questionable since we must recess at 12, and it is about 7 or 8 minutes to 12.

I think we will recess at this point and we will begin promptly at 2 o'clock, with the Glass Container Manufacturers Institute. They have a panel of witnesses that are going to appear, and I understand they are going to show some pictures or slides. I think this would be as good a time as any. They can be all set up and ready to go at 2 o'clock.

We will be in recess until 2 o'clock.

(Whereupon, at 11:53 a.m., the subcommittee was recessed, to reconvene at 2 p.m., this same day.)

AFTERNOON SESSION

Senator MOSS. The hearing will come to order.

Mr. Stewart, I understand, will introduce for us the representatives of the Glass Container Manufacturers Institute, who are appearing today. We would be pleased to have you do that, Mr. Stewart. You are a very distinguished gentleman I see from the listing I have here.

Mr. STEWART. Thank you very much.

May I present Mr. Richard L. Cheney. Mr. Cheney is the executive director and general manager of the Glass Container Manufacturers Institute. On his right is Gerald L. Roy. Mr. Roy is the manager of the plastic and metal packaging research section of the packaging products division of the Kerr Glass Manufacturing Corp. He is an expert on the subject of safety closures, and is here at the table primarily to assist in answering questions, should that become appropriate. On my left is John D. Northup, who is vice president of the closure division of Owens-Illinois.

Mr. Chairman, we have summarized the testimony of the witnesses and with your permission we would like to have the prepared statement appear in full in the printed hearings. Mr. Cheney will primarily make the presentation and he will be assisted by the presentation of slides by Mr. Northup. At the conclusion of the testimony, if time remains, it may be that I will make a remark or two.

Senator MOSS. Thank you very much. And welcome, gentlemen. We appreciate this method of procedure and it will be adopted, the statement will be in the record in full. We do have, as I suppose you have seen from the list of witnesses, many to hear from, and there is the pressure of time. We might get a bell from the Senate Floor and I might have to depart. So whatever can be done to expedite things, we would appreciate it very much.

Mr. CHENEY. We certainly will comply with that.

STATEMENT OF RICHARD L. CHENEY, EXECUTIVE DIRECTOR, GLASS CONTAINER MANUFACTURERS INSTITUTE; ACCOMPANIED BY JOHN D. NORTHUP, VICE PRESIDENT, CLOSURE DIVISION, OWENS-ILLINOIS, INC.; GERALD L. ROY, MANAGER, PLASTIC AND METAL PACKAGING RESEARCH, PACKAGING PRODUCTS DIVISION, KERR GLASS MANUFACTURING CORP.; AND EUGENE L. STEWART, LINCOLN & STEWART, WASHINGTON, D.C.

Mr. CHENEY. Mr. Chairman, gentlemen, we appreciate this opportunity to appear and express our support for the fundamental objective of S. 2162, the Poison Prevention Packaging Act of 1969.

Many of the drugs and household products covered by S. 2162 are packaged using containers and closures made and sold by our members. Hence we share the intense interest of your committee and indeed of the Congress in creating child-resistant packaging through the use of safety closures. In 1966 Mr. Richard E. Fisher, on behalf of our institute, testified before the House subcommittee which was then considering a child safety bill similar to 2162. Mr. Fisher in his statement demonstrated the complexity involved in establishing safety closure standards, by referring to a list of 18 criteria which such a closure should meet and he suggested that a joint Government-industry committee should evaluate the desirability and feasibility of legislation in regard to safety closures. Such a committee was indeed formed in late 1966 at the direction of FDA, as the FDA-Industry Committee on Safety Closures. Using the criteria outlined in 1966 by Mr. Fisher, that committee has been actively studying the feasibility of promulgating performance standards for the use of safety closures. Likewise, those criteria have served as a basis for extensive individual research and development by container and closure manufacturers, manufacturers of drugs and other household products, and independent inventors, all seeking improved closures to prevent accidental poisoning.

I would like to give you a condensed version of that list of criteria, to aid in your understanding of the problems and the progress which has been made in this field.

1. Safety with convenience. The closure must effectively defy the young child's efforts to open the package, but it must not appear to be a toy that would stimulate an enthusiastic youngster's interest. While defying the young child, the closure should not require unusual strength or dexterity, either to remove or reapply the closure.

Manipulation of multiple components to the safety feature should be avoided if possible. Closures should be of a design simple enough to permit positive uniform assembly for maximum safety function.

2. Consumer education. The closure construction concept must be such that all consumers can be educated to accept and know how to use and reuse the safety feature. The closure design must not be so involved or so inconvenient that consumers would be encouraged to discard the closure or the safety components at the time of the original removal.

3. Product protection. Closures must seal properly to retain the strength and purity of the product in the container. Particularly in the case of drugs, closures must effectively prevent contamination and loss of potency of the medication.

4. Consumer economic interest. The rising cost of all products is of great concern to this Congress and to our industry. The use of safety closures should not impose an undue cost penalty on consumers.

5. Material specifications. The closures must be made of a material that can be handled with commercially available converting equipment and that can retain its original dimensional stability after conversion and after repeated usage. The material also must be compatible with the product to be packaged.

6. Manufacturing and design feasibility. The closures must be of a design which lends itself to mold or tooling designs which will allow for release from those molds or toolings in the converting operation. The specifications and tolerances of closures and containers must be compatible to insure both product protection and safety function.

7. Feasibility of filling line procedures. The closures must be capable of being handled in commercially available automatic equipment, since disruption of manufacturers' filling lines can impose severe cost penalties. The closures must be adaptable to quality control testing procedures and to normal cleaning and maintenance in order to insure proper standards of cleanliness and sterility and avoid contamination. The design of the closures and containers should be such as to avoid any possibility of fracture of either component during assembly or capping operations. The foregoing list describes a challenge which the closure industry must meet in providing a safety closure for any given product. There has been good progress made in meeting this challenge and there exists today a variety of safety closures which for a particular product may in varying degrees meet the criteria I have just described. However, the closure manufacturers cannot by themselves make a final determination as to whether a particular closure meets all of the criteria. Obviously the manufacturer packaging the end product must determine whether a safety closure can be economically run through his filling lines. Ultimately only the consumer can determine whether he will pay the price and use and reuse the safety closure.

At this point I would like to ask Mr. John Northup, who has been introduced to you, to briefly describe for you the state of the art with respect to safety closures.

Senator Moss. Thank you. That is very fine. We are glad to have Mr. Northup.

Mr. NORTHUP. Thank you for this opportunity to appear and acquaint you with the progress which has been made in the field of safety closures, and with the present state of the art.

I hope to demonstrate that we have made considerable progress since 1966. I caution, however, that a number of the developments which I will show you are still in an experimental stage and we could not today provide an adequate safety closure for every product.

This is particularly true for liquid or highly hygroscopic products.

My printed statement which has been filed should not be misinterpreted as meaning otherwise.

Mr. Cheney has referred to Mr. Fisher's testimony before a subcommittee of the House of Representatives in 1966. At that time Mr. Fisher displayed 19 safety closures and containers. That group of closures can be classified into five distinct categories.

(Slide.)

Combination, mechanical turn and release, tablet dispenser, plastic snap cap, and push and twist.

Now, it is possible that someone has very recently invented a new type of closure with which I am not familiar. But in my experience these five categories describe the recognized principles upon which safety closures operate.

I have here today slides and samples demonstrating each one of these categories. Please bear in mind that there are a large number of closures which have been designed in each one of these categories. But in the interest of time, I am showing you only a representative sample of each category.

(Slide.)

Package 1 represents the group of combination closures having interrelated parts which, like a combination lock, must be brought together in one set position before the closure can be removed or re-applied. For removal, this closure must be turned counterclockwise twice, lining capital A up with the arrow on the shoulder of the container. The closure is then turned clockwise to capital B, then back to capital C. The closure can then be lifted from the finish.

To replace the closure, simply align capital C on the closure with the arrow on the shoulder and give the closure at least one complete turn, clockwise.

(Slide.)

This inside view of the closure shows the two locking wires with lugs which must remain aligned during closure application and closure removal for proper functioning.

(Slide.)

Package 2 represents closures in the mechanical turn and release category. This closure has two components; the first is a screw closure with ratchet-type lugs on the under edge of the skirt.

The second component is a separate ring with matching ratchet lugs. This ring is permanently positioned under a bead on the glass. As the closure is screwed on, the ratchets on the closure become locked into the ratchet lugs on the locking ring.

(Slide.)

When the tabs on the locking ring are pressed down by one hand, the ratchets are disengaged and the closure can be removed in the normal counterclockwise turning motion, with the other hand.

(Slide.)

Package 3 is typical of dispensing-type closures. The roller here rolls out only one tablet at a time. This type of closure is not child-proof, but is based on the theory that the child will lose interest before obtaining enough pills to get a lethal dose.

(Slide.)

Package 4 illustrates the plastic snap cap. This particular one incorporates a special glass bead and corresponding removal tab on the snap cap. The cap must be twisted on the bottle to orient the tab with the opening in the glass bead in order to use the thumb to push the cap off the container. The reduced height and the rounded design of this closure minimizes the possibility of children biting the cap off the container. More than 20 million of these closures are used annually to package baby aspirin today. (Slide.)

Package 5 covers press and release closures requiring top pressure, side pressure, or a combination of both, for release. They are based on the principle that a child under 5 years of age lacks the coordination to press and to twist at the same time.

The example shown here is currently being marketed under the trade name, "Palm-N-Turn." It has a sealing flange which creates a spring action. (Slide.)

For removal, the closure is placed in the palm of one hand while downward pressure is applied to the container by the other hand, along with counterclockwise turning. The closure is applied with a clockwise turn. (Slide.)

Now, this slide lists again the five categories of safety closures which I have just shown you. In the years since 1966, manufacturers and inventors have continued to introduce new safety closures and to evaluate existing designs. Commercial use of available safety closures has expanded, particularly in the prescription and the baby aspirin fields.

As I look at the current picture, I do not think that the first three of these categories have much chance of commercial success. However, in my opinion, practical, economical, safety closures of the types covered in the last two categories, that is, plastic snap caps and press and turn, can possibly be manufactured in volume to a consistent quality level. I presently know of no commercial safety closure possibilities in any of the other categories.

As this is a very attractive field for inventors, there is always the possibility that there is some very recent development which has not yet come to my attention, or that some innovative approach may yet be developed in one of these areas.

I will now show you slides on closures available in the market today, and what I think should become available in the next year, in the snap cap and press and turn categories. (Slide.)

In this connection it should be understood that conventional closures for a narrow-neck container fall in a price range at the closure manufacturer's level of one-half cent to 2 cents per package. The addition of the safety feature will generally increase the price by one-half cent, to 1 cent per package at the closure manufacturer's level.

The first slide I will show you are closures for plastic prescription vials. In the last 3 years most producers of prescription vials have added several sizes of safety closures, and containers, to their line. (Slide.)

Now, Mr. Chairman, I have samples of these if you would like to have them, that I can give to you.

Senator Moss. Yes, we may want to look at the samples. But go right ahead, I can see this fairly well.

Mr. NORTHUP. Package 6 is the Screw Loc closure. (Slide.)

This opens on the push and turn principle, as shown here. (Slide.)

This shows the bayonet lugs on the top of the vial. It also shows the lugs on the inside of the cap and a polyethylene sealing disc which can be varied in thickness—in order to make the pressure required for opening greater or lesser. (Slide.)

This is another picture of package 5, the Palm-N-Turn closure (Slide.)

As mentioned previously, this has the advantage of being a one-piece closure, the spring pressure being created by the sealing flange. It also uses the bayonet lock principle. (Slide.)

Package 7, the Pop-Loc prescription package. (Slide.)

To operate, the tab is pulled up and grasped between the thumb and forefinger and pulled off the container. (Slide.)

This shows the closure removed from the container. As you can see, it operates on the snap cap principle. (Slide.)

Package 8 is the press top prescription closure. (Slide.)

To open this closure, the top is pressed down in the center with a substantial amount of force. This releases the periphery of the closure from the locking flange. (Slide.)

This shows the constriction of the inside of the closure as well as the locking flange on the container.

Now, all of these closures were shown on injection molding plastic vials. Since these prescription vials are intended for use on pills and capsules, these closures in general are satisfactory for only dry products.

Injection molded plastic vials can be manufactured to closer tolerances than can glass containers or blown plastic containers. Consequently, the design and production of safety closures for glass bottles presents a different problem from the design and production of such closures for plastic vials.

I shall now show you the closure manufacturers' approach to the problem of safety closures for glass bottles. Several of these approaches are designed for bottles for liquids, but none has yet achieved significant commercial acceptance. (Slide.)

Package 9 is the Stay-Tight closure on a glass bottle. It will also work on containers of other rigid materials, and is designed to contain liquids as well as dry materials. This works on the push and twist principle. (Slide.)

This shows the cap and the container separately, so that you can see the inner cap which is rotated on and off the glass neck by meeting ratchets. It is claimed that because of this construction, the Stay-Tight closure can be operated on standard capping equipment. (Slide.)

Package 10 is a safety over cap. (Slide.)

This package can be available in quantities late in 1970. This illustrates the construction. It works on the principle that an adult can use more force on the side of a cap than can a child. It is designed for both liquids and dry products, and to be used on containers made of any rigid material. (Slide.)

Package 11 is another plastic safety closure. This one also works on the push and turn principle. (Slide.)

As shown here, this consists of an inner and outer cap, with means for temporarily locking them together on the application of top pressure. This closure is suitable for liquids and drys on all rigid containers. (Slide.)

Package 12 is a metal safety closure. This can be available in quantities by the fall of 1970. (Slide.)

This package also works on the push and twist principle. (Slide.)

It consists of inner and outer metal caps. The lock between the two caps is created by the engagement of the knurls. This package is designed for liquids and drys on rigid containers of any material. (Slide.)

Package 13 is the "U Press It" closure. It is opened by pressure in the center, as shown here. The pressure causes the lugs on the periphery to open up. It is designed for both liquids and dries on rigid containers of any material. (Slide.)

This is another picture of package 4, the safety snap cap. It costs no more than a regular snap cap. However, it is suitable only for dry products. It will also work on a container made of any rigid material. (Slide.)

Package 14 is the Screw-Lock closure on glass. As you can see, it works on the push and twist principle. (Slide.)

This picture is not very good, but this shows the special configuration required on the glass. This is a little tricky. This closure is only satisfactory for dries.

Mr. Chairman, thank you very much for the opportunity of presenting this information to you.

Senator Moss. That was very interesting and instructive. Thank you very much.

Mr. CHENEY. Mr. Chairman, shall I proceed?

Senator Moss. Yes, you may proceed.

Mr. CHENEY. Thank you.

We trust the foregoing background data will aid you in evaluating the ramifications of S. 2162. We understand the bill is necessarily vague as to the type of standard to be promulgated and that at this point in time we agree the bill should not be more specific in this respect.

The form or nature of such standards is the key question under investigation by the FDA-Industry committee on safety closures, and until that body is able to complete its work, it would be premature to try to define the term "standards."

The heart of the subject matter of this bill is concerned with how to keep children from opening containers of hazardous substances and the obvious answer is to provide a closure that a child cannot open, whether the container is a glass or plastic bottle, a metal can, or a plastic vial.

We believe, therefore, that the bill should be amended to place the emphasis on creating standards for the use of child-resistant closures, by deleting the first seven words in line 21, page 3, and inserting in lieu thereof the words "for the use of safety or child-resistant closures, in closing packages containing any such substances."

While we fully support the objective of this legislation, we are troubled by the scope of the bill insofar as it provides powers to promulgate for the entire package in which a product is contained.

Essentially we believe that this is a matter of closures, not one involving the entire package, and to the extent that accidental poisonings are caused by children opening containers of hazardous substances, we believe that use of safety closures provide a degree of safety over and above that afforded by cautionary labeling and the use of commonsense by consumers in handling and storage of hazardous substances.

The problem considered in the 1966 child safety bill and again in legislation introduced last year, the question to which the FDA-Industry committee has addressed itself, and the problem which poison

prevention authorities have been diligently nursing, is that of providing safety closures for containers of hazardous substances.

The broader matter of setting standards for the containers themselves, for packaging hazardous substances, has not been at issue and there is no indication or evidence that a problem even exists with respect to the containers, apart from the closures.

Perhaps the intent in the grant of broader authority over containers as well as closures is to cover the possibility that some kinds of containers cannot be sealed with safety closures, or an equivalent method of sealing. If so, then such intent should be clearly spelled out and an exemption from the broad authority should be provided for those containers such as glass containers capable of being sealed with safety closures.

In terms of administrative feasibility, it seems clear that the Secretary will have a formidable task in promulgating standards for the use of closures, even though the FDA-industry committee on safety closures has already done much of the preparatory work.

Setting standards for containers also would involve a whole new array of problems not unlike those involved with closures, but the scope of which cannot be anticipated until a problem with the containers, apart from the closures, has been defined.

We suggest that the work on standards for the use of safety closures not be impeded by premature consideration of standards for containers, where no problem exists.

It would appear that there is an unintended oversight in the lack of representation of closure manufacturers on the technical advisory committee contemplated by the bill. I believe that our testimony today reasonably indicates why it is appropriate that there be such representation and the potential contribution which the closure manufacturers can make to such a technical advisory committee.

We therefore recommend that, on page 4, line 3, the words "16" be substituted for the word "15" and on line 6, after the word "products" there be inserted "manufacturers of safety closures and" * * *.

In support of this amendment, we point out that no one would desire the establishment of a standard for the use of safety closures only to find that such closures meeting that standard could not effect a proper seal or be produced economically on existing machinery.

The manufacturers of closures and containers obviously are the most knowledgeable as to what can be achieved with available materials and processes and how best to minimize the costs involved in the manufacturing process.

All of these factors must be taken into consideration if standards are to be established, and those best qualified to discuss them should be represented on the committee.

I presume that the omission of this group of experts was simply an oversight which can be easily rectified.

We would also like to propose one final clarifying amendment. On page 2, line 7, insert between the syllable "stance" and the word "for" the words "which is a hazardous substance within the meaning of subparagraph 1 of this paragraph."

The purpose of this proposed amendment is simply to make clear that S. 2162 is to apply to hazardous substances, not to any and all products which are subject to the Food, Drug, and Cosmetic Act.

In conclusion, I again thank the subcommittee for affording us this opportunity to present what we hope is valuable background data, as to the progress which has been made in the field of safety closures, and against which to measure the necessity or desirability of this legislation.

Should you decide to proceed with this bill, we hope that you will consider favorably our proposed amendment.

Mr. Northup, Mr. Roy, and I will be happy to attempt to answer any questions which you may have. But before doing so, if I may, I would like to add one note, that we of course hope our statement has indicated that we have given serious consideration to the bill. And in further reviewing it, since the filing of our statement, our legislative counsel, Mr. Stewart, has recommended one additional change which we have not as yet had an opportunity to fully evaluate. Therefore, as a trade association, we are not able to take a position on it at this time. However, our initial reaction is that it appears to have significant merit to warrant having him briefly describe it to you if he may do so.

Senator Moss. All right. Mr. Stewart.

Mr. STEWART. Mr. Chairman, this suggestion is intended to expedite the establishment of feasible standards under your bill. You will recall that you called in your bill essentially for two determinations to be made. First, the Secretary of Health, Education, and Welfare must determine that there is hazard present in the availability to children of the contents of a package such that the package should have, should be child-resistant. That is, have a safety closure.

That first determination is clearly a matter for the expertise of the kind of personnel that are in the Department of Health, Education, and Welfare. It involves health and public safety. But when that determination is made, the job of establishing a standard for a manufactured article begins.

The second determination is that a certain standard can be developed and expressed which will then become a mandatory requirement for closures for packages for the defined substance.

That second determination is not so much one that lies within the expertise of public health officials as it is one within the domain of another agency that your committee is very familiar with, the Bureau of Standards and the Department of Commerce.

Now, taking my cue from legislation which this committee developed in the public interest, the Flammable Fabric Act amendments, Public Law 90-189, I would simply like to make the suggestion that you take a look at section 14 of that law which provided in that case that the Secretary of Health, Education, and Welfare and the Secretary of Commerce cooperate in determining when there was a risk to the public health and safety, and to develop standards for a manufactured article in that case fabrics, which would minimize the risk to public health.

In this case the Secretary of Health, Education, and Welfare should indeed determine when child-resistant packaging is called for in the public interest to protect children.

But the Secretary of Commerce, assisted by the Bureau of Standards, should then develop the statement of a performance standard or other standard which would enable manufacturers then, on a

reproducible basis, to manufacture safety closures meeting such requirements.

Anyone who has visited the Bureau of Standards at Gaithersburg must be impressed with the assembly of engineering, manufacturing and technical talent in that tremendous facility, and it is a credit to this committee that it has authorized that activity and it has helped secure the necessary funds.

It exists; it is a technical capacity in being that can more quickly be brought to bear on this problem, once the medical judgment has been made that there is a need to be filled.

So, I simply would recommend for your consideration the possibility of amending the bill along the lines of section 14 of Public Law 90-189, and the continuation of an advisory committee along the lines of section 17 of that public law, where the final responsibility for the articulation of a standard would be vested in the Secretary of Commerce, following a determination by the Secretary of Health, Education, and Welfare that a need exists for child-resistant packaging for a certain substance.

Thank you, Mr. Chairman.

(The entire statements follow:)

STATEMENT OF RICHARD L. CHENEY, EXECUTIVE DIRECTOR, GLASS CONTAINER MANUFACTURERS INSTITUTE, INC.

Mr. Chairman: I am Richard L. Cheney, Executive Director of the Glass Container Manufacturers Institute, a trade association whose members, both large and small, collectively manufacture over ninety percent of the glass containers and well over half of the closures (other than crowns) produced in the United States. Our members have 125 plants in twenty-seven states employing approximately 65,000 persons.

We appreciate this opportunity to appear and express our support for the fundamental objective of S. 2162, the Poison Prevention Packaging Act of 1969. Many of the drugs and household products covered by S. 2162 are packaged using containers and closures made and sold by our members; hence, we share the intense interest of your Committee, and indeed, of the Congress, in creating child-resistant packaging through the use of safety closures. The substantial efforts of our industry to provide adequate safety closures for use on household packages containing hazardous substances evidence our desire to contribute to the prevention of accidental poisonings.

In 1966, Mr. Richard E. Fisher, on behalf of our Institute, testified before the Subcommittee on Public Health and Welfare of the Committee on Interstate and Foreign Commerce of the House of Representatives, which was then considering a Child Safety bill similar to S. 2162 in providing for the use of safety closures with drugs.¹ In his statement, Mr. Fisher demonstrated the complexity involved in establishing safety-closure standards by referring to a list of eighteen criteria which such a closure should meet, and he suggested that legislative action be deferred until a joint Government-Industry Committee could evaluate the desirability and feasibility of legislation in regard to safety closures.

Such a committee was indeed formed in late 1966 at the direction of FDA as the FDA-Industry Committee on Safety Closures. Using the criteria outlined in 1966 by Mr. Fisher, that Committee has been actively studying the feasibility of promulgating performance standards for the use of safety closures. Likewise, those criteria have served as a basis for extensive individual research and development by container and closure manufacturers, manufacturers of drugs and other household products and independent inventors, all seeking improved closures to prevent accidental poisonings.

That list of eighteen criteria still provides the benchmarks by which to measure results in the field of safety closures, and I would like to give you a condensed

¹ 89th Congress, 2d Session, H.R. 13886.

version of that list to aid in your understanding of the problems and the progress which has been made in this field:

1. Safety with convenience: The closure must effectively defy the young child's efforts to open the package, but it must not appear to be a toy that would stimulate an enthusiastic youngster's interest. While defying the young child, the closure should not require unusual strength or dexterity, either to remove or reapply the closure. Manipulation of multiple components to the safety feature should be avoided if at all possible. Closures should be of a design simple enough to permit positive, uniform assembly for maximum safety function.

2. Consumer education: The closure construction concept must be such that all consumers can be educated to accept and know how to use and reuse the safety feature. The closure design must not be so involved or so inconvenient that consumers would be encouraged to discard the closure or the safety component at the time of the original removal.

3. Product protection: Closures must seal properly to retain the strength and purity of the product in the container. Particularly in the case of drugs, closures must effectively prevent contamination and loss of potency of the medication. The requirements of the various types of products necessitate differing closure qualities. For example, the sealing requirements for a dry product, such as a tablet, differ from those for a liquid type product. The closures should be designed to permit the utilization of packing such as cotton inserts where necessary.

4. Consumer economic interest: The rising costs of all products to the marginal income group is of great concern to this Congress and to our industry. The use of safety closures should not impose an undue cost penalty upon consumers.

5. Material specifications: The closures must be made of a material that can be handled with commercially available converting equipment and that can retain its original dimensional stability after conversion and after repeated usage. The material also must be compatible with the product to be packaged.

6. Manufacturing and design feasibility: The closures must be of a design which lends itself to mold or tooling designs which will allow for release from those molds or toolings in the converting operation. The specifications and tolerances of closures and containers must be compatible to insure both product protection and safety function.

7. Feasibility of filling-line procedures: The closures must be capable of being handled in commercially available automatic equipment since disruption of manufacturer's filling lines can impose severe cost penalties. The closures must be adaptable to quality control testing procedures and to normal cleaning and maintenance in order to insure proper standards of cleanliness and sterility and avoid contamination. The design of the closures and containers should be such as to avoid any possibility of fracture of either component during assembly or capping operations.

The foregoing list describes the challenge which the closure industry must meet in providing a safety closure for any given product. I am pleased to say that I think that there has been good progress made in meeting this challenge, and the continuing flow of new types of safety closures is highly encouraging. Through the efforts of the closure industry, the drug manufacturers and many small inventors, there exists today a variety of safety closures which for a particular product may in varying degrees meet the criteria which I have just described. However, the closure manufacturers cannot by themselves make a final determination as to whether a particular closure meets all of the criteria. Obviously, the manufacturer packaging the end product must determine whether a safety closure can be economically run through his filling lines. Ultimately only the consumer can determine whether he will pay the price and use, and reuse, the safety closure.

At this point, I would like to ask Mr. John Northup, who has served for many years as Chairman of our Institute's Committee on Closures and is Vice President in charge of closure operations for Owens-Illinois, a leading producer of containers and closures, including safety closures, to briefly describe for you the state of the art with respect to safety closures.

[The statement of Mr. Northup is appended hereto.]

We trust that the foregoing background data will aid you in evaluating the ramifications of S. 2162. We understand that the bill is necessarily vague as to the type of standard to be promulgated, and at this point in time we agree that the bill should not be more specific in this respect. The form or nature of such standards is the key question under investigation by the FDA-Industry Committee on Safety Closures, and until that body is able to complete its work it would be premature to try to define the term "standards." We are certain

however, that this Subcommittee would desire that any standards established pursuant to this bill be designed to foster invention, promote competition and minimize cost to the consumer. We caution that it is conceivable that a specification-type of standard could be established which would permit use of only one particular closure made by one particular manufacturer, thereby discouraging invention, promoting monopoly and increasing cost to the consumer. Thus, this Subcommittee may wish to give some guidance to the Secretary of Health, Education and Welfare in this regard.

The heart of the subject matter of this bill is concerned with how to keep children from opening containers of hazardous substances, and the obvious answer is to provide a closure that a child cannot open, whether the container is a glass bottle, a metal can, or a plastic vial. We believe, therefore, that the bill should be amended to place the emphasis upon creating standards for the use of child-resistant closures by:

Deleting the first seven words in line 21 page 3, and inserting in lieu thereof the words "for the use of safety or child-resistant closures in closing packages containing any such substance".

While we fully support the objective of this legislation, we are troubled by the scope of the bill insofar as it provides powers to promulgate standards for the entire package in which a product is contained. Essentially, we believe that this is a matter of closures, not one involving the entire package, and, to the extent that accidental poisonings are caused by children opening containers of hazardous substances, we believe that use of safety closures can provide a degree of safety over and above that afforded by cautionary labeling and the use of common sense by consumers in handling and storage of hazardous substances. Therefore, we do not think that the scope of the bill need go beyond the scope of the problem and the obvious solution.

The problem considered in the 1966 Child Safety bill¹ and again in legislation introduced last year,² the question to which the FDA—Industry Committee has addressed itself, and the problem which poison prevention authorities have been diligently pursuing is that of providing safety closures for containers of hazardous substances. The broader matter of setting standards for the containers themselves for packaging hazardous substances has not been at issue and there is no indication or evidence that a problem even exists with respect to the containers apart from the closures. Perhaps the intent in the grant of broad authority over containers as well as closures is to cover the possibility that some kinds of containers cannot be sealed with safety closures or an equivalent method of sealing. If so, then such intent should be clearly spelled out and an exemption from the broad authority should be provided for those containers, such as glass containers, capable of being sealed with safety closures. If there is a special problem as to some types of containers, it should be documented and thoroughly studied by both Government and industry just as we have been studying the question of safety closures, and bringing the research capability of industry to bear on the defined problem before powers are granted to any agency to regulate the containers. In the absence of a clearly demonstrated need, our system of democracy and free enterprise contemplates that government regulation be kept to the minimum consistent with protection of the public and the maintenance of free and open competition.

In the terms of administrative feasibility it seems clear that the Secretary will have a formidable task in promulgating standards for the use of closures even though the FDA—Industry Committee on Safety Closures has already done much of the preparatory work. Setting standards for containers also would involve a whole new array of problems not unlike those involved with closures but the scope of which cannot be anticipated until a problem with the containers, apart from the closures, has been defined. We suggest that the work on standards for the use of safety closures not be impeded by premature consideration of standards for containers where no problems exists. If standards in this regard are to be promulgated, we believe that the matter must be given the most careful legislative scrutiny, not left to administrative discretion which changes as administrators come and go. Certainly such administrative authority is totally unwarranted in terms of the problem facing this Subcommittee.

While the closure industry has made good progress in reducing the cost of safety closures, they still do cost more than standard closures. Changes in the container as well as the closure can only lead to yet further cost increases for

¹ 89th Congress, 2d Session, H.R. 13886.

² 90th Congress, 2d Session, S. 3547 and H.R. 17559.

consumers. And without knowing what the supposed problem is as to containers, no one could possibly estimate the extent of the increased costs, but they could be very substantial if manufacturers were forced to change their packaging lines.

Finally, as presently written the bill would allow the Secretary to prescribe that certain substances be packaged only in glass, or only in plastic, or only in paper; or, conversely, that certain substances never be packaged in one or more of these packaging materials. Strong competition exists among these various types of packaging materials, the effect of which has led to technological advances and reduction in packaging costs to consumers, and interference with this competitive process could cause an additional penalty to consumers resulting from reduced competition.

It would appear that there is an unintended oversight in the lack of representation of closure manufacturers on the Technical Advisory Committee contemplated by the bill. I believe that our testimony today reasonably indicates why it is appropriate that there be such representation, and the potential contribution which the closure manufacturers can make to such a Technical Advisory Committee. We therefore recommend that:

On page 4, line three, the word "sixteen" be substituted for the word "fifteen"; and on line 6 after the word "products", there be inserted the words "manufacturers of safety closures and containers and".

In support of this amendment, we point out that no one on this Subcommittee would desire the establishment of a standard for the use of safety closures only to find that such closures meeting that standard could not effect a proper seal or be produced economically on existing machinery. The manufacturers of closures and containers obviously are the most knowledgeable as to what can be achieved with available materials and processes and how to best minimize the costs involved in the manufacturing process. All of these factors must be taken into consideration if standards are to be established, and those best qualified to discuss them should certainly be represented on the Technical Advisory Committee. I presume that the omission of this group of experts was simply an oversight which can be easily rectified. I see no reason for intentionally excluding this group of experts.

We would also like to propose one final clarifying amendment:

"On page 2, line 7, insert between the syllable "stance" and the word "for" the words "which is a hazardous substance within the meaning of subparagraph 1 of this paragraph."

The purpose of this proposed amendment is simply to make clear that S. 2162 is to apply to "hazardous substances", not to any and all products which are subject to the Food, Drug and Cosmetic Act.

In conclusion, I again thank the Subcommittee for affording us this opportunity to present what we hope is valuable background data as to the progress which has been made in the field of safety closures and against which to measure the necessity or desirability of this legislation. Should you decide to proceed with this bill, we hope that you will consider favorably our proposed amendments. Mr. Northup, Mr. Roy or I will be happy to attempt to answer any questions which you may have.

STATEMENT OF JOHN D. NORTHUP, CHAIRMAN OF THE SUBCOMMITTEE ON SAFETY CLOSURES OF THE COMMITTEE ON CLOSURES, GLASS CONTAINER MANUFACTURERS INSTITUTE, INC.

Thank you for this opportunity to appear and acquaint you with the progress which has been made in the field of safety closures and the present state of the art.

Mr. Cheney has referred to Mr. Fisher's testimony before a subcommittee of the House of Representatives in 1966. At that time, Mr. Fisher displayed nineteen safety closures and containers. That group of closures can be classified into five distinct categories: (1) Combination; (2) Mechanical turn and release; (3) Tablet dispenser; (4) Plastic snap cap; and (5) Press and turn. It is possible that someone has very recently invented a new type closure with which I am not familiar, but in my experience these five categories describe the recognized principles upon which safety closures operate.

(Slide 1.)

I have here, today, slides and samples demonstrating each one of these categories. Please bear in mind that there are a large number of closures which

have been designed in each one of these categories, but in the interest of time, I am showing you only a representative sample of each category.

(Slide 2.)

(Package 1¹) Package One represents the group of combination closures having inter-related parts which, like a combination lock, must be brought together in *one set position* before the closure can be removed or re-applied. For removal, the closure must be turned counter-clockwise twice, lining "A" up with the arrow on the shoulder of the container. The closure is then turned clockwise to "B", then back to "C". The closure can then be lifted from the finish.

To replace the closure, simply align "C" on the closure with the arrow on the shoulder and give the closure at least one complete turn clockwise.

(Slide 3.)

(Package 1) The inside view of the closure shows the two locking wires with lugs which must remain aligned during closure application and removal for proper functioning.

(Slide 4.)

(Package 2) Package Two represents closures in the mechanical turn and release category. The closure has two components. The first is a screw closure with ratchet type lugs on the under edge of the skirt. The second component is a separate ring with matching ratchet lugs. This ring is permanently positioned under a bead on the glass. As the closure is screwed on, the ratchets on the closure become locked into the ratchet lugs on the locking ring.

(Slide 5.)

(Package 2) When the tabs on the locking ring are pressed down by one hand, the ratchets are disengaged and the closure can be removed in the normal counter-clockwise turning motion with the other hand.

(Slide 6.)

(Package 3) Package Three is typical of dispensing-type closures. The roller, here, as you can see, rolls out one tablet at a time. This type of closure is not childproof, but is based on the theory that the child will lose interest before obtaining enough pills to get a lethal dose.

(Slide 7.)

(Package 4) Package Four illustrates the plastic snap cap. This particular one incorporates a special glass bead and corresponding removal tab on the snap cap. The cap must be twisted on the bottle to orient the tab with the opening in the glass bead in order to use the thumb to push the cap off the container. The reduced height and rounded design of this closure minimize the possibility of children biting the cap off the container. More than twenty million of these closures are used annually to package baby aspirin.

(Slide 8.)

(Package 5) Package Five covers press-and-release closures requiring top pressure, side pressure, or a combination of both for release. They are based on the principle that a child under five years of age lacks the coordination to press and twist at the same time. The example shown here is currently being marketed under the trade name "Palm-N-Turn." It has a sealing flange which creates a spring action.

(Slide 9.)

(Package 5) For removal, the closure is placed in the palm of one hand while downward pressure is applied on the container by the other hand, along with counter-clockwise turning. The closure is applied with a clockwise turn.

(Slide 10.)

This slide lists the five categories of safety closures which I have just shown you. In the years since 1966, manufacturers and inventors have continued to introduce new safety closures and evaluate existing designs. Commercial use of available safety closures has expanded, particularly in the prescription and baby aspirin fields. As I look at the current picture, I do not think that the first three of these categories have much chance of commercial success. However, in my opinion, practical, economical safety closures of the types covered in the last two categories, that is, plastic snap caps and press-and-turn, can possibly be manufactured in volume to a consistent quality level. I presently know of no commercial safety closure possibility in any of the other categories, although, as this is a very attractive field for inventors, there is always the possibility that there is some very recent development which has not yet come to my attention or that an innovative approach may yet be developed in one of these areas.

I will now show you slides and give you relative cost data on closures available

¹ See photograph attached to this appendix for illustration of all packages mentioned herein.

in the market today, and what I think should become available in the next year, in the snap cap and press-and-turn categories. All costs indicated are my best estimates of the increased price over conventional closures at the closure manufacturer's level. There could well be other increased costs arising from necessary changes in filling line procedures.

First are closures for plastic prescription vials. In the last three years, most producers of prescription vials have added several sizes of safety closures and containers to their lines. However, all costs indicated are for the 7 dram vial because this is the most popular size.

(Slide 11.)

(Package 6) Package Six is the Screw Loc closure distributed by Owens-Illinois. It has an additional cost of 5 mills per package over the conventional snap cap.

(Slide 12.)

(Package 6) This operates on the push-and-twist principle as shown here.

(Slide 13.)

(Package 6) This shows the bayonet lugs on the top of the vial. It also shows the lugs on the inside of the cap and a polyethylene sealing disc which can be varied in thickness in order to make the pressure required for opening greater or lesser.

(Slide 14.)

(Package 5) This is another picture of Package Five, the Palm-N-Turn closure, distributed on prescription ware vials by Kerr Glass Manufacturing Corporation. It also has an additional cost of 5 mills per package.

(Slide 15.)

(Package 5) As mentioned previously, this has the advantage of being a one-piece closure, the spring pressure being created by the sealing flange. It also uses the bayonet lock principle.

(Slide 16.) (Package 7) Package Seven is the Pop Loc prescription package distributed by Lermer Plastics. The additional cost of this package is also 5 mills.

(Slide 17.) (Package 7) To operate, the tab is pulled up and grasped between the thumb and forefinger and pulled off the container.

(Slide 18.) (Package 7) This shows the closure removed from the container. As you can see, it operates on the snap cap principle.

(Slide 19.) (Package 8) Package Eight is the Press-Top prescription closure distributed by Basic Products Company. The additional cost is 2 mills per package.

(Slide 20.) (Package 8) To open this closure, the top is pressed down in the center with a substantial amount of force. This releases the periphery of the closure from the locking flange.

(Slide 21.) (Package 8) This shows the construction of the inside of the closure, as well as the locking flange on the container.

(Slide 22.) (Blank slide) All of these closures were shown on injection molded plastic vials. Since these prescription vials are intended for use on pills and capsules, these closures, in general, are satisfactory only for dry products.

Injection molded plastics can be manufactured to closer tolerances than can glass containers or blown plastic containers.

Consequently, the design and production of safety closures for glass bottles presents a different problem from the design and production of such closures for plastic vials. I shall now show you the closure manufacturers' solutions to the problem of safety closures for glass bottles.

(Slide 23.) (Package 9) Package Nine is the Kerr Stay-Tight closure on a glass bottle. It will also work on containers of other materials and will contain liquids as well as drys. The additional cost for this closure is 6 mills in the 26 mm. size which is shown here.

(Slide 24.) (Package 9) This works on the push-and-twist principle.

(Slide 25.) (Package 9) This shows the cap and the container separately so that you can see the inner cap which is rotated on and off the glass finish by mating ratchets. It is claimed that, because of this construction, the Kerr Stay-Tight closure can be operated on standard capping equipment.

(Slide 26.) (Package 10) Package Ten is Brockway Glass Company's safety overcap. The additional cost for this closure is 5 mills per package in the 24 mm. size. This can be available in quantities late in 1970.

(Slide 27.) (Package 10) This illustrates the construction. This works on the principle that an adult can use more force on the side of a cap than can a child. It will work on both liquids and dry products and on containers made of any rigid material.

(Slide 28.)

(Package 11) Package Eleven is Formold Plastics safety closure. The additional cost of this closure in 22 mm. size shown here is 9 mills per package.

(Slide 29.)

(Package 11) This package works on the push-and-turn principle.

(Slide 30.)

(Package 11) As shown here, this consists of an inner and outer cap with means for temporarily locking them together on the application of top pressure. This closure is suitable for liquids and dries on all rigid containers.

(Slide 31.)

(Package 12) Package Twelve is the Owens-Illinois metal safety closure. In the 28 mm. size shown here, the additional cost is 5 mills. This can be available in quantities by the fall of 1970.

(Slide 32.)

(Package 12) This package works on the push-and-twist principle.

(Slide 33.)

(Package 12) This consists of inner and outer metal caps. The lock between the two caps is created by the engagement of the knurls. This package works on liquids and dries on rigid containers of any material.

(Slide 34.)

(Package 13) Package Thirteen is American Flange's U-Press It closure. It is opened by pressure in the center as shown here. The pressure causes the flanges on the periphery to open up. This closure has an additional cost of 13 mills. It is satisfactory for both liquids and dries on rigid containers of any material.

(Slide 35.)

(Package 4) This is another picture of Package Four, the Owens-Illinois Safety Snap Cap. It costs no more than a regular snap cap. However, it is suitable only for dry products. It will also work on a container made of any rigid material.

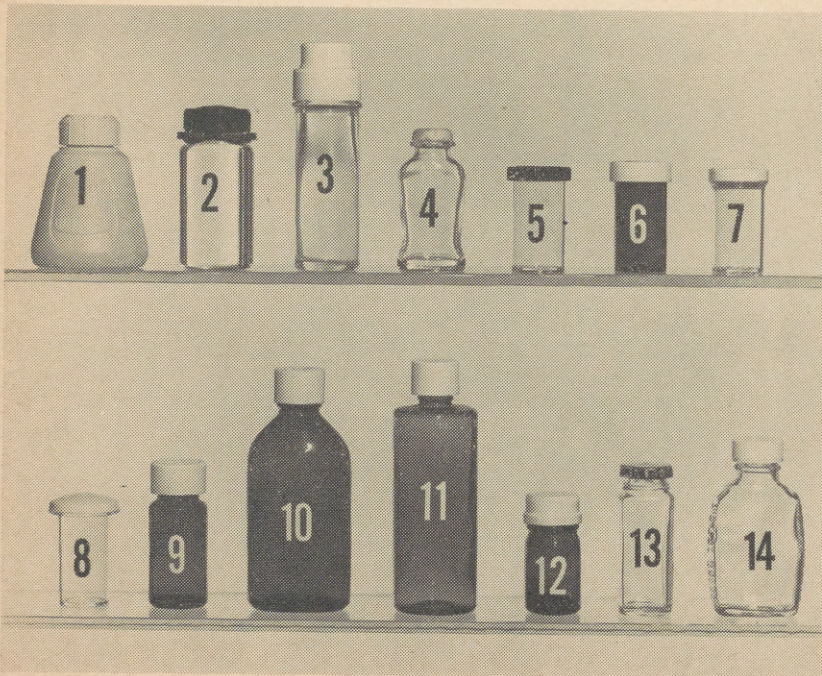
(Slide 36.)

(Package 14) Package Fourteen is the Owens-Illinois Screw Loc closure. The additional cost on the 20 mm. and 24 mm. sizes is 3 mills. As you can see, it works on the push-and-twist principle.

(Slide 37.)

(Package 14) This shows the special configuration required on the glass. This closure is only satisfactory for dries.

Thank you for the opportunity to present this information to you.



Senator Moss. Thank you, Mr. Stewart. What you are pointing out is that we ought to bring to bear on this an existing Government agency, with expertise in the area of standards, and that the Secretary of HEW, perhaps, if he didn't refer it through there, would have to build up a somewhat duplicative staff to accomplish this.

Mr. STEWART. Correct, Mr. Chairman. As the witness from that agency said in responding to your question, they would require additional funds to staff their responsibilities under the bill and I thought it singular that in describing the personnel that would thus be needed, he referred to one person, a packaging engineer, as though that would somehow be equal to the needs of this bill.

In fact there is a vastly greater amount of expertise at the ready, waiting to be called into play, and that is the essence of my suggestion.

Senator Moss. Thank you. That is a very good suggestion and one we will consider, I am sure, as we work with this bill.

Well, I appreciate the very fine presentation made by you gentlemen. It certainly has been revealing and indicates that you are not only aware of the problem, but you have already done a great deal of work trying to find solutions to the problem.

I was rather impressed at the testimony of Mr. Northup that the additional cost is estimated, on at least these two types of closures, at only one-half cent to one cent higher for the safety closure than the normal one that is already necessary for any bottle or container for either dry or liquid products.

So, this would indicate that we are not at least initially talking about anything that would make a great increase in the cost of the product. I realize that if standards were applied that caused an appreciable increase in the cost of the product, then there would be resistance to that by consumers and by manufacturers as well because of the competitive nature of our marketplace. We are always seeking to find the lowest level in order to be able to compete and sell a product.

Any one of you can volunteer to answer this question. I wonder what your estimate is of the ability to keep this competitive, inventive idea alive and moving if we get standards set? Do you feel we might then just freeze innovation and come to rest at a certain place where they can meet the minimum standard, or do you think there will be a continued effort by those who work in this field of providing closures to go on and find new and better ways to do it?

Mr. CHENEY. That would, of course, depend on how it was administered. I think your question is a very significant one; I am glad that it causes you concern, and I noticed this morning in another question you raised this point. If improperly administered, it could create a monopoly situation, and kill off initiative and innovation.

And perhaps the subcommittee in some way might choose to direct the Secretary in the bill that administrative action should be designed so as not to bring about that negative economic effect. I think it could properly; I believe standards could be written that would not have that monopolistic effect or anti-invention effect.

Senator Moss. I am glad to have your opinion on that. It does give me concern because obviously the age of invention is not over and there ought to be continued research and innovation and invention in this field. I want to see that that is kept alive if it is possible to do so.

One way occurs to me, of course, if the seller of a product tends

to seek customers by having a better stopper, then, of course, it will keep it alive.

Mr. CHENEY. Yes. That is the way progress is going to be made and we need considerably more progress, as you can see in this field.

Senator Moss. I gather there is some concern that the Secretary in providing the standards might in some way require that the container itself be a plastic bottle or something of that sort. You are anxious, as I get it, to keep that open, so that, too, may be a competitive factor. Is that right?

Mr. CHENEY. Yes, that is certainly an element in our view.

From what we know of the situation and the problem, as I think you very well defined it in your opening remarks, it would seem to us to spread it over the container, would definitely take the interest away from the clearly defined problem as we see it today and might result in less progress in the closure area, which is what is needed.

Senator Moss. I take it, Mr. Stewart, from your testimony that you would prefer the more positive approach of the Secretary prescribing the standards, rather than moving over to the negative approach of saying he may disapprove and prohibit the use of certain kinds of closures.

Mr. STEWART. It is my opinion that the evil that exists that requires correction in the public interest would be more promptly addressed by the positive approach rather than the negative. But this is my personal view as an attorney and not necessarily the view of the Institute.

Senator Moss. I appreciate your recommendations here on amendments, and especially on having a representative of the closure industry as part of this advisory board if it is created and set up, because certainly this is where the greatest amount of expertise resides at the present time and we should look to them for advice certainly.

I think that is all of the questions I have, and I thank you once again. I think your presentation has been very helpful. Thank you.

Mr. CHENEY. Thank you very much.

Senator Moss. Our next witness is Leon L. Wolfstone, who is president of the American Trial Lawyers Association. We are pleased to have you, Mr. Wolfstone.

They have said there is a live quorum on. I want to see if it is a live quorum so we can proceed.

STATEMENT OF LEON L. WOLFSTONE, PRESIDENT, AMERICAN TRIAL LAWYERS ASSOCIATION, SEATTLE, WASH.; ACCOMPANIED BY JERRY FINN, CHAIRMAN, LEGISLATIVE SECTION, AMERICAN TRIAL LAWYERS ASSOCIATION

Mr. WOLFSTONE. May I have the pleasure of introducing to you, Mr. Jerry Finn of New Jersey. Mr Finn is the chairman of the legislative section of the American Trial Lawyers Association, which was created to make a study of legislation to lend its guidance and assistance whenever helpful or appropriate to assist in evaluating legislation. Ordinarily Mr. Finn would make the presentation to you today, but he has been good enough to defer to me, because he has heard me yak, I think is the term he would use, on the Federal Hazardous Substances Labeling Act probably 50 times.

Senator Moss. We are pleased to have you, Mr. Finn. We are glad to have you here, we may want some questions directed to you. But we will listen to Mr. Wolfstone first.

Mr. WOLFSTONE. With your leave, sir, I will refer last to such portions of the prepared statement as I deem necessary, and perhaps lead off by commenting on some of the matters that have come forth thus far today, and responding to some of the questions raised by yourself and other members.

Senator Moss. Very good. Your full statement will be put in the record.

Mr. WOLFSTONE. Thank you very much.

I am Leon Wolfstone. I am a lawyer. I practice law in Seattle, Wash. My address is the Norton Building, the firm of Wolfstone, Panchot, Kleist & Bloch. I am here, however, as president of the American Trial Lawyers Association, a group of some 23,000 lawyers and we feel that we speak for and represent the consuming public.

You mentioned previously the absence of consumer representation. We hope to fill that gap in some slight degree, because it is to us, the lawyers, that the families of the injured, the maimed, the burned, and the deceased come when tragedy has come about. It is to us that falls the task of investigating the occurrence, what led to it, how it could have been avoided. We are safety conscious. Indeed you will find on inquiry, the members of our association probably called the attention of the Government and the municipalities to the need for safety measures more than all of the other organized bodies in the country collectively, whether it be the need for a stop sign or a light or the repainting of crosswalks or industrial or manufacturing standards.

I find that I am pleased to agree with the industry representative, although only in small part. I would urge that members of the industry especially be added to your advisory committee. I think that is a very commendable suggestion. I had just assumed and taken it for granted that the Department of Health, Education, and Welfare would consult with the Bureau of Standards and avail themselves of their expertise and manpower. And it might be well to have a representative from them as well on the consulting staff and perhaps even a caveat that the Department of Health, Education, and Welfare shall consult with and confer with the Bureau of Standards and the Department of Commerce.

On the point raised by you a moment ago of the fear of interference or bringing to a halt inventiveness and ingenuity, I see no such fear. I think the assurance of the attack upon the negligent manufacturer, dispenser, or distributor will insure that continued inventiveness, by the constant appeal to their economic conscience, by the bringing of lawsuits when products are found to be inadequately packaged or inadequately closed. Just as this Congress has concluded that the label containing the instructions, the warning, the admonition, the contents, are, all part of the package, so too I feel the container is part of the package. And rather than come back before you at a later day and say now let us have another amendment directed to containers, as distinct from the closures only, I think better it be that the power is granted now and if there is no need of correction or study now, nothing obviously need be done. But if for competitive or other reasons the industry or segments of it see fit to use less expensive and less safe

containers, the authority implementing, directing, will exist. The Department of Health, Education, and Welfare can proceed without the delay necessarily incurred in seeking another amendment of the act at a later date.

What to do about it? The suggestion was made that the act in present form by way of amendment is too strict, it should be sufficient with warnings and common sense compliance. This might hopefully be true, but unfortunately common sense is not always utilized. Unfortunately the warnings are not always adequate.

I think in terms of a dry cleaning product that used the word "safe" or safety or some such, with a quiet admonition that it is better to use it in a well ventilated room. After appropriate action for damages, the manufacturer now says "The use of this product in closely confined quarters may kill you." This is a warning, in shirt-sleeved basic English. This is what your act seeks to accomplish; namely, there will be not only improvement in the closure, but there will be warnings that will be meaningful, consistent with the risk, and capable of being readily understood.

You inquired as to perhaps some type of a sign or symbol that could be an alert. I am not an artist, but my immediate reaction was to sketch on my note pad a coffin with a child in it or a hospital bed with a child in it. This would be meaningful. This indeed would be meaningful.

I have been invited to talk to you not only upon the closures, but also upon the pressure containers, and I will crisscross somewhat back and forth, because the problems cut across into both areas.

I too am shocked at the extent of the poisonings and the harms in this country and the bellyaches and sicknesses that do not get up to the poisoning. I was impressed by a manufacturer of a pressurized container that contains an epoxy glue for model airplanes, that added an ingredient of a noxious odor to insure the children would not use it for glue sniffing. This is meaningful, and they put it on the label and said so and the kids won't use it.

There is a built-in predisposed injury risk with small children. If they can't break it, they want to eat it. And sometimes they prefer to eat it. My heart was torn a bit by Mr. Snodgrass' description this morning, because I have known of other dishwasher detergent cases, far more serious than his, involving a different product. As a result of which I was told if the infant child, who has licked a few granules, is not in the hospital within 30 minutes, if he is lucky, death will ensue. The alternate is the destruction of the esophagus, the constant stretching and dilation over the ensuing years, the possible mutilation of the scar tissue perhaps a predisposition to cancer, because of the chemical burn even in the occasional case. This has occurred. These matters are known in the industry. We of the American Trial Lawyers Association have called the Government's attention to the product, to the problem. We have called the attention to the Environmental Research Department of the University of Washington in Seattle, the Livermore Research Institute in California. They have publicized it widely and broadly. And I think these things call for and cry out for attention.

In an economy that can spend billions to go to the moon and in a minute would spend millions to retrieve a child from the bottom of a mine shaft, I don't get shook up about the cost of a cent or a cent and

a half per closure. Out in our educationally darkened area we have heard of some other types of safety closures.

I am not a physician, a container manufacturer, safety engineer, but the pediatric consultant to the poison control centers tells me these work. The dry pills encased in two sheets of clear plastic, perforated so you can remove as needed, is difficult to separate although taking you or I an extra half minute, perhaps, and probably frustrating the child. Some of them with a raised bubble to assure the safety of the product when necessary. Expensive? I am told the cost is trivial, and it is indeed very, very effective. This is a simple type of enclosure. If that required further inventiveness, development and improvement, we certainly don't want to cut it off.

I was pleased with the suggestion of the drip bottle controlling the amount of liquid that comes out. I think that is a great idea, it has great promise. We too want to lessen the frequency and severity of injuries. I think that is something—I have seen it, but didn't realize it was important. A little plastic insert in the neck of the bottle, so it doesn't come pouring out.

Alluding back again to the dishwasher detergent, not the one mentioned this morning, in a case in my State, with which I had nothing to do, experiments showed that the mother, followed always by the toddler underfoot, washed the dishes and put the dishwasher detergent container back in that convenient compartment, under the sink. The toddler underfoot reached down, took the container and there were a few granules, licked, and you know what happened. That child did not die, they got to the hospital, but the child's throat was scarred for life.

There are some of these that don't dissolve as speedily as they should. The container in the electric dishwasher doesn't pop open, it doesn't dissolve, the door is down, and the child can and has gotten into it.

In the case I earlier mentioned, there was an experiment, they took a quarter of a teaspoon of granules and sprinkled them on a beef tongue freshly bought and they ate holes in the beef tongue while you watched, so it looked like Swiss cheese, far more caustic than lime.

In another area, pesticides—and this is not directly contained in your proposed bill—perhaps at a later moment it would not be inappropriate to require that those that spray from the air with power pressure of pesticides and insecticides warn those nearby who may be affected by the fall or the wind dispersal.

I am not impressed with the suggestion of voluntary compliance. I have studied voluntary compliance as a lawyer for 30 years. It is great when it works, but so rarely does it work. The most significant voluntary compliance I have seen is when a manufacturer refused to make corrections in a threatening death dealing situation and they receive a copy of a letter to the local prosecuting attorney and to the papers that should death ensue, we assume the corporate officials and their counsel, if you please, will be charged with manslaughter. Then there has been immediate voluntary compliance.

The effect on the economic sales of course is important. On the other hand, as I sat in Detroit about 2 months ago and had the chief physician of one of the Nation's largest pharmacological manufacturing companies tell me that he had warned of the need of something on that package and in the PDR, the package insert, of the danger of toxic

poisoning, bromide poisoning and the need of bromide serum tests, and he said he had been overruled by the sales department. Yes, it will slow down sales, I am sure. But maybe it should if these dangers exist unnecessarily.

On closures, I have read, as I sat here this morning, of ordinary nail polish, the fumes of which were inflammable, lady of the house using it while lighting a cigarette, a warning keep away from nails, cigarette already lit, no flame. The fumes being volatile, exploded, a fire occurred and major injury. The warning was not adequate.

Many of these pressure containers exude a highly volatile and highly explosive or inflammable or combustible fragrance or spray. And they tell you keep it away from flames. But do they tell you keep it away from a cigarette? Do they keep it away from the electric tooth brush or a room where there is an electric motor? Those fumes may ignite with a flash flame that will immediately destroy the person.

Again, as an aside, I read this morning of a tragedy involving an electric blanket that had a failure. A few years ago the industry was prevented from using as a fabric in sweaters material that showed a tendency to have a torch flame, a "you are fried" effect. We learned when they quit using it for sweaters, they used it for electric blankets. Hopefully not now.

Another case I read, the exploding drum of Prestone, which exploded in the presence of a discarded cigarette. The warning was "Keep closed, do not open. Keep away from open flame." Not an adequate warning.

I submit to you that compliance even with industry standards or government standards does not immunize from liability when there is in fact and in reality negligence. As we have served as advisers to your National Commission on Consumer Safety and more recently in the Department of Pollution, we hope to serve when and where we can here. Permanent wave solution, not a complicated drug, but what warning is there that originally some of these permanent wave home solutions were sold for the purpose of removing unwanted hair? And they got complaints it only kinked it. A brilliant guy in the sales department said great, we have the greatest home permanent solution in the world. But every once in awhile it is too strong and removes the hair again.

I used the term before about shirt-sleeved English and I mean that. I recognize toddlers can't read the warnings. But if we can make them meaningful enough, perhaps the parents will read them. Perhaps if we vex the parents with the delay in the opening of the container, with a warning that there is a risk to the children they will be more careful where they put the drugs. They are not all prescription drugs that produce these harms. We know the ordinary aspirin is a great cause of injury among the children of this country today. I think it is economically feasible to improve the types of containers we use in these pressurized containers. These pressurized cans, everything excepting table jelly comes out in it now.

I have filed with my statement a letter from Northwest Laboratories of Seattle and I have the picture they referred to, where a gentleman using a pressurized freon container hastily and ill-advisedly tried to heat it up, because it wasn't exuding its contents speedily and there was

no warning and the cap blew off and took his nose off of his face and it flew 50 feet beyond.

Take one of these empty shaving soap cans and throw it in the fireplace, but watch out. It will blow everything in the fireplace out. The top, the bottom, the sides may fly depending on which end opens first, the charcoal, the wood, sparks, whatever there is, like a hand grenade, with the speed of a bullet.

Mr. Smith of Northwest Laboratories has suggested, and I think wisely, in the case of pressure containers, one might think in terms of a low temperature, fusible plug or pressure sensitive safety release, such as found on industrial gas cylinders. That is inexpensive, it makes sense, it appeals to me.

Not all of the 300,000 products reported in your study of the Federal Hazardous Substances Act will lead to such solutions. Certainly the solutions do not lead to the elimination of common sense.

I have met with the families of maimed, crippled, burned and even dead children, and have seen the great despair, the guilt, the self-blame that they have carried on for the rest of their lives. But that didn't bring back the child. It didn't remove the burns or the scars.

I think with suitable warnings and protective devices, we can minimize it. We will never eliminate it entirely, but we can certainly minimize it.

I referred in my paper to a study made at Madigan, two 1-year periods, where they made a study of a safety-type top on the bottles of one kind or another of dry medicine only, with a 47 percent drop in poisoning from capsules and tablets as compared to prior years.

It is not just pills. Of 595 cases of poisoned children; only 118 had taken drugs and another 85 had taken the household preparations, such as cleaners and furniture polish.

Why the kids eat these things can best be explained only by those that tell us they are curious, they are imitating, they see the parents do things, they want to do them. They have the most bizarre set of taste buds in the world. That which would be repulsive to us seemingly is not repulsive to the child, even with a bad odor, and worse when we put it in an attractive taste and odor as in child aspirin.

If these pressure cans explode on prolonged heat or high heat, is it sufficient to simply say Do not incinerate, Avoid high temperatures? Why don't we specifically say, Don't throw it in the wastebasket where perchance it will be thrown in the fireplace, because prolonged, even high heat will cause the selfsame explosion and the selfsame injuries. Swivel tops—they showed you something of the type where, you know, with my lady's hair sprays, it says "Don't get in your eyes, nose or mouth." I don't know how they are supposed to avoid it and still see what they're doing. Occasionally they spray it in their face unintentionally.

Perhaps a simple, grooved, interlocking device that would control the direction in which it sprays, so it must be pointed in the right direction and not directly at your eyes. Not as exotic, as sophisticated, but meaningful, and I'm sure, helpful. These nonsensical warnings about keeping the sprayer 6 inches from the body amuse me. I'm told it is even contained on a pressure can of vaginal contraceptive foam, with a warning, "Keep it 6 inches from the body."

On the first-aid pressure can it says "Do not spray on burns or

deep cuts," yet the freon is of sufficient pressure to assure that it will penetrate the tissue. If you don't want it getting deep in the tissue, why sell it at all, if it can't be used safely? Who is going to stop and read that? Of course, they will take the Johnson & Johnson, or Jones & Jones first-aid can and apply it liberally, and then if perchance they read the warning, they will sweat. Hopefully they will have no problems.

The caps on the spray cans come off and they leak, and the toxic ingredient they tell you to keep off your hands is all over your hands. If you are economically minded, you will try to—you can't get the cap back on—so you try to activate the tip with your finger, or a screw-driver, and get it all over you.

It is ridiculous the way these caps come off. Not only on Prestone, but many other products.

I think of another one. You are encouraged to buy a pressure can container so that, if your wife has a flat tire, she doesn't ruin the tire driving to the service station. She takes the can and threads it onto the valve stem and reinflates the tire and seals the puncture temporarily. And there is the warning to avoid unnecessary contact with your hands. There may be something about washing it off if it does get on. But there is nothing that tells you that within minutes it will strip the flesh off your hands.

Let's have a warning that is meaningful. If hair sprays cannot be utilized without a danger of ingesting through breathing, let's say so. And if they want to be darned fools enough to take the chance, so be it.

But let's warn them fairly, clearly, and unmistakably what the risk is. If the fumes are volatile and will burn or explode, what about the fumes that are left back in the bathroom when the lady has sprayed her air and walked out? Or the fumes from the can of paint or lacquer.

What about the man whose can of lacquer jams up so the jet is clogged, so he takes the nail or toothpick or wire or pin and tries to open it, and to see if it is open he is pressing on the pressure device, and there you are—all over his face.

What meaning is there, then, to the warning, "Avoid contact with face, eyes, nose, and mouth?"

I think we have got a long ways to go. Some of these warnings are helpful. Some of them are nonsensical mumbo-jumbo.

There was an antiperspirant out some years ago that if you could read it, if you read it and understood it, you would know you shouldn't use it under your armpits or in your crotch. But they don't tell you where else you should use it, because that's the normal places you would use it.

Later, after litigation, they saw fit to warn of the danger of aluminum oxide poisoning from use.

It gets back to proper containers, proper cans, proper pressure cans. Let's explore this low temperature fusible bit. What about the cans that will deteriorate from within and then leak and explode? Many of these products are caustic and can deteriorate the can from within. Is there a dating on there to tell the merchants when to throw them out?

What about the man at the garbage dump, when he picks up the garbage brought out by the truck, picked up at your home and mine.

It is dumped into the garbage and too often there's a fire there to reduce the bulk of the garbage, and the can blows—and gung ho, it's like a hand grenade, with fragments in all directions.

I submit to you, Mr. Chairman, there is a crying need for further consumer protection. I am delighted at the bill. I hope it is adopted.

I would concur, urge, and have complete confidence that you would rely upon the experts in the industry, in the Bureau of Standards, and wherever, whenever, and as often as you can find them. We are interested in cutting down the frequency and severity of injury. We are interested in bringing about speedy treatment for the injured. And in that connection, on a concluding note, God forbid that others adopt the thought expressed by the AP in a release out of Los Angeles. We know that in the field of poisoning and caustics, speed of treatment is necessary. That is why you required the labeling of the contents.

They proposed down there, and have under study, a plan that before the poisoned or the caustic burned or the injured or the ill will receive medical care or treatment or hospitalization, he will first sign a release of any possible claims, should malpractice, negligence, incur in his treatment. Thereby, while they dawdle to find out by checking with their attorney and finding the release is against public policy, void, unenforcible, the child may die.

I submit we need action. We need it now. We need it forcefully and meaningfully, and we of the American Trial Lawyer's Association congratulate you. It is a pleasure to be here.

(The statement follows:)

STATEMENT OF LEON L. WOLFSTONE, PRESIDENT, AMERICAN TRIAL LAWYERS ASSOCIATION

My name is Leon L. Wolfstone, Senior Partner in the law firm of Wolfstone, Panchot, Kleist & Bloch of Seattle, Washington. I appear before this subcommittee as President and representative of the American Trial Lawyers Association, a body of some 25,000 members engaged in the trials of lawsuits—mainly on the plaintiff side but sometimes on the defense side as well.

The American Trial Lawyers Association is dedicated and committed not only to assuring that those suffering injury or death through the fault of another shall receive fair and just compensation, but also to preventing avoidable injury and lessening the severity and consequence of injury.

Because the injured, their families and dependents come to us for a determination of their rights and for an evaluation of the responsibilities of others, we are called upon to make a prompt and complete investigation of the facts leading to the injury or death and to ascertain the extent to which tragedy could have been avoided.

I am pleased therefore to have this opportunity to appear before you. In these proceedings you are considering the proposed amendments to the Federal Hazardous Substance Labeling Act. We are mindful that the Congressional studies which led to the adoption of the act initially disclosed that there were in everyday common household usage in America some 300,000 products that were or might become dangerous through use, foreseeable misuse, storage, handling, and accessibility to children and we know of the effectiveness of the act in lessening the frequency and severity of injuries. We are therefore, anxious indeed to assist in the further strengthening of the Act itself.

Professionally we are immediately and especially alert to those factors and conditions that cause or contribute to injury and death. We are similarly alert to those steps that could have been taken and should have been taken to lessen the likelihood of injury or death, to lessen the severity or degree of harm and thereby save lives.

Our members continually call attention to the need for improved safety measures in all areas ranging from improvement in the marking and lighting of pedestrian crossings to improvements in manufacturing and industrial designs, to

instructions and labeling. Our recommendations exceed in number, quality and meaningfulness those submitted by all other organized groups collectively.

It is to us that come the families of the poisoned, maimed, or deceased.

The "flip top" medicine bottle has long been obsolete just as has been the screw top medicine bottle. These tops or caps serve only as a challenge to the small child to prove his dexterity and demonstrate his ability to remove the top and imitate or emulate adults by consuming all or a portion of the contents.

The combination of unlimited curiosity, and desire to imitate or emulate coupled with a bizarre set of taste buds all but assures that a sense of challenge or competition will be met with a successful effort to get at and consume the contents, however dangerous. It is axiomatic that whatever a child cannot break he will swallow and often times he will prefer to swallow than to break.

Of course the five-year-old may be able to remove the so-called safety caps or separate the sheets of plastic stripping or open a bubble that contains the pill or capsule. Of course the adults will be vexed by the increased nuisance and delay in taking their medication.

On the other hand that very factor of adult vexation and increased nuisance perhaps, hopefully, will remind the adults to be more careful in the manner of storage of the medication so as to make it less accessible to the child. Perhaps the delay in the child's gaining access to the medication will occasionally permit the adult to come on the scene soon enough to take the medication away from the child. The remnants of the plastic stripping, bubble, and difficult-to-restore safety cap will more speedily focus attention to the fact of danger and the need of immediate professional care and treatment. Indeed the toddlers may well be frustrated entirely and shielded from the danger.

I am deeply impressed by and distressed with the report "Child-Resistant Containers Can Prevent Poisoning" appearing in *Pediatrics*, Vol. 43, No. 1 January 1969. This report covers a study over 2 one year periods involving a mixed population of over 100,000 servicemen, retirees and their dependents at Madigan General Hospital in Tacoma, Washington. In this study tablets and capsules, but not liquid medications were dispensed in child resistant containers. It was found there was an overall decrease of poisonings from all causes and a decrease of 47% in poisonings from capsules and tablets as compared to the prior period of dispensing in snap top containers. Obviously the reduction would be even greater as compared to the continued use of the cardboard pill box or screw or twist tops. Since that time there has been even greater improvements in the facility of dispensing pills and capsules enclosed in perforated double sheets or bubbles. This report speaks only of known poisonings. What of the belly-aches and fright that did not reach the level of reported poisonings.

We are told that a study in Sweden of 595 cases of poisoned children disclosed that 118 of them had taken drugs, and another 85 had consumed household preparations such as cleaners and furniture polish.

The poison control centers of this country and the environmental research facilities of the universities have deplored the catastrophes resulting from toddlers gaining access to highly caustic dishwashing detergents customarily stored in the convenient under-the-sink storage compartment and thereby equally convenient and accessible to the always curious, always hungry and always underfoot mother's toddler. In practically every instance in pouring the needed amount of the detergent into the dishwasher some of the residue granules remain on the package itself or land on the floor, where they can be reached by a child's wet hands—which he then immediately places in his mouth.

We are told that one or more of these very commonly used dishwasher detergents are far more caustic than lye, and that if a few granules are sprinkled on a beef tongue they will eat their way through the tongue so that it will look like swiss cheese. We are told that if there is not immediate hospitalization and meaningful treatment within 30 minutes the esophagus and other tissues will have holes burned into and through them.

If the child lives the scarred tissues resulting will necessitate frequent and painful stretching for life and the chemically burned tissues will be a prime target site for cancer.

The point of this, though it does not involve safety caps for medicine bottles or pressurized containers is the fact that we need not only truly safe containers and packaging but warnings that shout out loudly and clearly in shirt-sleeve English rather than pussy-footing around—instead of merely saying, "Keep out of the reach of children," who can't read, comprehend, or respond.

So, too, with the pressurized containers. Instead of saying, "Do not incinerate," "Avoid high temperatures," or, "Keep in a cool place," why do we not require

the clear and unmistakable warning that if exposed to high heat or prolonged heat, the container will explode like a hand grenade. The explosion will send the top, bottom, or sides of the fireplace, incinerator, or their contents through the air long distances, maiming, blinding, killing, or burning those in its path.

Let me read you a report from Northwest Laboratories dated December 6, 1969, attached as an exhibit.

Why permit swivel-top pressure cans that greatly increase the probability and danger that the contents will be sprayed in the eyes, mouth or nose. It is not enough to say, "Avoid spraying contents into eyes, mouth or nose," when the likelihood could be slightly lessened by a fixed directional controlled spray device, clearly marked, which perhaps must be lined up or coordinated in such a manner as to prevent accidental or premature discharge. Let's eliminate easily dislodged tops, caps, and covers that lead to accidental spraying or leakage.

Many of these sprays contain the ingredients that cause chemical, caustic or other types of irritations on contact even with the finger. Yet the use of the screwdriver, finger, or what-have-you to attempt to use the expensive pressure container and its contents is inevitable. Repeated exposure is frighteningly dangerous according to the physicians. Indeed, I would challenge any of you to successfully use or have your wife use the pressurized can intended to be attached to the valve of the auto tire to inflate or reinflate without getting a liberal amount of the contents on your hands.

True enough the container mildly suggests that one should avoid skin contact or promptly wash which is a long ways from telling you that if you do not wash or neutralize promptly the skin will probably be denuded down to the bone.

Casual warnings to keep spray at least 6 inches away neither effectively prevent closer contact nor eliminate body ingestion through the pores. How meaningless it is to say on a can of first aid spray not to use on burns or deep cuts when it appears logical to use it on burns and when the pressure spray will penetrate even the shallow cuts.

If inhalation of hair sprays and other sprays is likely to result in chemical pneumonia, why not say so.

If the spray contents are so combustible that they might ignite and the can explode if someone walks into the room with a lighted cigarette or if it is used in a room with electric motors, or electric hair curlers, or perhaps even automatic toothbrushes why not say so clearly and unmistakably.

We should take a good hard look at the nature of the product contained in such cans. If hair sprays are dangerous upon inhalation what of the residue left in the air after spraying one's hair. So, too, with other sprays, presenting eye contact and fire hazards.

Perhaps, as suggested by Northwest, there should be required a low temperature fusible plug or pressure sensitive safety release.

What of the can with caustic content which may ultimately eat into the container lining and destroy it from inside.

What of the anti-persperant sold some years ago with a mumbled jumbled warning, which would tell you not to use it in the crotch or under the armpits.

What of the pressured cans containing inflammable paint and lacquer that tend to harden and seal the opening or spray jet, compelling the user to try to insert a pin or nail, looking towards the jet while simultaneously applying the pressure release device.

Instructions as to disposition of the cans could adequately warn of the danger of placing them in a wastebasket lest they inadvertently wind up in the incinerator or fireplace, along with the paper debris, only to explode later.

Not by way of jest, but keeping in mind "Distance from Body" warnings and "Avoid mucous membranes" how does one expect the lady user of the contraceptive vaginal foam to use the device.

I and we of the American Trial Lawyers Association implore you by resolution, memorial or whatever means, to urge the various states to adopt the Federal Hazardous Substance Act as amended by reference so as to make it applicable to the many intrastate products. Hopefully it will be enforced strictly but even the mere State adoption without more should result in at least some compliance and lessening of harm. Perhaps some action would encourage some lawyers, teachers, and other safety minded people to alert parents and students at PTA and other civic or problem-conscious meetings.

Who knows? Hopefully, it might even prod some members of the press to join in giving some loud, clear, and effective warnings at the risk of incurring the ire of their advertisers.

I would be derelict however, if I did not tell you that the magnificence of your work and the effectiveness of the Act will indeed be hamstrung if not castrated if doctors and hospitals ill-advisedly adopt a plan reported by the associated press to be under study in Los Angeles, whereby doctors and hospitals would refuse treatment or hospitalization until the patient first signs a waiver of the right to recover damages should malpractice ensue.

Totally aside from the fact that such releases would be void as against public policy, of doubtful legality, a clear violation the hypocritical oath and medical ethics in general, and aside from being shocking and outrageous, the dawdling delay may well needlessly endanger life or prevent life-saving treatment.

It is obviously my view that any doctor or hospital that makes such a demand or any insurance company that so urges should immediately forfeit its right to do business or engage in its profession.

Certainly the changes anticipated by the amendments suggested by me and others may result in some relatively slight economic cost. That increase is nothing, however, compared to the human grief and misery that might be avoided and the economic loss that might be lessened or avoided.

How do we balance the slight increase in manufacturing cost against the agonizing painful death and misery, the years of remorse grief and self-condemnation for not having heeded what truly was a hanky-panky inadequate warning.

Warnings must not be concealed in or confused with instructions. To be meaningful, they must be obvious, loud, and clear.

NORTHWEST LABORATORIES,
APPLIED INDUSTRIAL RESEARCH,
Seattle, Wash., September 26, 1969.

Mr. LEON WOLFSTONE,
Norton Building,
Seattle, Wash.

DEAR Mr. WOLFSTONE: My acquaintance with behavior of Freon type pressurized dispenser cans relative to explosion hazards from heat are as follows:

(a) In 1959 a local person had his nose cut off with a flying can bottom when he applied heat to a can to hasten its discharge. Attached is a photograph (and negative) of a duplicate can obtained from the market for establishing explosion pressures. This unit exploded by blowing the top at approximately 1000 psi which easily explains the forces involved in this accident.

(b) Within the last six months while burning rubbish on my property a household product can blew up, throwing charcoal and debris for 10 or 15 feet with an explosive report equal to a shotgun.

There probably is no pre-determined type of failure in seamed and soldered junctions in the cans. If the top blows, the can becomes a "jet engine"; if the bottom blows off it will travel also because it's large and light. If the side bursts open the action would be sidewise. In any event the gas expansion would blow loose material in all directions. Any explosion from a can in a fireplace would be most apt to scatter the contents across the room even if screened.

In addition to heat warnings of ample magnitude perhaps the cans in question should have a low temperature fusible plug or pressure sensitive safety release for protection of the public as do the industrial gas cylinders and the like.

Sincerely,

C. V. SMITH.

Senator Moss. Thank you, Mr. Wolfstone. That was certainly an eloquent dissertation, and I appreciate it very much. You obviously have had much contact with this. You know a great deal about it, and you have added to our record greatly.

I am happy to have your endorsement of the bill. Because you defend it so well, it makes me feel we certainly must move ahead on this.

Mr. WOLFSTONE. If either Mr. Finn or I can answer any questions we would be delighted to do so.

Senator Moss. I have one or two I would like to ask you. I think I

asked one of the witnesses earlier whether he thought there ought to be a preemption of State regulations, whether it all should be centered in the Federal regulations. Do you think we need State regulations too?

Mr. WOLFSTONE. I'm glad you asked that, because in my prepared statement I strongly urged that by resolution or whatever be necessary, that the Congress urge each of the States to do as they did in California, and to adopt by reference the Federal Hazardous Substances Labeling Act, so far as applicable to intrastate commerce.

Some of the States obviously are not going to enforce it very well. But the very act, if they will adopt it, will be meaningful. Hopefully this will stir up lethargic lawyers, teachers, parents, and other people, to go out and lecture to the public on the risks. But we need their help too. There are too many products that go only in intrastate.

Senator Moss. Thank you. That is a sound recommendation too.

Now, on the recommendation we had before that the Department of Commerce, Bureau of Standards, be written in, do you feel that would be more cumbersome and bring in more delay than simply having HEW responsible and expect that they would coordinate?

Mr. WOLFSTONE. In my experience working for this Government I found when you have to have the approval of two governmental departments, it takes six times as long. I would prefer that the HEW would be admonished to consult with and avail itself of the expertise of the Bureau of Standards, and I'm sure they would be delighted to let the expense be on their budget, rather than their own.

Senator Moss. And not have an absolute requirement that another department approve a move before it becomes final?

Mr. WOLFSTONE. Consult, advise, assist, testing, by all means. Hopefully it could be done without being reminded. But if it takes a reminder prod, let's have it.

Senator Moss. Finally, on this advisory panel, how could we involve the consumers in this more?

Mr. WOLFSTONE. Well, we have encouraged in the American Trial Lawyers Association, that lawyers and those who will become informed, go out and lecture to the local safety groups, the PTA's, the teachers, and those who have once been informed of the risks and hazards can't wait to go out and help save another life.

We find they are not only willing, but anxious to do so, once they are informed.

We hope to stimulate, we hope you will stimulate their increased interest in so doing.

Senator Moss. Thank you very much. I was very pleased to have you talk about these aerosol pressure cans. We hadn't gotten into these before, but as you point out, they can be so lethal because of the pressure, and if they get heat on them.

Mr. WOLFSTONE. You will find I touched on that in greater length in the prepared statement, but didn't want to use up your time here today.

Mr. FINN. Mr. Chairman, if I might add, I would like to endorse the suggestions made by Dr. Wegner with respect to the section 2(b), as it is now drawn, to broaden that language to include products that are not only, as it is stated, for personal care or performance of services ordinarily rendered within or about the household, that it be

broadened to include such products as may be stored within the household and which may very well be used at some distance from, and not necessarily in connection with personal care. There are many chemicals, ammunition, antifreeze, things like that, which may not be construed to be included.

The language, I respectfully suggest, should be broadened to make that clear.

Mr. WOLFSTONE. I would think also his suggestion on adding the repackagers—those who buy in bulk and repackage—was excellent.

Senator Moss. Very good. Knowing the background of you gentlemen, and representing the trial lawyers, I can understand very well your care in seeing the necessity for broadening this definition.

I thank you very much, both of you, gentlemen.

Mr. WOLFSTONE. Thank you, Mr. Chairman.

Senator Moss. Mr. Charles C. Sullivan, representing the Committee for Continuing Study of Improved Safety Closures. He comes to us from Canada.

We are pleased to have you, Mr. Sullivan. We look forward to hearing your testimony.

STATEMENT OF CHARLES C. SULLIVAN, REPRESENTING THE COMMITTEE FOR CONTINUING STUDY OF IMPROVED SAFETY CLOSURES, MALTON, CANADA

Mr. SULLIVAN. Thank you very much. I appreciate the opportunity of being heard.

My name is Charles C. Sullivan. I am president of Plough (Canada) Ltd., a wholly owned subsidiary of Plough, Inc. of Memphis, Tenn. I am a native Tennessean presently residing in Toronto, Canada. I have been personally involved in the search for improved safety closures and safety packaging both for my company and the drug industry since the introduction of the first safety closure on children's aspirin in 1957.

My appearance here today is on behalf of the committee which was appointed in November, 1966, by then Commissioner James L. Goddard of the Food and Drug Administration at a meeting in Washington to—(and I quote from Dr. Harry Shirkey—then medical director of Children's Hospital in Birmingham, Ala.—who presided over the conference)—“make a continuing study of improved safety closures * * *.” As a member of that committee and in my capacity as chairman of the subcommittee which was subsequently appointed to develop methodology and protocol for testing safety closures, I have been asked to apprise your committee of the work that has been carried out to date and the work which is now in progress.

Before I go into the subject at hand, however, if you will allow me, I would like to take just a few moments to give you a very brief history of the development of safety closures and safety packaging which we feel is an integral part of putting this subject in proper perspective.

On February 14, 1955, a meeting was held in Washington, D.C., sponsored by the Bureau of Medicine, U.S. Food and Drug Administration. This meeting was called “Meeting of Medical Advisory Panel on the Accidental Ingestion and Misuse of Salicylate Preparations by Children.” The meeting was presided over at the request of

the Food and Drug Administration by Dr. Charles McKhann, who was at that time professor of pediatrics at Jefferson Medical College, Philadelphia. Official representatives of the American Academy of Pediatrics, the American Medical Association, the American Public Health Association, the Bureau of Medicine of the Food and Drug Administration, and the drug industry were present. In addition to recommendations made at this meeting as to size and number of tablets to be contained in the retail package of children's aspirin and recommendations for cautionary labeling, manufacturers were charged to "do all possible to develop the most effective and practical safety closure."

The recommendations on size and number of tablets and the cautionary labeling were immediately adhered to by all major manufacturers. Although there were smaller manufacturers who did not, it was because of the lack of knowledge of the deliberations of the 1955 Conference. Some time later when advised of these recommendations, they immediately took steps to comply.

The more complex problem of developing a safety closure for aspirin for children was put before major closure manufacturers; and in early 1956 several closures were tested in homes through the Homemakers Guild and under the auspices of such well-known pediatricians as Dr. Jay Arena, professor of pediatrics, Duke University; Dr. Gilbert J. Levy, a life member of the American Academy of Pediatrics; and Dr. George Starbuck, a member of the Accident Prevention Committee of the American Academy of Pediatrics. From the results of these studies, a plastic snap-cap for children's aspirin was developed and introduced in early 1957 and for some time was prevalent on such products.

The results of these studies, which originally encompassed 14 different closures, were published in an article which appeared in the *Journal of the American Medical Association* of March 14, 1959.

My own company, however, not being satisfied with the original closure, in 1966 developed, with Owens-Illinois, a modification of this original closure, which called for a two-step operation in opening. Clinical studies proved that this closure was superior to the original closure, and it was adopted nationally in early 1967. This improved closure was also adopted by other companies in the field.

In the interim period we built molds for and tested a number of other closures as did other manufacturers.

A new closure developed by Owens-Illinois in late 1968 has been tested extensively under the supervision of Dr. Alan Done, professor of pediatrics at the University of Utah Medical School in Salt Lake City, Utah. This closure, which incidentally is being tested in a number of cities by my own company and a leading competitor in the aspirin field, is in the final stages of test market.

One important factor which I feel should be brought out at this point is that every time our company has either tested, changed, or modified a safety closure, we have received numerous complaints from the consumer. Many persons who are faced with using a product which is packaged with a safety closure designed to be difficult for children to remove oftentimes find it more difficult for them to remove than the children. Many consumers will empty the contents of such a package into one which is more easily opened, or they will discard the hard-to-open top thereby leaving the contents subject to deterioration

and readily available to the children whom the original packaging was designed to protect.

If a closure is too difficult to open, the consumer is either reluctant or unwilling to accept it. This is extremely critical with the elderly and with people who suffer from arthritis or some other hand disability. At the suggestion of a number of doctors, my company introduced a safety closure on our adult aspirin in 1960 on a nationwide basis. This safety closure was advertised extensively as a safety feature in the hope that people would buy St. Joseph Aspirin to have a safer package in the home. We began to receive letters within weeks of introduction from people who were affected by arthritis and were physically unable to open the bottle and others who could just not figure out how to open it. It affected our sales so adversely that we had to abandon that closure.

I bring these points up only to show that a tremendous amount of work has been done and is being done in this area and that the problem of finding a closure which is inaccessible to a child, and at the same time readily accessible to an adult, is a complex one, indeed.

At the suggestion of the Congress, in November 1966, a conference was called in Arlington, Va. It was hosted by Dr. James L. Goddard, then Commissioner of the Food and Drug Administration, and presided over by Dr. Harry Shirkey, then medical director of the Children's Hospital in Birmingham, Ala., and presently at the Kauaikeolani Children's Hospital in Honolulu.

This meeting was called "Conference on Prevention of Accidental Ingestion of Salicylate Products by Children." The meeting was attended by pediatricians, officials of the Food and Drug Administration, poison control experts, packaging experts and representatives of drug manufacturers.

At this conference, the subject of children's aspirin was again discussed and recommendations on its labeling, packaging, strength, et cetera were formulated. Once again all manufacturers are in voluntary compliance with these recommendations.

At the same meeting, Dr. Goddard appointed a committee—which I am now representing—made up of representatives of the Food and Drug Administration, the medical profession, the drug industry, and the container industry to make a continuing study of improved safety closures. Dr. Edward Press, presently the health officer of the State of Oregon, was named chairman of this committee.

At our first meeting in January of 1967, a subcommittee was set up as a working group to tackle the problem. I was named chairman of that subcommittee and serving with me were Dr. Jay Arena of Duke University Medical School, Mr. H. L. Verhulst, Director, Poison Control Division of the Food and Drug Administration, Mr. J. B. Carroll of the Glass Container Manufacturers Institute, and Mr. A. S. Johnson of Owens-Illinois.

Our first objective was to determine what safety closures were currently commercially available. We searched the U.S. Patent Office and found that patents for more than 60 different closures had been issued between 1960 and April 1967. We received copies of the patents, complete with mechanical drawings. A number of these were ruled out automatically because they proved to be tamper-proof closures, but not safety closures. Tamper-proofing means designing a closure to

prevent housewives from sampling products on the shelves, which seems to be almost as big a problem as pilferage. Once the tamper-proof feature is removed, it becomes a regular closure.

A number of the closures were found to be commercially available, and we were able to obtain samples. We wrote to the inventor of those samples which were not available and asked for prototypes. Once these were assembled, we classified them into categories and picked the most representative closure in each group for future testing. We were not concerned at this point with trying to prove one closure better than another. If, in fact, we set up a test by which you could compare closures, we might come up with one answer; and someone else might design a test and come up with another.

In testing closures, especially with children, there are many variables such as time of day, age of child, sex of child, history of previous ingestion, and any number of others. If these variables are not considered, and either included or excluded in test studies, it would be possible to test a closure with one group and get an entirely different result than you would with another group. We have found, as an example, that in testing children in an orphanage we got an entirely different result than testing children who came from a seemingly normal home environment.

Children often emulate their parents. They have seen their parents take medicine. They have seen their parents open packages; and, in the crucial age groups of from 2 to 5 years with the greatest incidents of accidental ingestion, these children are in a learning phase of their development. In the case of the orphanage, the child is not exposed to packages in a medicine cabinet or on the shelf or under the sink. The few times that they are exposed to medicine are when they are taken to the dispensary and given a tablet or a dose of cough syrup by a nurse. They are not in the kitchen, they are not exposed to other dangers.

We have also found that testing children in groups, rather than testing them singly, brings significant differences in results. They observe and learn from one another.

For this reason, we concerned ourselves at this particular stage with trying to develop methodology and a protocol for testing closures. As I pointed out before, we are not trying to prove that any one closure is better than another. We do not want to write engineering standards. We are not qualified at this time—nor in our view is anyone else—to write engineering standards for a closure that would solve all problems. Instead we want to find a way to develop a minimum performance standard; but, before finding this minimum performance standard, we must find a way to uniformly compare against this standard any closures that might become available.

Without such standards, manufacturers and governmental agencies have no uniform basis on which to judge the many inventions presented for their consideration. They must, therefore, go to the time and expense of conducting such tests themselves; otherwise, they would have to rely solely on the data supplied by the proponent of the particular invention.

I recently read about a closure which is "childproof." That means to me that it cannot be opened by a child, and there are tests to prove it. However, in another recent test, this same closure was compared to

a newer closure; and, based on the results of tests of this "new" closure, the "childproof" closure was less effective than the "new" one. Just last Thursday, I read an ad for still another new closure which was reportedly "four times better" than the first one—which was already "childproof"—this based upon still another, but different, test.

Gentlemen, I am in a quandry and I have been in this field for nearly 12 years. I am supposed to know something about safety closures. If I had to choose one today based upon "independent tests" of available safety closures, I would not know where to start.

Before any valid judgments can be made, minimum performance standards must be established. Setting a minimum performance standard, however, is not an easy task. It gets down to what you are willing to accept. You may say that you are willing to accept 60 percent failure, in opening by children aged 12 to 60 months, or you may say 75 percent or 95 percent; but there the problem begins—as you increase the percentage of failure you are willing to accept in children, you proportionately decrease the percentage of success by adults . . . especially among the elderly and disabled.

We felt that the worst possible thing we could do would be to pick a closure and say, "This is it." The competitive aspect of developing better closures from the standpoint of the inventor or from the standpoint of closure and bottle manufacturers can, and does, bring about improved closures. There are new closures coming out all of the time. There is a competitive spirit in this field. But, if we were to come out of the committee and say, "This is the answer," where is the incentive for improvement? However, on the other hand, if we develop a standard test and a minimum performance standard which is acceptable, then it still behooves all of us to try to find better closures.

With this in mind, we began experimenting with methods of testing, using acceptable crossover and comparison techniques; and we developed our own protocol. One important criterion in a test like this is projectability; so we determined that the first step was to do a pilot study with a limited number of children and a limited number of adults to test our methods and techniques and consider and screen the possible variables. Based upon the results of this pilot study, we could then modify and improve our techniques and from there go into an expanded study to determine the projectability and reliability of data.

Once these protocols were developed, we began searching for companies who had either done work in this area or could do work in this area. Recommendations came from the Food and Drug Administration as well as from industry representatives. An outline of our protocol was put out for bids to the six or so companies suggested. We found three companies willing to bid. After discussion with these three companies, copies of the bids and summaries of our discussions were presented to the full committee. The committee authorized Foster D. Snell, a division of Booz-Allen & Hamilton, to begin work on the study. Funds for the study were supplied by the Proprietary Association.

Our subcommittee then met with representatives of Snell: and, after the consultation, we refined our protocol into a workable study utilizing 36 children in each of two age groups—a total of 72 children. The first age group encompassed children from 12 to 36 months, and the second group children 36 to 60 months. We used both male and female sub-

jects, and each group was broken down using a bell-curve system to simulate the actual age of incidence of ingestion as reported to the National Clearinghouse for Poison Control Centers.

Two groups of adults were used: a normal (healthy) group of adults, aged 18 to 45, 60 percent of whom were females and 40 percent were males; and a second group of people who were classified as manually disabled from arthritis.

The first stage of this pilot study was completed in the fall of 1968, and a preliminary report was issued to our committee. The final phase of this pilot study, which involved the manually disabled adults, was not completed until early this year since it was a little more complex and not quite as straightforward as the other phases of the study. We had to develop an entirely separate methodology for testing this group; and, after consultation with the Arthritis and Rheumatism Foundation in New York, we were able to set up a series of tests whereby we could test the actual extent of manual disability.

The final report was submitted to the full committee several months ago, and it was determined that we should immediately go into a full study to test the projectability and reliability of the results. The Proprietary Association has once again offered to supply the funds necessary to do the complete study. Foster D. Snell has been awarded a contract for the full study using the expanded panel.

As I mentioned before, one of the critical areas on a test of this type is reliability and projectability of data. For this reason, we have added a second study group under the direction of Dr. Alan Done in the Salt Lake City area. A third study group is under the supervision of Lt. Col. Robert Scherz of Madigan Army Hospital in Tacoma, Wash. All three study groups are following the same protocol. Lieutenant Colonel Scherz's portion of the study is near completion, and the other two are getting underway. Hopefully, we will have a final report and corollation between the three study groups of this study completed in approximately 6 months.

For these reasons, it is the considered judgment of many of our Committee for Continuing Study of Improved Safety Closures that legislation on this subject is premature. We do not, however, want to go on record as opposing the objectives of the bill. Our committee is made up of dedicated individuals, many of whom work with children day in and day out in the practice of medicine. Many are in Poison Control Center work, and those of us in industry feel the tremendous responsibility that we have. Consequently, we all support the objective of the bill to promote child safety. However, in a poll of the committee, the majority would like to see this legislation deferred until more is known. We feel that we have made progress and are making progress. We have a committee which has gained a certain expertise in this area, and we submit that our committee should be allowed to continue as we are now constituted. May I suggest that you allow us to continue and report back to your committee at a predetermined time with a definitive report.

Thank you.

Senator Moss. Thank you for your testimony, Mr. Sullivan, and your representation of the Committee for Continuing Study of Improved Safety Closures.

How was this committee appointed? How does it come into being?

Mr. SULLIVAN. At the 1966 conference called by the FDA Dr. Goddard appointed the committee. He appointed Dr. Press as chairman of this committee and there are 13 members. There are two or three closure manufacturers. The Glass Container Manufacturers Institute has a representative on it; there are four doctors on the committee and there are five companies represented.

Senator Moss. Is it a voluntary advisory committee or is it funded in some way by Food and Drug?

Mr. SULLIVAN. No; it is not funded by Food and Drug at all. The studies we have undertaken have been funded by the Proprietary Association. It is a voluntary committee in the sense that each one of the members pays his own expenses to go to the meetings and gives his time for all of the work that is done. The only thing we pay for out of supplied funds is, of course, the research done by outside companies and investigators.

Senator Moss. This was in 1966 that the appointment was made?

Mr. SULLIVAN. That is right.

Senator Moss. Other than these studies that are underway still, you haven't completed any definitive conclusions, is that right?

Mr. SULLIVAN. We have no definitive conclusions at this point. Of course, much work has also been done by individual companies in this same period. Nothing has stopped there.

Mr. WOLFSTONE. Excuse me, I have Colonel Scherz' report here. If you like, I will be glad to leave that with the committee.

Senator Moss. We do have Colonel Scherz coming to testify tomorrow. We appreciate it very much anyway.

But the thing that gives me concern, of course, is that the study has not yet focused on the problem, or gotten any sort of solution for it, because we still have the problem.

I think you said you had been working in this field of safety closures for 12 years—

Mr. SULLIVAN. With my own company, yes, approximately 11 to 12 years.

Senator Moss. It seems like a long time to me.

Mr. SULLIVAN. We have made two or three changes in closures in that time. We have done a lot of testing, we have marketed safety closures of various kinds. We change the closure when we find a better one. We are marketing our third closure now with my own company, since the first one was introduced.

As far as the committee is concerned, we feel we have done a lot of the groundwork; it has taken a long time to do it, but we feel we now have a clear-cut protocol and methodology and within 6 months the study will be completed and we will have definitive results.

The groundwork has taken time, but now we feel our expanded study can be done in 3 to 6 months.

Senator Moss. Even though you have gone through the changes in closures, the incidence of child poisoning has not gone down and the problem hasn't been alleviated to any statistical degree, has it?

Mr. SULLIVAN. I think it has. I think the incidence has gone down on the ingestion of drugs, and certainly deaths. I think Mr. Verhulst gave the report this morning. It was some 400-odd deaths in 1963 and it has gone down each year.

Senator Moss. I don't have those figures before me now but at the time they were given, I didn't see any appreciable change. There is some little change from year to year.

But it seemed to me they were staying up in about the same area from year to year. Of course, I believe we ought to have a full and complete study. But I just wonder if it is because the matter is being done on a voluntary basis, rather than a mandatory basis, that that is why we aren't moving along faster.

Mr. SULLIVAN. Well, I don't feel that we have moved any slower than we could have any other way. This is not something that you can snap your fingers, and devise a safety closure or device.

Senator Moss. Now, if upon completion of your studies you do arrive at certain standards that can be defined, compliance would still be only voluntary; wouldn't you have to have some legislative power to make that mandatory for those who market the products that were dangerous?

Mr. SULLIVAN. I happen to feel that at least my own industry has lived up to what they should be doing all along, and I feel if we find a safety closure that is economically feasible from the standpoint of the consumer, one the elderly can use, one that is a deterrent to children, we are all going to jump on the bandwagon and use it.

My company, and all of the companies in my industry, have spent untold thousands of dollars in research in recent years to find a better closure. A universal closure is just not available at this point.

Senator Moss. Suppose you could design a closure that was relatively safe for children; it was somewhat of an impediment for older people to use; would you still say you shouldn't go to that because of the impediment on the upper side?

Mr. SULLIVAN. Maybe there should be a choice there. You have got this problem, especially with salicylates, with elderly people who have arthritis who cannot manipulate certain types of closures. They have to have the aspirin.

Senator Moss. What about the possibility of requiring a person who had this difficulty to get a certificate or at least ask for a container different—

Mr. SULLIVAN. That is why I said choice. They would have a choice.

Senator Moss. This is the choice you are talking about. But the standard one that you get ordinarily, if you just went up and bought it in the store, would be the safety one that the child can't get into. Normally children are in the homes of parents who have not reached the aged situation, although, of course, they may be physically handicapped at an earlier age. But generally the parents of children are in the prime of health, isn't that right?

Mr. SULLIVAN. That is right. That is why we had one panel which I described as a normal healthy group, what you would consider the childbearing ages, and these are the parents that would be concerned, who have the small children in the home. We feel they are ordinarily dexterous enough to open most closures.

Senator Moss. What do you find about this bill that would bring on the recommendation that you bring from your group, that it is premature and should be postponed?

Mr. SULLIVAN. It looks as if they are trying to set up another committee that would almost have to be starting from scratch. We feel

we have a lot of expertise in this area. We have been working on it a long time and I would hate to see the work we have done obviated.

Senator Moss. There wouldn't be any reason you wouldn't want to cooperate with HEW if they started to move on it, would there?

Mr. SULLIVAN. Not in the least.

Senator Moss. I would expect if the responsibility were placed on the Secretary, the first thing he would look for is to find any group that had any expertise that could help him.

Mr. SULLIVAN. I should hope so.

Senator Moss. In getting his standards ready.

Well, I appreciate your testimony, Mr. Sullivan. You do bring to us information that has been developed or is being developed now by an illustrious committee that is studying this very problem we are talking about. The only thing that gives me a little concern is that it just seems to me we are not getting down to the case fast enough.

Mr. SULLIVAN. That is why I say we would like to report back to you. You set the time.

Senator Moss. Very good. We will take that into consideration. Thank you very much.

We are going to have to recess the hearings now because of the situation on the floor and go over until 10 o'clock tomorrow. At that time we have eight witnesses to hear, which means we will have to move along very rapidly tomorrow.

To those who are yet to be heard, I would suggest that you might wish to look at your statements overnight, and if they are somewhat lengthy, you may want to put the statement in full in the record and come prepared to summarize and point out and emphasize the things that you would like to emphasize for the committee. However, the whole statement will be in the transcript of the hearings.

As is perfectly obvious to you here, this afternoon, at least, I have been sitting alone at the hearing. So, the members of the committee are going to have to read that record. And that is where it is most important that we have all that you want to say printed in the record.

But since I am holding the hearings, I would like to have you emphasize things that I will be able to talk to my colleagues about when we sit down and mark up the bill, as we say, and point out to them the emphasis that was laid on certain points and the witnesses who gave us that emphasis. But it does enable us to move along a little faster if you are able to do that summarizing and emphasizing of your testimony, and the statement in full goes into the record.

We will recess until 10 o'clock tomorrow morning.

(Whereupon, at 3:50 p.m., the subcommittee was adjourned, to reconvene at 10 a.m. on Thursday, Oct. 2, 1969.)

TO AMEND THE FEDERAL HAZARDOUS SUBSTANCE
ACT, TO PROVIDE FOR CHILD-RESISTANT PACK-
AGING TO PROTECT CHILDREN FROM SERIOUS
PERSONAL INJURY OR SERIOUS ILLNESS RESULT-
ING FROM HANDLING, USING, OR INGESTING
ANY HAZARDOUS SUBSTANCE, AND FOR OTHER
PURPOSES

THURSDAY, OCTOBER 2, 1969

U.S. SENATE,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE FOR CONSUMERS,
Washington, D.C.

The subcommittee reconvened at 10:15 a.m. in room 5110, New Senate Office Building, the Honorable Frank E. Moss (chairman of the subcommittee) presiding.

Present: Senators Moss and Pearson.

Senator Moss. The hearing will come to order.

I am sorry we are a little late and I realize some of the people are still withdrawing from the room. We will ask them to do that quietly and we will proceed with the hearing, because, as I indicated at the conclusion of yesterday's hearing, we are pressed for time and we must hurry on to be able to complete the witnesses who have come to testify for us. Many of them have come very long distances to be here and we owe them the courtesy of getting the hearing underway, enabling them to present their testimony for which they have been invited to come here.

I think we had a very excellent hearing yesterday and made a good record. I am sure today will be similar.

As I explained at the end of yesterday's hearing, we will make it a general rule that the full statement that is presented in writing will be put in the record and will be part of the record. If the person testifying then is able to summarize or to highlight the testimony, to emphasize the points he thinks are of greatest importance for the committee to hear, that will be helpful, it will save some time. I don't want to preclude anybody, however, if they feel that they would like to go through the whole text, we will be glad to have that. I am sure it is all valuable material. But it will be in the printed record and will be available to all of the members of the Commerce Committee and, indeed, to the entire Senate who wish to inform themselves on the subject matter of the hearing.

I should also point out that a printed transcript of the record after it is finished will be mailed to all of those who appear as witnesses. If

there are others who would like to get a printed copy of this transcript after it is complete, you can leave your name with a member of the staff here and it will be mailed on to you after it has been put into print.

Our first witness this morning will be Dr. Alan K. Done, professor of pediatrics, director of the Poison Information and Therapy Center, University of Utah. We are very glad to have you, sir. We are particularly pleased to have a citizen of my home State of Utah before this committee.

**STATEMENT OF DR. ALAN K. DONE, PROFESSOR OF PEDIATRICS,
DIRECTOR OF THE POISON INFORMATION AND THERAPY CEN-
TER, UNIVERSITY OF UTAH, SALT LAKE CITY, UTAH**

Dr. DONE. Thank you, Senator Moss.

I appreciate the opportunity of participating in this hearing. In the interest of time, I will just summarize very briefly a rather large amount of data which we have derived over the past few years. Details of the data and descriptions of the methods that were employed are in the written statement and I will not repeat them here.

We have been interested, in the last 2 or 3 years, in the problem of safety packaging from two standpoints: One is comparing the efficacy of various forms of safety packaging, one with the other, in the prevention of childhood poisoning. Second, and perhaps most important, we have been interested in developing methods and standards for the evaluation of such packages. In approaching this problem numerous possible methods were investigated and I will not enumerate these; they are all described in the written report. I will simply say that the experimental design upon which we finally settled—and this, too, is described in detail in the statement—was one in which each child to be tested was tested with each of the packages in a given experiment in random sequence on separate days. This is important, I think, because it means that each child in effect serves as his own control and it eliminates many of the extraneous variables that make for difficulties in experiments of this type.

To date we have studied 239 children who have had this complete crossover type of study. We selected children in nursery schools for reasons I will not go into here, but these also are spelled out in the written report. The children were allowed 30-minute contact with each package. But their progress was recorded throughout that entire 30-minute period. Because we wished to include forms of packaging other than closures, this created some problems of statistical manipulation which required a slightly different approach than would be necessary otherwise: With the closure, of course, one is dealing with what might be referred to as an all-or-none phenomenon; either they get the cap off or they don't. If they do get it off they have immediate access, of course, to all of the contents. With some of the so-called unit packaging forms which we selected for study this is not the case. Children may get into these packages almost routinely, but the packages have the effect, if they are effective, of preventing ingestion of a large dose in a brief period of time. So in this type of situation time is the important factor, much more so than quantity. But it made it necessary for us to use a rate factor as well as just a quantity factor.

Now because of these difficulties, the statistical treatment of data posed some significant problems which I won't go into here, except to mention that the problems I think tend to be generally underrated. We required a great deal of very expert statistical help with these problems. In fact, part of the method of analysis that was ultimately used was developed specifically for these studies. After we examined numerous possible measurements which might be used, the ones that seemed both from the data and from theoretical considerations to be the most meaningful were (1) the number of dosage forms ingested in the allotted time or any fraction of that time, and (2) the period of time required to obtain an arbitrary number of pills. The arbitrary number on which we settled for no particular reason except it was convenient was 10.

In our first experiment we included (1) an ordinary screw cap bottle, (2) one type of a snap cap such as described yesterday—this is the one that was formerly used on children's aspirin tablets—and (3) a strip pack. The strip pack consists of pills being encased in two sheets of cellophane and the pack must be torn open for each individual pill.

In the second experiment the packages evaluated were: (1) the same type of snap cap, with minor modifications, that was described yesterday (this is the cap that is currently used on most bottles of children's aspirin), (2) the same strip pack as was used in the previous experiment, and (3) what is called the blister pack, a card containing holes covered by a blister of plastic in which each pill resides; the card is covered by aluminum foil which is perforated, and the idea is that the pill must be punched out in order to be obtained.

In the third experiment—we included (1) the same snap cap as we used in experiment No. 2, (2) in this case we included also a form of opaque strip packing (with the idea that perhaps if the pills couldn't be seen by the children they would be less enticed and it might be more effective, which proved not to be the case), (3) the same blister pack, and (4) one of two pressure-release type caps: the Palm-N-Turn cap or the Owens-Illinois "Screw-Loc" cap which is a variant of the same type of mechanics.

I should like now to summarize the data at the 30-minute interval with respect to three different types of measurements (Tables 1-3 in written report): (1) the percent success in opening the container, (2) the number who ingested the arbitrary figure of 10 or more, and (3) the average number of tablets obtained by the various children from each of these forms of packaging. I won't dwell on these because details of these data are presented in the record, but I will simply point out that there was a fair degree of success in preventing children from opening all but the ordinary screw cap closure, and especially effective were the pressure-release type of closures. With the unit forms of packaging (e.g., strip or blister) we don't expect a high degree of success in preventing opening, because here we are dependent on the time element and not upon the inability to get into them at all.

In terms of the percent who ingested 10 or more, there is a fairly significant reduction all of the way across the board with each of these forms of safety packaging.

Finally, in terms of the average number of pills ingested by the children, again there is a fairly significant reduction, pretty much all

of the way across the board with each type of safety packaging. We have to keep in mind that these are the 30-minute figures, and they suffer from the fact that if a child is given sufficient time, he can get into almost anything. I think the figures become more meaningful when we introduce the time element.

I should like now to review each of the three experiments side by side with regard to one measurement: the percentage of children who would have been poisoned had the packages contained a product which was toxic in a dose of 10 or more tablets [Fig. 1 in written report]. When one looks at the 30 minute figure I showed a moment ago, there is no great difference. However, when one focuses on the results obtained at 10 minutes we can see as we get to the strip pack, the blister pack, and either the palm and turn or other pressure-release cap, a very striking reduction in the number of children who would have been poisoned under the conditions I just mentioned.

Now the significance of this 10-minute figure, even though it is arbitrary, is enhanced when one considers that the majority of children in our studies were willing to cease their efforts to get pills from the difficult packages within 10 minutes. Furthermore, of course, children are much more likely to be left unattended for 10 minutes than they are for 30 minutes.

Senator Moss. Did these children know that the pills in there were good to eat? Were they attracted by it? Were they candy or what?

Dr. DONE. The children were told nothing at all. The pills, however, were brightly colored and were attractive in a visual sense. The children were not told to open them nor that they were candy. Of course they determined that they were candy as soon as they ate the first one.

Figures 3 and 4 in the written report show the degree of protection afforded by each of these various packages, plotted against the number of tablets. In other words, how well the package prevented the child from taking a given number of dosage forms. Under the conditions of these studies, the strip and blister packs afforded their greatest protection against the ingestion of many tablets (several or more), while the pressure-release caps were far superior in preventing the ingestion of lower doses or the ingestion of any at all.

In interpreting these data, one must bear in mind the fact that in a significant percentage of cases of accidental poisoning in children, the cap is not on the container at the time of ingestion. How commonly this occurs is difficult to determine, but this factor must be subtracted from the apparent protection afforded by any type of closure. So in this sense forms which do not require a closure at all have at least a minor advantage, all other factors being equal.

Now from this I think we can conclude that for materials of moderate or relatively low toxicity, the unit forms of packaging, such as the strip or blister or something of this kind, may actually be superior to the pressure-release type of caps. I think the prime example here would be aspirin, either of the adult or children's variety, but particularly the latter. Conversely, with some substances it is imperative that no tablets at all or at most only a very few be available to the child. In these instances the pressure-release type of cap or perhaps one of the new variants which we have not yet studied would clearly

be preferable, although a small percentage of children would be able to remove the cap and thereby gain access to all of the tablets available. The upshot of all of this I think is that it is necessary for us to decide whether, for a given product, it is better to risk complete access by a small but significant percentage of children or to essentially insure that the material will be taken but probably not in large doses.

These findings demonstrate, I think, that relatively simple and inexpensive forms of safety packaging can be highly effective in preventing the ingestion of solid dosage forms by children. Our data do not permit the exclusive endorsement of any particular type of safety packaging and, indeed, suggest that the same form may not be appropriate for all materials. More importantly, perhaps, our experience indicates that with the experimental design that evolved from these studies, various forms of safety packaging can be evaluated effectively, economically, and with facility. Our experience also underscores, I think, the importance of actually evaluating closures in the hands of children rather than making assumptions on an engineering basis, for example, about what may be safe and what may not. We have been surprised on numerous occasions when we have developed an innovation that we were absolutely certain would be childproof and the children would fool us. We had one cap, for example, which we specifically designed, on the basis of previous failures, to get around the defect that we thought existed in the earlier closure. It was absolutely foolproof; you could not get it off. Adults couldn't get them off either unless they knew what to do. The children in their frustration quickly learned that if they turned the bottle upside down and hit it on the table one time, the cap would crack and they could immediately get it off.

So I think it is imperative these things be evaluated, that we don't make assumptions based upon what we think is engineering knowledge.

I should like to mention, in closing, that the studies which I have described in this report, as well as one which is currently in progress, were initiated and sponsored largely by the pharmaceutical industry and involved packaging innovations which were developed by them and by the packaging industry. Significant progress has already been made, I think, and even more I would expect will occur in the near future.

While it is true that the problem of childhood poisoning has gone unsolved for far too long, a concerted industrywide effort for finding effective packaging has really been underway only for about 2 or 3 years and then not under the threat of imminent legislation.

I would respectfully suggest, therefore, that industry be given the opportunity to complete what has already been started and that this bill or one like it be invoked if they fail to solve the problem voluntarily in a prescribed and, hopefully, relatively brief period of time.

I could not be more in favor of having effective safety packaging for all hazardous substances. I simply wonder whether legislation at this point is the best answer. In addition to sharing the concern expressed by some yesterday that innovation may be impeded, I feel that the expense and the administrative headaches involved in a program of this type should be borne mostly by industry, not by our Government.

Again I appreciate this opportunity to be heard and I commend the authors of this bill for their obviously sincere interest in the welfare of our children.

Thank you.

(The statement follows:)

STATEMENT OF ALAN K. DONE, M.D.

Portions of this work have been read before the American Pediatric Society (Atlantic City, May 3, 1969) and the International Conference on Poison Control (New York City, June 4, 1969) and presented as Scientific Exhibits at various scientific assemblies including the American Medical Assoc., American Academy of Pediatrics, American Public Health Assoc., American Pharmaceutical Assoc., American Academy of General Practice, and others.

Various portions of this work were supported by Plough, Inc., Sterling Drug, Inc., the Wyeth Co., and the U.S. Public Health Service.

One of the most promising potential means of preventing accidental childhood poisoning is the use of safety packaging. Some so-called safety packages have been introduced sporadically; however, there have been no critical comparisons of the effectiveness of various packages. This report is of studies which were aimed at (1) comparing the effectiveness of various safety packages and (2) developing methods and standards for their evaluation.

Methods

Numerous possible approaches were evaluated preliminarily. The experimental design which was finally selected was one in which each subject was tested with each of the packages within an experiment, in random sequence on separate days. Data were accepted only for those children who completed the entire experiment. It was felt that this approach minimized the influence of extraneous variables, effectively allowed each child to serve as his own control, and made it possible to obtain statistically valid studies employing smaller groups of subjects than would be needed otherwise. From 3 to 5 packages were included in each experiment and one package was always duplicated among the various experiments in order to provide a basis for comparison of one experiment with another. To control the possibility that exposure to one package might possibly influence the ability to open others, complete randomization was obtained by assigning each child to a predetermined sequence which was followed inviolate. All possible sequences within an experiment were entered on cards, and the deck was shuffled; after it was determined that a child was to be included in the study, a card was drawn and the assigned sequence followed. In addition, the data were analyzed for the influence of sequence, but substantial effects were not found.

Children were selected for study only on the basis that they were within an age range which was predetermined for the experiment, that their parents were willing to give permission for their participation, and the child was likely to be available for completion of the entire series. Children were removed from the study only if they were unable to complete the series; this happened rarely and was usually due to the child's being removed from the institution in which the studies were being performed.

The decision to use children in nursery schools was based upon considerable exploration. The need to be able to study the child on from three to five separate occasions made it necessary to select a situation in which children were available on a more-or-less continual basis. Hospitalized children or those in an out-patient hospital setting proved to be inappropriate subjects; they were so apprehensive and preoccupied with the events occurring about them that they usually tended not to take much interest in any of the packages. Testing children in their own homes through cooperation of their parents proved difficult because parents so often gave either explicit or implicit instruction to the child along with the package, and the children tended to perform in a manner consistent with their concept of the parents' expectations. Further, studies under home conditions were difficult to control satisfactorily, and collection of accurate data was impossible. Several nursery schools were utilized, including indigent, middle-class and upper-class agencies. In each instance these were places to which the children were taken regularly so that the surroundings, the routine and the personnel were fairly familiar to them. Every effort was made to disrupt the schedule as little as possible and to minimize exposure to strangers. The children were taken into a playroom and

seated at tables (a common occurrence) on which the package to be tested had been placed. They were given no instruction whatever; they were neither told to open the packages, nor that the contents were candy. The children were observed and their progress tabulated by a female member of the study group with whom the children were familiar (since they were accustomed to the presence of female attendants she was less conspicuous than would be a male). At the beginning of the studies, each child was tested individually and observed through a one-way mirror. However, it soon became apparent that such arrangements were not necessary, since the children actually performed more naturally when several were present in the room, because in the routine of the schools it was unusual for them to be alone, and the female observer was accepted by them as being a familiar and non-threatening figure. The children, being at individual desks or tables separated by distances of several feet, usually concentrated on the task at hand and tended to pay very little attention to one another. In the rare instances when they attempted to help, or derive help from, one another, this was prevented by the minimum effective amount of intervention by the observer.

Children were allowed 30 minutes' contact with each package. Both the number of tablets ingested in that period of time and the length of time required to open the container (in the case of a closure) were tabulated. The inclusion of forms of packaging (such as strip or blister-pack) which do not entail the all-or-none phenomenon of opening, or failing to do so, requires somewhat different parameters than would apply otherwise. With such packages, the principal benefit likely to be derived is a slowing of the ingestion; i.e., increasing the amount of time required to obtain the toxic dose. For this reason, data were obtained concerning the rate at which the materials contained within the packages were ingested.

With the more difficult forms of packaging the children often tended to "give up" in 10 or 15 minutes. They were required, however, to remain in the vicinity of the package for the allotted period of 30 minutes. Consequently, measurements of the deterrent effect of such packages presented here must be viewed as minimum figures. They indicate only what could be accomplished by the children in the allotted time, not necessarily what would be likely to be accomplished were they left to their own devices.

The statistical treatment of data posed some problems because of differing and skewed distributions: with the closures the majority of children either ingested all or none of the contents, while with the "unit" packaging forms the data tended to be distributed more between these extremes; in no case was there a statistically "normal" distribution of data. Consequently, conventional treatment of data, such as calculation of means, standard deviations, etc. would be inappropriate and misleading. To avoid the assumption of normality medians* rather than averages were employed as quantitative expressions, and ranks and probability (p) values for simultaneous paired comparisons were used for statistical analysis by the method of Friedman and Nemenyi. In the tabulation of data in the following tables a rank score of 1 (which never occurred) would have indicated that the package in question was consistently best in deterring ingestion, while a rank similar to the total number of packages under study (3 or 4) would indicate that the package was the least effective. Differences were accepted as significant only when the p was less than 0.05 (less than a 5% probability of a chance occurrence).

*Median refers to the central tendency; i.e., half of the observed values are above and half are below the median.

After examining numerous possible measurements, the ones which seemed both from the data and theoretical consideration to be the most meaningful were the number of dosage forms ingested in the allotted time (or a fraction thereof) and the period of time required to obtain ten. The figure of ten was chosen arbitrarily on the basis that this would be a moderately toxic dose of adult (5 grain) aspirin tablets for a child of this age. The purpose of selecting such a figure was to add the time dimension to the evaluations. It was theorized that a form of packaging which retards the progress of ingestion (and, therefore, increases the likelihood of detection before a toxic dose is obtained) may be worthwhile, as well as one which prevents access altogether for a certain percentage of cases. The 30-minute duration of study was selected arbitrarily on the theory that few children would be allowed more than this amount of time without benefit of supervision. It should be noted, however, that most of the children studied reached their achievements within that period of time and very few would have accomplished more had they been given more time.

Results

Because the controls were intrinsic within individual experiments it is necessary to consider each individually.

Packages included in Experiment 1 (Table 1) were: (1) an ordinary screw cap bottle, (2) a snap "safety" cap of the type used until recently on bottles of children's aspirins, and (3) a strip-pack in which tablets are sealed individually in a cellophane strip. The subjects were 66 children with an age range of 19 to 51 months and an average of 33 months. The packages contained 50 candy pellets in varying colors. In terms both of the number ingested in the time allotted and the length of time required to obtain 10, the snap cap was safer than the screw cap, but significantly less effective than the strip pack (Table 1). It is noteworthy that extremely high degrees of significance were achieved even with these relatively small numbers of subjects, especially in the comparison of the strip pack with the screw cap where the probability of chance occurrence (p) was less than 1 in 1,000,000.

Table 1. Experiment 1: Comparison of screw cap, snap "safety cap" and transparent strip pack.

		<u>Screw</u>	<u>Snap</u>	<u>Strip</u>
NUMBER INGESTED	MEDIAN	50	34	7
	Rank p	2.62 ↖ (<.0002)	1.90 ↖ (<.05)	1.48 ↖
		↖ (<10 ⁻⁷) ↗		
MINUTES TO OBTAIN TEN	MEDIAN	3	16	30+
	Rank p	1.35 ↖ (<.0003)	2.05 ↖ (<.006)	2.61 ↖
		↖ (<10 ⁻⁷) ↗		

In Experiment 2 (Table 2) the packages evaluated were: (1) the "double-lock" snap cap currently in wide use on bottles of children's aspirin, (2) the same strip pack as was used in the previous study and (3) a "blister-pack" consisting of a card containing multiple holes covered by plastic blisters in which each tablet is sealed by a backing of aluminum foil. This experiment involved 63 children ranging in age from 24 to 65 months, with an average of 44 months. (With the inclusion of children in an older age group, the mean age was nearly a year older than in Experiment 1.) The same 50 candy pellets were used. In this instance the blister pack was highly superior to the strip pack, but there was no significant difference between the latter and the snap cap (Table 2). As will be noted subsequently, this was attributable to a striking age effect on the ability to open the strip pack. Parenthetically it should be noted that there was no significant difference between the old and the newer snap caps used in Experiments 1 and 2.

Table 2. Experiment 2: Comparison of "double-lock" snap cap, transparent strip pack and blister pack.				
NUMBER INGESTED		<u>Snap</u>	<u>Strip</u>	<u>Blister</u>
	MEDIAN	50	30	11
	Rank p	2.32 ↗ (2.5) ↖	2.22 ↗ (.0002) ↖	1.46 ↗ (.0002) ↖
		↗ (10 ⁻⁵) ↖		
MINUTES TO OBTAIN TEN		<u>Snap</u>	<u>Strip</u>	<u>Blister</u>
	MEDIAN	10	11	27
	Rank p	1.71 ↗ (.5) ↖	1.77 ↗ (.0002) ↖	2.52 ↗ (.0002) ↖
		↗ (.00004) ↖		

In Experiment 3 (Table 3) we compared four packages including: (1) the same snap cap as in Experiment 2, (2) a form of opaque strip-packing (incorporated in the hope that rendering the tablets non-visible would further add to the safety feature), (3) a blister pack similar to that used above and (4) one of two pressure-release types of caps: the Palm-N-Turn or the Owens Illinois Screw-Loc cap. (The latter two caps were treated as a unit in the randomization; i.e., each child received one or the other, but not both). In this experiment the

Table 3. Experiment 3: Comparison of "Double-Lock" snap cap, transparent strip pack, blister pack and pressure-release (Palm-N-Turn or Owens-Illinois "Screw-Loc") caps.					
NUMBER INGESTED		<u>Snap</u>	<u>Strip</u>	<u>Blister</u>	<u>Press.</u>
	MEDIAN	36	18	12	0
	Rank	3.13	2.82	2.45	1.61
	p	(.4)	(.2)	(.0002)	
MINUTES TO OBTAIN TEN		<u>Snap</u>	<u>Strip</u>	<u>Blister</u>	<u>Press.</u>
	MEDIAN	13	18	26	30+
	Rank	1.88	2.20	2.62	3.31
	p	(.3)	(.07)	(.003)	

SAFETY PACKAGING STUDY

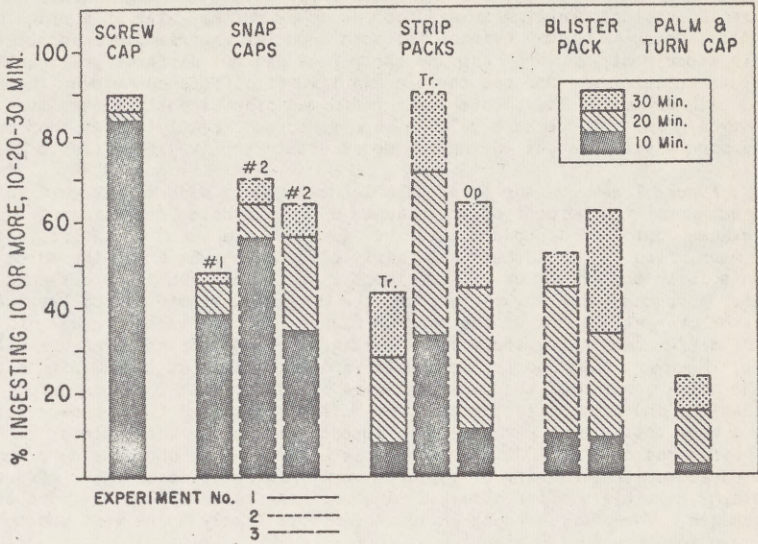


Fig. 1. Percent of children in each experiment who ingested 10 tablets in 10, 20 or 30 minutes from various types of packages.

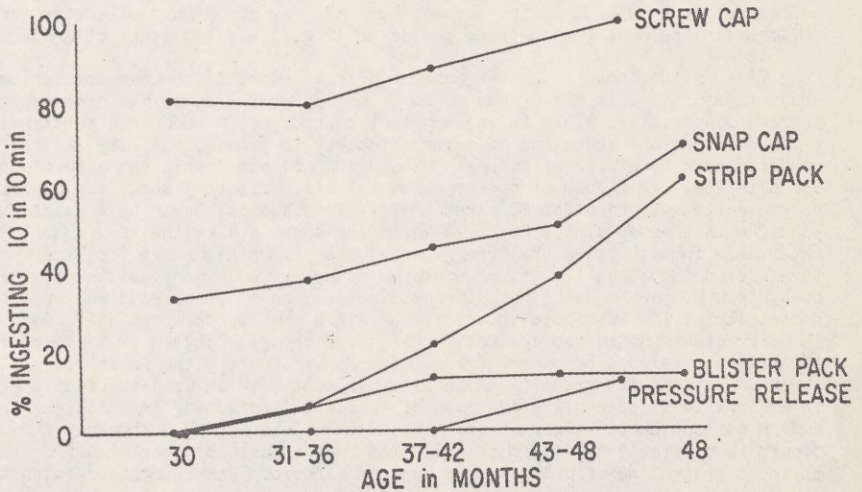


Fig. 2. Age effect on the percent of children who ingested 10 tablets in 10 minutes from various types of packages.

packages contained 36 flavored tablets which were identical to a popular children's aspirin except for the omission of the active ingredient. Included were 100 children ranging in age from 24 to 52 months, with an average of 39 months, which is midway between the mean ages for Experiments 1 and 2. In this experiment, the snap cap and strip pack did not differ significantly in either measurement, nor was there a significant difference between the strip and blister-pack. The blister-pack performed significantly better than the snap cap, and the pressure-release caps performed greatly better than any of the others with respect to the two measurements employed here (Table 3).

Figure 1 reviews the three experiments side-by-side with regard to one measurement: the percent of individuals who would have been poisoned had the packages contained a product which was toxic in a dose of 10 tablets. It can be seen, firstly, that there was fairly close agreement among the three experiments, with the exception of Experiment 2 which included the older-aged children. When the children were allowed the entire 30 minute period (represented by the over-all height of the bars in Figure 1) there were no great and consistent differences among the various packages, except for the pressure-release cap. However, with shorter intervals, and especially at the 10-minute period (the solid portion of the bars in Figure 1), all of the forms of safety packaging and especially the strip or blister-packs and the pressure-release caps were better than screw caps in impeding access to the tablets. The significance of this 10-minute figure is enhanced when one considers that, as noted above, the majority of children were willing to cease their efforts to obtain the tablets after about 10 minutes when frustrated by the more effective packages. Moreover, a young child is far more likely to be left unattended for 10 minutes than for 30 minutes.

Figure 2 shows the age-effect in regard to the percentage of children who ingested 10 tablets within 10 minutes. There is a very striking age effect with the strip-pack, but within the range studied age made only a minor difference with the blister-pack or the pressure-release caps. It is evident from these data that for other than very toxic materials either of these two unit packaging forms as well as the pressure-release cap are highly effective for children in the most poison-prone period of life (i.e., 1-3 years of age).

Viewing the data in another manner makes it possible to draw conclusions about the suitability of various forms of packaging for materials of varying degrees of toxicity. This is an important consideration because a substance which requires the ingestion of several tablets to produce toxicity may be rendered safe by different packaging than would be applicable for a substance which is toxic in a dose of one or a few tablets. Figure 3 shows the degree of protection afforded for 30 minutes at various dosage levels by each of the packages thusfar studied. Figure 4 shows the same data at the 10-minute interval. In both cases children greater than 52 months of age (in Experiment 2) were excluded so that the groups would be as homogeneous as possible for this analysis. It can be seen that under the conditions of these studies, and especially at the 10-minute interval, the strip and blister-packs afforded their greatest protection against ingestion of several tablets or more, while the pressure-release caps were far superior in preventing the ingestion of lower doses. In interpreting these data one must bear in mind the fact that in a significant percentage of cases of accidental poisoning in children, the cap is not on the container at the time of the incident. How commonly this occurs is difficult to determine, but this factor must be subtracted from the apparent protection afforded by any type of closure. This, together with the

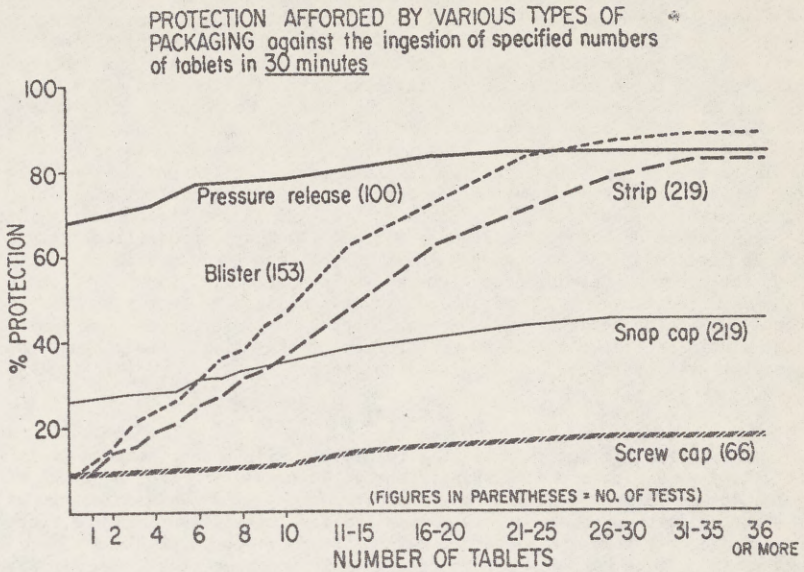
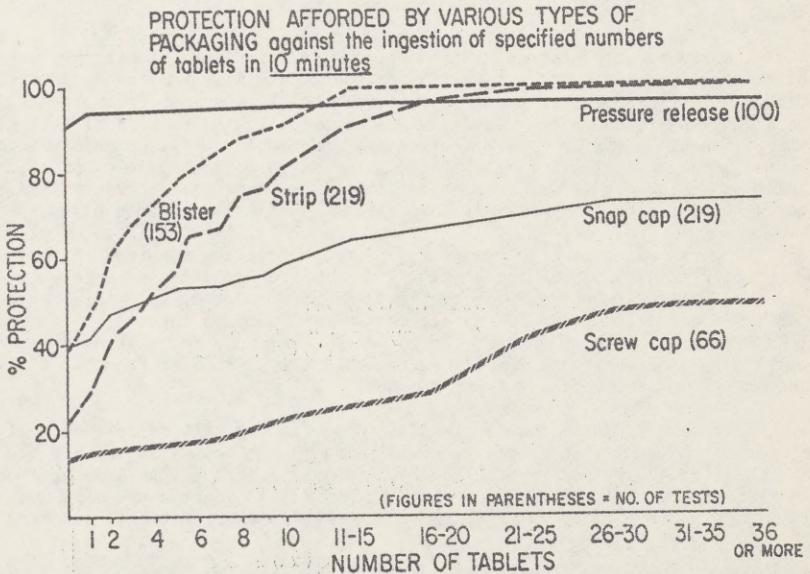


Fig. 4



observations presented in Figures 3 and 4, suggests that for materials of moderate or relatively low toxicity the unit forms of packaging (blister, strip, etc.) may actually be superior to the pressure-release types of closures. A prime example here would be aspirin of either the adult or the children's variety, but especially the latter. Conversely, with some substances, it is imperative that no tablets at all, or at most a very few, be available to the child; in these instances the pressure-release caps would be preferable, although a small percentage of children would be able to remove the cap and thereby gain access to all of the tablets available. No acceptable closure is likely to be entirely foolproof; by observing the level at which each curve in Figures 3 and 4 intercept the vertical axis one can determine the frequency with which children removed each closure. Even the pressure-release caps were removed by 32% (mainly the older children, as noted above) in 30 minutes so it is necessary to decide whether, for a particular product, it is better to risk complete access by a small (but significant) percentage of children or to essentially ensure that the material will be taken, but not in large doses.

Conclusions

These findings demonstrate that relatively simple and inexpensive forms of safety packaging can be highly effective in preventing the ingestion of solid dosage forms by children of poison-prone age. Our data do not permit the exclusive endorsement of any particular form of safety packaging and, indeed, suggest that the same form may not be most appropriate for all materials. It is evident that screw-cap closures are virtually ineffective, and snap cap closures have only limited effectiveness in thwarting children. The pressure-release closure proved to be the most effective in totally preventing access to contents, while unit forms of packaging such as the strip and blister-packs were the most effective in preventing ingestion of large doses.

The experimental approach which was employed in these studies provided statistical data which were highly significant even with relatively limited numbers of trials. It is concluded, therefore, that various forms of safety packaging can be evaluated effectively, economically and with facility. Further, it seems probable that performance standards can be developed in this manner, so long as the toxicity of the material to be packaged is known in human subjects. It is our recommendation that packages not be advertised as being "safe" unless they meet or surpass these yet-to-be-defined standards.

A fourth experiment is presently underway under the auspices of the Proprietaries Association and a joint Industry-FDA Committee on Safety Closures. It is essentially a repetition of Experiment 3, but will also be performed concomitantly and independently by two other investigative groups in other parts of the country. The purpose is not only to enlarge the experience, but also to examine the reproducibility of results from one time and one group of investigators to another.

It should be noted that the studies described in this report, as well as the one currently in progress, were initiated and sponsored largely by the pharmaceutical industry and involved packaging innovations developed by them and by the packaging industry. Significant progress has already been made and even more is expected in the near future. I would respectfully

suggest, therefore, that legislative intervention at this time might be premature and undesirable. In my opinion, Industry has already accepted the responsibility of developing and promoting safety packaging; considerable momentum has been generated, and a healthy competition for development of still safer packages has started. This, it seems to me, should be nurtured. As unquestionably meritorious as are the aims of the proposed legislation it will require the development of specifications for compliance, and these are apt to stifle such progress. My suggestion is that Industry be given the opportunity to complete what has been started and that this Bill be invoked if they fail to solve the problem voluntarily.

Senator Moss. Thank you, Dr. Done, for that very fine testimony and your full statement which is in the record.

How long have you been conducting these experiments with children?

Dr. DONE. About 2½ years, sir.

Senator Moss. Is it completed or near completion now?

Dr. DONE. We completed the three studies that I mentioned. We are now involved in a fourth study in cooperation with two other investigators. This one is aimed more at the problem of developing performance standards that could perhaps be utilized by whatever agency is finally elected to see that safety packaging is carried out.

Senator Moss. Would you suggest that the definition of safe closure in the bill include also the blister pack and the strip pack type of packaging that was part of your experiment?

Dr. DONE. As I understand the usual use of the word closure, I would suggest it be omitted and rather "safety packaging" be included, because the term may be interpreted to exclude things other than safety caps. I would not want to see them excluded. I think for some things such forms of packaging would be preferable.

Senator Moss. Of course the blister and the strip are adapted to pills or solid pieces and would not be adaptable to liquids or powders. Is that correct?

Dr. DONE. This is correct. We have done no work on other than solid dosage forms at all as yet.

Senator Moss. I gather from your testimony you think that a widespread use of safety packaging can significantly reduce the level of child poisoning we experience now?

Dr. DONE. I think more than that is needed to totally solve the problem, but I have no question but what this would significantly reduce the difficulties.

Senator Moss. I wonder what you think would be the appropriate criteria for the Secretary to use in determining whether or not a particular container is a safety container?

Dr. DONE. This is very difficult. I would have difficulty at this juncture even making recommendations to the Secretary about this. My suggestion may be politically naive, but I wonder if it is not possible for the Secretary to determine on the basis of performance of a product that it has become unsafe? That is to say, if a product continues to cause poisoning in children, this of course will be known (these things are reported) and the product could then be dealt with individually. I think this may be preferable. It would certainly retain the innovative elements that we have been concerned about. It would in effect tell the company making this particular product that it ought to do something, but it would not necessarily specify what that something was. This then would be up to them to determine and up to them to pay for. It seems to me that it would remove a lot of the administrative difficulties that I think would automatically be entailed in a program of this type administered solely by the Government.

Senator Moss. Do you envision then that the Government would do the designing and testing and all of these things that have been carried out such as your experiments?

Dr. DONE. Oh, no, sir. I think this belongs in the hands of industry. They are the experts in this. They are the ones that have the most

at stake in terms of seeing to it that this is done. And they really have a great deal of experience behind them. I think they are in a far better position to do this than any agency of the Federal Government.

Senator Moss. Don't you think it is possible at this time for the Government to set up standards that must be met, and then for industry to meet them with some type of safety container?

Dr. DONE. My reservation here, Senator, is that from our data I couldn't indicate that we would have better than a 75 or 80 percent success rate with anything. Now for the moment that might seem acceptable, because it is probably the best we can do with what we presently have available. I would hope that someday someone could make this 90 or 95 percent. I am a little fearful that if we prescribe something, that will be what is used, and the best that will be used. This is my concern in that respect. I am not satisfied with 80 percent protection.

Senator Moss. You suggested in your testimony that you thought no legislation was necessary or appropriate at this time and that there should be a delay of that. I wonder if you could elaborate on that a little bit in view of our talk about setting standards?

Dr. DONE. Yes, sir. My feeling that way has to do with the fact that they—and by “they” I mean the industry—are really now beginning to make progress. I think they can make more rapid progress if they know that the alternative is legislation. This has not been given a trial. I would prefer to see it be given a trial for the reasons that I mentioned: to retain the innovative element, to prevent the Government from having to assume great administrative responsibility which really belongs to industry and great expense that really belongs to industry. I think if they know that if something is not done within “x” number of months or years, that it will be done for them, and this is why I made the suggestion that perhaps we should wait and at least give them another chance to see if they can't solve this problem themselves.

Senator Moss. The thing I don't understand is why this sort of inducement or pressure, whatever you want to call it, wouldn't be available if the Government set up standards and said containers of products that are damaging must meet these standards, and industry had to measure up to that, or holding off in abeyance somewhere the threat of a law that will be enacted to do just that.

Dr. DONE. My objections to that approach, Senator, come again to the problem of innovation. It seems to me that it would be absolutely essential, for administration of such an act, to spell out in very precise terms what is acceptable in the way either of closures or performance by a closure. I am afraid that this would be adhered to and only this, that the innovative element would be removed.

Senator Moss. Well, you speak of industry in rather general terms and indicated the pharmaceutical industry is the one that has been financing the sort of studies that you have done and they are pressing on. But, of course the most dramatic testimony we had yesterday didn't have to do with what we would call a pharmaceutical, it was a washing powder, under the sink in a paper or plastic box with a little spout and that was all there was for that. So we are talking about safety packaging in a much wider range than just pharmaceuticals.

Dr. DONE. Yes, sir; I realize that. Unfortunately, I can't really

speaking about other forms of packaging, because I have had no personal experience; all of my studies have been confined to pharmaceuticals. I know much less about other aspects of industry than I do about the pharmaceutical industry. I really don't know what the prospects are that they will clean their own house. I think the pharmaceutical industry would clean its own house if they knew it was going to be cleaned for them. I can't speak for the rest of the industry; I don't know.

Senator Moss. Well, other witnesses said that the big offenders really in this field of poisoning were largely cleaning fluids and furniture polish, such things as that, more than just pills and medications that would come under the heading I suppose of pharmaceuticals.

Dr. DONE. This is certainly true. Pharmaceuticals account for approximately 50 percent of childhood ingestions.

Senator Moss. Well, I appreciate your testimony, Dr. Done. It is very interesting and I wish we had more time really to discuss it. I think it is a fascinating study and I appreciate having you come to testify and give us this rather full statement. I am sure that if the committee has further questions, we will be able to write to you and you will be willing to reply in writing?

Dr. DONE. Yes, indeed, sir.

Senator Moss. Thank you very much.

Our next witness will be Dr. Jay Arena, professor of pediatrics, Duke University. He is also president of the American Association of Poison Control Centers.

We are very happy to have you, Doctor. We appreciate your coming.

STATEMENT OF DR. JAY M. ARENA, PROFESSOR OF PEDIATRICS, DUKE UNIVERSITY AND PRESIDENT, AMERICAN ASSOCIATION OF POISON CONTROL CENTERS

Dr. ARENA. It is my pleasure, Senator Moss.

I would like to reiterate what Dr. Done has said; I would like to commend you, Senator Moss, for your amendment, S. 2161, to the Uniform Hazardous Substances Act in behalf of the welfare of children.

This act, of course, the Uniform Hazardous Substances Act was enacted in February 1960, so, here we are now 9 years later with a fine amendment.

Before I read my statement, to expedite and save time, I would like to say it seems to me, although I wasn't here yesterday, as you indicated in your questioning of Dr. Done, that we are concentrating too much on safety packaging for drugs, where much research has already been done and is being done now, instead of safe packaging for household products which cause almost 50 percent of all of the poisoning in children.

I wonder if most of us realize that we have now accessible to us a quarter of a million household products or household agents that you and I can buy and bring into the home, many of which contain potentially toxic chemicals.

I think this amendment certainly has this in mind, and I think this is an area that we need a lot more investigation and research in, the safe packaging for household products.

Senator Moss. It was suggested yesterday, and I think a very good

suggested amendment, that we talk not only of household products, but things that may be stored in and around the home, pointing out that sometimes there is antifreeze kept in the house that is going to be used away from the home, and other products like that. So, this should be very broad.

Dr. ARENA. Right. As I read your amendment, I think this amendment includes that group of agents.

Senator Moss. Well, that is the intent of it. It was suggested we might make that more clear by broader language.

Dr. ARENA. I at least felt from reading the amendment that these agents were included.

I will go on now to my statement.

I am a pediatrician who for many years practiced pediatrics in Durham, N.C. Recently I have joined the full-time staff of the Department of Pediatrics of the Duke University Medical Center as professor of pediatrics. At the present time I am chairman of district IV of the academy and a member of the executive board. I am also president of the American Association of Poison Control Centers. Along with two other academy members, I serve on the committee to develop standards for safety closures appointed by the FDA Commissioner late in 1967; the chairman of this committee is Dr. Edward Press, an academy fellow and a long-time authority on poisoning prevention. Dr. Press regrets that, because of other commitments, he is unable to attend these hearings, and has asked me to present the views of his committee, the academy, and my own personal opinion regarding this legislation.

A recent review of this bill by the academy's Committee on Accident Prevention and Accidental Poisoning reveals unanimity in favor of passage of S. 2162. I can also report that the three academy members on the FDA Safety Closure Committee favor the passage of this legislation.

As a pioneer 20 years ago in the safety package concept and as an original member on the Committee on Toxicology of the American Medical Association that initiated and promulgated the Uniform Hazard Substance Act, I am in complete agreement as to the amending of this act as outlined in S. 2162. I believe it is high time that industry, with its know-how and assets, accepts more responsibility in developing these mechanisms for the prevention of ingestion of their potentially toxic chemicals in household products by small children.

Much of the red furniture polish, with its mineral seal oil, a real culprit, is still put up in very attractive containers, most enticing to children, producing considerable morbidity and mortality.

I might say, it has been as long as 18 years ago when I had the unfortunate incident of two children dying from ingestion of red furniture polish. It was at this time that I wrote to the manufacturer and suggested a label be put on a product, which was not on the product at that time, and also that they should make their container less attractive to small children.

This was a very, very attractive container for small children; they wouldn't hesitate to drink this material and unfortunately some aspirated it into the lungs which often caused a serious and fatal pneumonia.

I might say that much of the red furniture polish is now put up in aerosol containers which is far safer than the old original glass containers. But unfortunately there are a number of red furniture polish agents that are still put up in these attractive bottles and children don't hesitate to sample this product if they see it.

Why not a less attractive and safer container—aerosol or other type—for this and similar products? We are told that safety packaging is not the entire answer to this problem of poisoning, and I agree; nor is labeling, for regardless of what preventive measures are taken, there are some children who will circumvent them in any case. Nevertheless, safety packaging and labels do have an important role, for there are many parents who read labels, and there are many children thwarted by safety closures or packages. I believe, in addition to the development of safety packages—and perhaps much more important—is the time and thought that industry should give to substituting less toxic but still effective chemicals in their household products.

For example, the use of methyl chloroform for carbon tetrachloride; trichloroethane for sodium or potassium hydroxide in drainpipe cleansing agents; and the recent lengthy research by the Testor Corp. to find an additive (allylisothiocyanate—"oil of mustard") that would make it impossible for kids to sniff glue. Without changing the quality of their product, this corporation because of their concern, and as a public service, was able to come up with a solution to the serious problem of glue sniffing (which in spite of much publicity is more prevalent among teenagers than most parents and physicians realize). Here are just a few examples of what industry can and should do in this area. Since their concern is no less than ours, I am sure they will cooperate in all of these endeavors when they are made aware of the problems as they exist today. Finally, if industry can sell the effectiveness or superiority of their products via the various news media, surely they also can sell the American public their safe use, without loss of prestige or sales.

There is one comment I would like to add and that is there is a danger from this bill and that would be in imposing unrealistic requirements on manufacturers. But I believe that this would be minimized by the appeal clause in the amendment and by the appropriate and effective use of the Technical Advisory Committee by the Secretary.

Finally, I would like to say that five or six States that I know of have already passed laws of their own, and it appears a Federal law with uniform requirements would be more realistic for industry than many such laws.

Senator Moss. Thank you very much, Dr. Arena, for your testimony. It comes out of a long period of experience and background in this area we are talking about.

I wonder if you think the Food and Drug Administration Committee could have moved faster and reached results earlier if it had had more money and legislative incentive to reach results?

Dr. ARENA. I don't see why it couldn't.

Senator Moss. You began your testimony by pointing out that this is about 9 years later and we still haven't set a standard and required obedience to it.

Dr. ARENA. Right.

Senator Moss. I am sure you agree that we ought to get safety packaging and closures into effect as early as possible because we are still losing lives and we ought to move ahead. That is the burden of your testimony, isn't it?

Dr. ARENA. Yes. I think this is definitely part of the problem, although not the full answer.

Senator Moss. What I am really trying to get around to is to find out your opinion as to whether or not voluntary industry efforts, laudable as they are, can move us rapidly enough to getting the problems attacked as it would be if we set up some standards through legislation and required meeting at least minimum standards by those who sell goods in the open market.

Dr. ARENA. From my experience with industry, I would say yes, I think industry would cooperate fully, especially if—I think the drawback in the past, Senator, has been that industry has been much more concerned about sales, about the effective use of their products, and they have rarely thought of the safe use of their product.

Therefore, they have not thought of packaging, they have not thought of changing their chemical products to perhaps a safer product. But I believe they are ready at the present time to do so.

The problem is being brought out more forcefully, because of the activity of the poison control centers, and of the 14,000 or 15,000 pediatricians who are greatly concerned about this problem in the United States. Industry is just as concerned and I do believe they will cooperate.

Senator Moss. Well, they are in a very competitive economic market, trying to sell the product and they make it as appealing as they can, at the same time they try to reduce costs in order to compete economically with one another. And this safety factor is somewhat outside.

One of the bits of testimony yesterday was that to have what was offered as a safety closure on containers might cost, maybe, a cent more for the product. And, therefore, it ought to be acceptable. Well, I would say that is acceptable, except if you have severe economic competition.

If some fellow can mark his product one cent cheaper, he may want to do that in order to compete in the market, unless he has a standard which he has to meet.

Dr. ARENA. I think you are perfectly correct there. I do know from experience, because I was an instigator of the first safety closure on one of the aspirin bottles some 18 years ago. I know that this particular pharmaceutical house was very concerned about the effect on sales.

When they first put the safety closure on they indicated this might very well greatly limit the sale of their product, because of the difficulty in removing the safety closure.

I told them—and I don't know, maybe I was naive at the time—but I told them I thought if they presented the facts and told the American public why they were putting this safety closure on, that I didn't think it would affect sales; it might even help it. I would like to report the sales went up 25 percent the first year.

Senator Moss. I am glad to have you report that, because I believe that is the other side of the coin. If people become safety conscious, then if a seller will utilize this in presenting his product, saying that it not only is a good product and whatever else he wants to say about it,

but also that it has a safety feature on it that will guard against indiscriminate opening by children particularly and by others who by mistake might open it.

Dr. ARENA. I would be 100 percent in agreement with that statement, sir.

Senator Moss. Well, thank you very much, Dr. Arena. We surely appreciate your coming to be with us and to give us the benefit of your experience and background. I know that we will be able to communicate with you if we need to at a later time.

Dr. ARENA. It would be my pleasure, sir.

Senator Moss. Thank you.

The next witness is Dr. Roger J. Meyer, associate professor of pediatrics, Northwestern University School of Medicine, and executive director, Infant Welfare Society of Chicago.

STATEMENT OF ROGER J. MEYER, M.D., ASSOCIATE PROFESSOR OF PEDIATRICS, NORTHWESTERN UNIVERSITY SCHOOL OF MEDICINE, AND EXECUTIVE DIRECTOR, INFANT WELFARE SOCIETY OF CHICAGO

Dr. MEYER. Senator Moss, ladies and gentlemen: I certainly appreciate the opportunity to share my thoughts about child safety with you.

I come as a member of the Accident Prevention Committee of the American Academy of Pediatrics, as well as the chairman of the Illinois Academy Accident Prevention Committee.

After 10 years of child safety research I would like to share with you a different approach.

As a physician, I am guided by the child's physical symptoms to the underlying cause. I think this committee should attack the underlying cause of poisoning in order to be effective.

Five States have now enacted chemical hazard bills, a trend which will increase. A national bill or policy would avoid confusion and make it easy for industries to cooperate.

Senate bill 2162 poses some significant problems. It does not have the specificity of a followup in terms of enforcement or evaluation in terms of child injury and mortality reduction.

At this point in this country there is very little proof that most of the child and home safety efforts have reduced the rate or severity of poisonings significantly.

My purpose in appearing here is to help define the issues and the problem rather than the symptoms.

There is a big disparity between the measures now attacking the problem of the rather small decrease in the number of poisonings.

The method of reporting poisoning is imperfect. The wide variety of statistics, (even the mortality figures of 400, 600, et cetera) are incorrect.

This bill cuts across all of the hazardous fields, which I think is important. No other bill in the past has done this as well. It puts a lot of industries on notice, not just the pharmaceutical industry, which I think has done its share in the last 2 years on this problem.

Legislative and product safety efforts leading to limitation of toxic

dosages, safety containers and other related issues, must be continued, since there is evidence that this has some effect.

These isolated triumphs in poisoning control are neutralized by the many other problems of lead poisoning, hydrocarbon and aspirin poisoning, which are major unresolved issues.

Setting aside environmental and product safety controls, some of the evidence concerning underlying child and family factors in poisoning, should be brought to light.

Senator Cotton's demands for specificity and less "comprehensive", "optimalism", more hard-hitting facts about how to do this should be considered for such a bill. A number of child development factors appear to be in evidence.

First, the peak period of ingestion occurs between 1 and 4 years of age when children are most orally curious, mobile and uncritical in judgment about potentially hazardous substances. They also spend a great deal more time continually exposed to household chemicals than children of older ages.

Studies conducted by our Childhood Injury Study Group for 10 years have studied some of the human factors. Developmental information almost conflicts with some of the current measures, the safety caps and so forth. No matter how hard we try to build safety capping, the children will learn to bite off the cap or break it. I think children are a great deal more clever than we who are planning things.

Pica is important as Craig and many other people have pointed out, these children are specifically orally curious children, are chronic ingesters of nonfood substances. The Pica—which is Latin for Magpie—child will eat a lot of nonfood substances, will put these things into his mouth and in this 1- to 4-year old period, gets into all sorts of trouble. These youngsters need to be carefully watched, because once poisoned, they have a four times greater chance of repeating it. In this pool of 400,000 or a million, poisoning episodes, these youngsters are more heavily represented because they get into trouble again and again. I have seen four or five episodes of poisoning in one child.

Poisoning episodes are not random throughout the day. They are more common between 3 and 6 p.m., when two common factors are involved; the child is hungry before mealtime, and the mothers are distracted, everybody is tired in the family. These are really different children often daredevils, the kind that tend to get into things more often.

Children's play activity is involved. Children that play alone in the upstairs bathroom or in the front room with mother's purse after seeing adults medicate themselves might be tempted to imitate these actions in their play with the real thing. With a significant number of poisonings, children imitate the adults in this pill-taking culture. Look at the TV advertisements. I don't think you can legislate this, but the influence of the manufacturer and the commercials about pills are building conditioning into pill taking.

A study we did 10 years ago in Boston, indicated at least three kinds of circumstances under which children may get poisoned.

First, poisoning can be social. The children get together in the absence of parents and share pills. I can recall a 5-year-old who took a bottle of aspirin out and lined up the pills in a long line and had

the baby start at the other end and race to see who could eat the most pills.

In the second group illness in the family lowers the family's usual protection of the children. Aspirin is left at the bedside, the parents are sick, and poisoning often occurs at this time.

A third, more serious problem is the family who leaves children completely unguarded and seem unconcerned about the child's life and welfare.

In Vermont we began to study the family's subsystem of attitudes and beliefs and practices, which I think is the heart of where things begin. We found that many of these families were so thinly stretched with regard to their own energies that the timing of poisoning was almost predictable by illness, when a family was moving, when a new baby was on the way, and so forth, the time the poisoning took place, wasn't random throughout the year.

Commercial products present serious problems, as in the case of a 2½ year old who ate some scented attractively colored caustic soda in the bathroom. Products are so attractive that they are irresistible to children. Added to this is the fact that the child's mother went off for an hour and a half to the store, leaving her by herself.

These combine in the overall poisoning symptom. In the inner city we have a serious problem of a different nature. The children are exposed to family deprivation, left alone in circumstances to deal with life as best they can. I think they are often hungry and neglected and these children may eat lead paint off the wall or eat hazardous chemicals.

In this chemically oriented society, poisoning is going to be increasingly possible. In the rural areas a more serious thing goes beyond drug packaging. At one location deadly insecticide was marketed by an enterprising merchant in small paper sacks; it look like flour or candy and a number of children died before this was isolated and stopped.

We need some regulation which cuts across the field. Our own studies this last year indicate that the family seems to be ignorant of the degree of toxicity of many thing, there is extremely dangerous careless chemical storage around the home. We have talked to families of poisoned children, and they said, it was because the poison was left around. We talked to unpoisoned families and they said we didn't have any poisoning, because we store things carefully. When we inspected the homes of both groups, no difference in the amount of careless chemical storage was found.

To compound it, when a poisoning occurred, the family almost inevitably never changed the location and left the other poisons around the same way.

I would like to offer my own prescription for this bill in terms of the underlying causes.

First, it seems to me that there should be recognition of the child life needs, particularly as they relate to those at greater risk from pica or the mouthing of nonfood substances. Developmental stimulation during the preschool years in order that susceptible children be given safer, more positive play experiences is important to include as a positive program.

This bill might consider reaching out to coordinate all other Gov-

ernment agencies, like Headstart, which is concerned with child health and which has not been used for poison control.

We must improve the understanding of all family members and those who are given responsibility for young children in or outside the home about the risks to young children as they relate to periods of family stress, moving, hunger, and other times of greater "poisonability." This must be considered as one launches a national campaign against poisoning.

We must deemphasize the chemical attraction. Just look at the TV; you see how life can be made instantly more beautiful if you take such and such a pill or use such and such a detergent. Children are caught up in this, and they cannot judge where the line is to be drawn.

We must increase child and family poisoning and other injury prevention through all professional outlets. The physician, the community nurse, the pharmacist, the manufacturer, have to join together. Legislation could have a positive influence on our whole national approach. We shouldn't have to go 9 years in piecemeal fashion to control childhood poisoning.

Research about poisoning control, as Dr. Done pointed out, must be advanced first before we nail it down into law. Chemical packaging, other control measures should be evaluated scientifically for effectiveness. Funding should be provided to the States and at the Federal level. I would like to see the country begin with a series of three or four to a dozen national child injury control centers that take specific parts of this and are very specific.

For example, in the Southeastern United States kerosene poisoning is more common than in the rest of the country. The reason is that families start their fires with kerosene in soft drink bottles and children drink it thinking it is a soft drink.

That particular problem, which is very high in the Southeast, is a specific disease entity; there should be a specific task force to attack that.

The chemical poisoning in my own home State of Washington with agricultural spray toxicity is more common. This has to be looked at as a specific disease entity, which will be greater before it is less in this country.

The bill is very significant, because it does cut across a variety of hazards and this should be strengthened. This Council that it provides for, if included, should represent those who know the field, pediatrics as well as human engineering, and manufacturing.

Finally, the point made yesterday by Senator Hartke and Senator Moss, that the Government agencies which are involved in chemical control of any sort, whether it is agriculture, or commerce, or whatever, really should get together and pool their thoughts and begin to really swing together, communicate together, so there really is a common effort nationally. There is no excuse for any of the Government components, whether the Children's Bureau or Headstart or the Commerce Committee, not sharing facts about this problem and a common approach across the country.

We have the manpower now. We have a lot of pieces of the legislation now. Maybe this bill could strengthen this total approach.

(The statement follows:)

STATEMENT OF ROGER J. MEYER, M.D.

Each year approximately 400 children in the United States die and an estimated 400,000 require medical attention as a result of poisoning.¹ During the past decade, increasing attention has been paid to the problem by physicians, manufacturers and many others concerned with the welfare of children. Despite the incredible effort and expenses involved in the attempt to control poisoning, the toll has not been significantly altered. The effects of "shotgun" community control and nationwide advertising efforts while well intended, are unclear and non-specific. Why does the disparity exist between increasing community safety measures and the continuing toll of mortality and morbidity? Some authorities have indicated that the widespread availability of toxic hazards to children added to careless storage and easy access to the population at greatest risk account for an important explanation of the problem.² Certainly, no student of the poisoning problem in society today would discount the importance of minimizing both toxicity and availability of harmful chemicals. While the poison control centers scattered across the country might be improved with respect to their influence on prevention, no one would seriously advocate that they cease making available information that might lead to more prompt, effective treatment of poisoned individuals. Legislative and product safety efforts leading to limitation of toxic dosages, "safety" containers and other related issues must be continued, since there is evidence that this has some effect. While isolated triumphs of poison control can be identified, they are neutralized by unresolved problems like lead, hydrocarbons and aspirin poisoning, for example, that represent major issues confronting those who would increase poisoning control.

Setting aside the contribution of environmental and product safety controls, let me turn to some of the evidences concerned with child and family factors in poisoning.

First, a number of child development factors appear in evidence. The peak period of ingestion occurs between one and four years of age when children are likely to be most orally curious, mobile and uncritical in judgment about potentially hazardous substances. They also spend a great deal more time continually exposed to household chemicals than children of older ages. A series of studies conducted by our Childhood Injury Study Group have attempted to sort out the child and other human factors in poisoning and other injury circumstances. There appears to be little sex difference in poisoning incidence, but boys are inclined to be involved with more outdoor and garage chemicals than girls. Pica played an important role in over half of all cases studied.

The Pica story, which has been well documented by Craig³ reveals that children ingesting poisons are more frequently chronic ingestors of non-food substances than children who are not poisoned. This characteristic helps explain why those who once ingest poison are four times more likely to repeat. Poisoning episodes are far more likely to occur just prior to mealtime, particularly during the 3:00-6:00 P.M. period when families are the most under pressure and the children more likely to be both hungry and fatigued. Several studies have also revealed that these children are more likely to be characterized as "daredevils"⁴⁻⁵ than other children not so involved with poisoning. Whether this is the parents' defensive description rather than measurable fact is as yet unclear due to the absence of suitable prospective studies.

Children's play activity can be considered to vary with their location and supervision as well. Consider that the child who is playing alone in the upstairs bathroom or in the front room with grandmother's purse after seeing adults medicate themselves might be tempted to imitate these actions in their play with the real thing. Koumans believes this to be a significant factor in poisoning of young children.⁶ Since we are very much a pill taking culture, this certainly is difficult to rule out. A study of aspirin ingestion indicates that one-third of the ingestions took place in a very social play situation where several children shared pill-taking: an equal number of children did so at home during a time of illness where aspirin was made more accessible, and in a third group poisoning appeared to be symptomatic of chronically careless child rearing practices.⁷

This leads to discussion of family factors contributing to childhood poisoning. In our work, the majority of parents appeared to lag behind their children in understanding or meeting their child rearing needs. While reasons for this varied from parental immaturity to lack of training in child supervision prior to marriage, the entire family "sub-system" of attitudes, beliefs and practices about caring for children appeared involved. Moreover, many families at the time of

poisoning ingestion were further distracted by illness, moving or other life events that could only compound marginal awareness of children's needs for continual supervision during the dangerous pre-school period.⁸ Many one parent families find themselves so thinly stretched that this supervision is impaired.

"The case of 2½ year old Louise serves as an example. Louise ate an unknown amount of caustic bathroom sodium hydroxide. Despite her young age, mother recently divorced, had left her completely alone in the home for several hours while she ran an errand just before the evening meal. The child had been hospitalized many times for extensive corrective surgery for her burned esophagus."

Cultural factors surrounding the family life style may be important determinants of poisoning. It is well known that the storage of Kerosene in soft drink bottles for fire starting is extremely common in many Southern low income homes using coal or wood burning stoves. The complex problems of the urban poor lodged in ancient dwellings with peeling paint is another illustration of a type of poisoning that is linked to poverty and often to the inner city cycle of family deprivation, children left alone in depressing circumstances to deal with life as best they can, often hungry and neglected. An added factor concerning the hazardous agent must be included, since Dr. Byers of Boston stresses that lead paint and plaster may have a sweet taste that tends to add further attraction.

Recently on a Caribbean Island an epidemic of mysterious childhood deaths from poisoning was traced to the since-outlawed practice of supplying lethal insecticide in small brown bags as roach powder. Changing containers may make many dangerous chemical agents more accessible or attractive. Society clearly has not viewed its practices with a respect to their negative consequences. The tragic episode several years ago of an unscrupulous merchant selling toxic jet-plane fuel as cooking oil to unsuspecting families, many of whom were stricken or killed with the neuro-toxic materials, illustrates the backwash of negative effects on other cultures by the advanced technologic products of our own. This list can be extended indefinitely, not only in the toxicology field, but in other areas of childhood injury.

Family ignorance of chemical toxicity has been cited as an important contributor to childhood poisoning. In a recent study of parental attitudes and knowledge about poisoning, no significant difference statistically was discovered between the knowledge of mothers of poisoned and comparison children and selected for match by age of child, area of residence, social class and other variables.¹ Moreover, the overall quality of knowledge was good, as shown by the fact that 80% (42/52) of mothers knew that agents ingested were poisonous before the ingestion occurred. Most of the ingested chemicals were accounted for by aspirin, bleach and kerosene. When a wide variety of other household products was studied, a similar level of awareness was reported. Most mothers of poisoned children mentioned improved storage as a means of decreasing the incidence of poisoning. Mothers of the "comparison" group mentioned careful storage as a major reason for their children's safety from poisoning. Thus both groups of mothers agreed that careless storage was a major causation in childhood poisoning. When interviewers inspected the homes of both groups, no difference in amount of careless chemical storage was revealed, however. One of the study questions was the amount of storage change episodes. Only a few families made changes in other hazardous chemicals around the house to prevent recurrences (after the poisoning episode). Berfenstam's work further supports the widespread extent of careless chemical storage.²

These observations point up the need for formulation of a new poisoning control policy which does not depend largely upon environmental control and pamphleteering. Since hazards are virtually universal, yet continue to change as new products are brought onto the market, a renewed focus on child and family factors contributing to poisoning must be considered. The secondary importance of safety closures, cabinet locks and other control measures appears very evident when one realizes that it requires human motivation to replace caps, lock cabinets and place the hazardous substances out of children's reach. It then seems obvious that a direct approach to the sub-system of family attitudes, beliefs and practices is primary in poisoning control.

If poisoning episodes are merely symptomatic of child rearing and supervision lapses, as evidence seems to indicate, this implies that these areas should be the primary emphasis in attacking the problem. New methods must be designed for communication with children and families, as well as with parent substitutes who have the responsibility for young children. With an increasingly hazardous chemical world impinging on the home and community, a more effective approach

to poisoning control is imperative. While a great deal more information about the human aspects of childhood injury is required, the following prescription might be a useful step:

1. Recognition of the child life needs, particularly as they relate to those at greater risk from pica or the mouthing of non-food substances and the need for proper developmentally attuned stimulation during the pre-school years in order that susceptible children be given safer, more positive play experiences.

2. Improvement in the understanding of all family members and those who are given responsibility for young children in or outside the home, about the risks to young children as they relate to periods of family stress, moving, hunger and other times of greater "poisonability". While the traditional reliance on first-aid measures should be mentioned, it should be particularly used to emphasize the importance of primary prevention. Protection combined with education should be the predominate note in pre-school period.

3. Community de-emphasis of medication and other chemical attractions should be made, with parents taking care not to give too conspicuous an example of medicine ingestion for children to imitate.

4. Increasing child and family poisoning and other injury prevention should be included in the advice given to parents by all professional people. The children's physician, the community nurse, the pharmacist and all of us who are concerned with the quality of child life should join with parents of young children to control the poisoning problem.

Consumer education funding through poison control centers, pediatric hospitals and other qualified agencies should be provided.

5. Research about poisoning control must be advanced. Chemical packaging and other control measures should be evaluated scientifically, for effectiveness. Funding should be provided for this at the state and federal level. Society owes such protection to its children and families.

REFERENCES

1. Poisoning Report Data for Children Under Five Years of Age. National Clearinghouse for Poison Information Bulletin, Food and Drug Administration, 1968-69.

2. Storage of Poisons in the Homes of Families With Small Children. Berfenstam, R. and Beskow, E. Brit. J. Prev. Soc. Med. 16:3, 1962.

3. Oral Factors in Accidental Poisoning. Craig, J. O. Arch Dis. Child. 30:419, 1963.

4. A Study of Storage, Child Behavioral Traits and Mothers Knowledge of Toxicology in 52 Poisoned Families and 52 Comparison Families. Baltimore, C. L. and Meyer, R. J. Ped. 42:312-317, 1968.

5. Personality Characteristics of the Child Accident Repeater. Manheimer, D. I. and Mellinger, G. D. unpublished data.

6. A New Aspect of "Accidental" Poisoning in Childhood. Koumans, A.J.R. Ped. 25:1067, 1960.

7. Acetylsalicylic Acid (Aspirin) Poisoning. Meyer, R. J. Am. J. Dis. Child 102:17-24, 1961.

8. Accidental Injury to the Pre-School Child. Meyer, R. J., Roelofs, H. A. Bluestone, J. and Redmond, S. J. Pediat. 63:95, 1963.

Senator Moss. I appreciate your testimony very much. It was most interesting, Dr. Meyer. Your paper is an excellent one. We are glad to have that. I was interested in your feeling that our efforts at public education, trying to get over to people the need for safety, have not been particularly successful to date. They haven't reduced the incidence of poisoning. I wonder if, just having the requirement on a safe package and safe closure might not be a factor in bringing to the minds of the adults the need for surveillance and safety practices, as far as children are concerned.

Dr. MEYER. You must pardon my skepticism. I think the public will gradually be educated as they were in the '30's about immunization. The people resisted it then and gradually accepted it and now demand it for their children. I think we are now in the same era, where we must sell immunizing against injuries and poisoning par-

ticularly, and it will be just as tough a job. There is no easy way. I do feel the safety packaging effect on family life, and attitudes and beliefs and practices have not been measured scientifically. This is an area of information we lack. Unless someone else has better information, this would be a primary thing for this bill to fund and spell out and on the basis of that knowledge move forward.

Senator Moss. Well, assuming we don't have the definitive study facts yet, aren't you convinced, however, that we at least can reduce the poisoning considerably by requiring safety packaging and closures to meet at least some minimum standard?

Dr. MEYER. I would hope this might be so. Some of the work to be offered in evidence by Dr. Scherz suggests this is a very important area to pursue. I am very skeptical. The preschool child is clever and any scheme we provide for safety capping will have to be looked at very critically. I don't believe children that age can read. I have seen many safety cap efforts and poison labels and so forth—you were talking about safety symbols yesterday. One has to get into the human engineering aspect of this. To change the attitude of families, by putting labels on and safety packaging alone, is not going to do the job. I would agree completely with Dr. Done that I am not satisfied with 50 or 80 percent. I think this has to be a total approach and the bill can get us moving in that direction.

Senator Moss. Do you think the family would be unimpressed with a label and would not take the trouble to store the items where the children could not reach them?

Dr. MEYER. That is right. There is an increasing number of young, inexperienced parents who have not had responsibility; they come into a chemically loaded environment, with all of these attractive chemicals around. Look in the average kitchen. The average family has, in our studies, over 50 different chemicals stored around in the reach of children. I just don't believe that safe packaging is going to be that significant, but I think we have got to do it. I am in favor of all efforts to control the chemical world in which we live.

Senator Moss. Senator Cotton expressed some concern that perhaps we were getting into the field of advising families on child rearing. Basically what you are saying is that we need an educational campaign that does get through to the family, when you say we might make this as necessary as immunization now is in the minds of those who have children and get immunization for them.

Dr. MEYER. I would agree completely. The Government has been in the business of child rearing advice for a long time, when it established the Children's Bureau. The Children's Bureau in fact pioneered in a significant way for child safety, and has given advice to parents who need it. It is not a matter of thought control, but simply acquainting the parents with children's developmental tendencies. Many of these parents in our studies are not aware of the children's dangerous developmental tendencies to mouth things or of the toxicity of the products. The Government has a significant role in this already. It is up to us to show positive leadership.

Senator Moss. Well, you wouldn't discard, would you, the idea of labeling to warn the family, or some package that is harder to get into, even though it didn't give us 100 percent?

Dr. MEYER. This is an important step. I feel that for an increasing

number of young families, Spanish speaking families, for example, the labels might have to be in Spanish for example. We have to look carefully at the population we serve. And test whether these are really effective before we swing into a legislative network.

Senator Moss. Thank you very much, Dr. Meyer. We do appreciate your testimony and it has been helpful to the committee.

Senator Moss. Our next witness will be Dr. Murray Franklin, vice president of Hayes Albion Corp., Jackson, Mich.

Before we hear from Dr. Franklin, I have a notification that Mrs. Esther Peterson, President Johnson's first adviser for consumer affairs, who has a great interest in the subject of these hearings, has submitted a statement.

A large number of cases of child poisoning caused by household substances came to her attention during her term in office. She had hoped to be able to testify today to bring before us another statement in the interest of the consumers in having household products packaged in safe containers. But previous engagements have kept her away.

She has submitted a statement of her views for the record and strongly urges enactment of S. 2162. Further, she has submitted samples of a safety closure that have come to her attention and asks that I inspect it. Of course, she is not endorsing this container, but she does believe it shows what can be done in this field.

It is interesting that this particular safety closure can be used on aerosol cans, perhaps remedying some of the problems that Mr. Wolfstone brought to our attention yesterday.

This is the container that Mrs. Peterson submitted: It has spines on the top of the can, but if the lower ring is seized and held with the fingers, it will screw off. This is one more suggestion.

If we keep this American ingenuity going, we will find a safe one, I am sure.

(The statement follows:)

STATEMENT OF MRS. ESTHER PETERSON

I am Esther Peterson, presently legislative representative 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, Senator 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 re-design, re-structuring and re-setting 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 pot 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 five 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 & Drug Administration has had a Safety Closure Committee working since 1966. But it is under-

financed, under-manned. In almost four 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 life saver . . . 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.

**STATEMENT OF DR. MURRAY J. FRANKLIN, CORPORATE VICE
PRESIDENT, HAYES-ALBION CORP., JACKSON, MICH.**

Senator Moss. Thank you for waiting, Dr. Franklin. You may now proceed.

Dr. FRANKLIN. Senator Moss, ladies and gentlemen, I have a written statement which I would like to have submitted for the record. With your permission, sir, I would like to make a few extemporaneous remarks, because it now seems to me, after listening to other testimony, that there might be still another way in which our company might contribute.

Senator Moss. Thank you. Your statement will be in the record in full.

Dr. FRANKLIN. I find myself in somewhat a unique position of being the first company representative here at the hearing who is in a position of trying to promote and actively market a safety closure.

Hayes-Albion Corp. is a public company of medium size listed on the New York Stock Exchange. Its Med-A-Safe Division has as one of its products a product which has been mentioned here frequently in the hearings, namely Palm-N-Turn.

I rather got the impression from some of the testimony, particularly yesterday, that the problem of child safety was one of extraordinary difficulty. And perhaps of such difficulty that there was no immediate solution.

I should say to all of you that I am not a doctor in the sense of a medical doctor. My degree is in economics. But I think I have still some of the social sense that originally took me into this field.

We do not pretend that our particular product will solve all kinds of safety problems. What we do say is that it currently is on the market; it currently is being sold by such drug chains as Walgreen's and Cunningham's, and wholesale drug companies throughout the country. It is having success in reducing substantially the problem of child poisoning, particularly in the area of dry substances.

With your permission, sir, I would like to show you how these things work. I agree with other testimony that some children can do anything. But we have had enough experience now to know that it would have to be a superhuman little boy or girl to open these containers (Palm-N-Turn).

Senator Moss. Are these the Palm-N-Turn type?

Dr. FRANKLIN. This is the product called Palm-N-Turn. It is one of those types of products referred to yesterday as being a practical

solution to the problem. There are others on the market, and there are other types of products that also are practical.

First, I would like to see if you can open this product. I assume you haven't been——

Senator Moss. I haven't been coached on this.

Dr. FRANKLIN. Haven't been pretrained.

Senator Moss. Let me see if there are any directions on it. [Demonstrating.]

No problem on that.

Dr. FRANKLIN. Well, that is pretty easy. Let's see if this gentleman can open this. [Handing to staff.]

Now basically what this means is, that if you try to twist this product in any way, you simply cannot get it off. There are little cams and little notches. This vial is made out of polystyrene; this cap is made of polypropylene.

The chemistry of all this is far beyond me. But one is more rigid than the other. You simply cannot open this product.

I suppose that some child might be able to bite the thing off. We have had people stamp on them. We have had people cut them off with electric knives. But any consumer who can read (other than a child who cannot read) can see that this says on the top: "To open, press cap in palm and turn." This one is branded Walgreens. It even shows the direction in which the cap is to be turned. You simply hold it in your right hand (if you are right handed), you press it into your palm, and turn it slightly and off it comes.

Now, here is another container—so far here we have been concerned primarily with the drug industry in the sense of drugstores or drug-chain stores.

Here is another product which might be used in the proprietary market (demonstrating). This could be a bottle of aspirin or anything else for that matter. But again the same principle applies. As a matter of fact, it is exactly the same cap and exactly the same series of lugs, cams, and notches. Try this one. (Handing to Senator Moss.)

Senator Moss. Yes, same thing; palm it and turn it.

Dr. FRANKLIN. So, that is really all there is to it. I will submit samples of these for the record.

Senator Moss. Thank you. We would like to have them for the committee to look at.

Dr. FRANKLIN. Now, there are a few other comments that do not require my walking around the room. I know that the committee is concerned about the matter of cost and I would like to face up to this kind of thing. What I would like to offer now is merely an example, a classroom type of an example.

We do not intend to do this, but it is an example that will demonstrate the minimum nature of cost involved. Let us suppose that this particular 20-dram size (Palm-N-Turn is available in a complete series of sizes) was sold—and this is not the actual pricing, but it is in the area—let us suppose this particular size was sold for \$16 a thousand at the wholesale level. That would be 0.016 per unit. At the consumer level, that would be about 0.032, or 3 cents that the consumer might pay.

Now, just by way of illustration, and solely by way of illustration, let us suppose that we get exceedingly greedy; competition will pre-

vent us from doing that, but let's suppose that that were to take place and we doubled the wholesale price. So, now it is \$32 a thousand or 3 cents per unit at the wholesale level, or 6 cents a unit at the consumer level. We have now raised the price from 3 cents to 6 cents to the consumer. Or put differently, let us suppose we are talking about a \$5.95 prescription, such as I showed you in the beginning, versus a \$5.98 prescription. At that particular price range the demand would be almost completely inelastic.

Certainly I am sure that Mr. Snodgrass who testified yesterday would be willing to pay the extra 3 cents. And it is not an extra 3 cents. It is only an extra 3 cents because of the extreme example that I used in doubling the price to begin with.

Now, let me tell you a little bit about our marketing research activities. The marketing research activities that we have engaged in have been from the point of view of trying to find out what one had to do to get this particular kind of industry off the ground: because I think Palm-N-Turn has received more publicity than any other single product.

In the first place, we are now doing, as a result of our marketing research, a great deal of advertising. This will begin to break this fall. One will find this advertising in Parent's magazine and other magazines that appear, particularly to families with small children.

Our research has indicated this: That there is no more than 1 or 2 percent of the public aware of the fact that such a safety closure even exists. So, consequently the need is for education.

We simply have to somehow or other find a way, and no one company can do it by itself; we simply have to find a way to make the public aware that such a thing exists.

Call it marketing research or not, I have stood in the City Bank in Jackson, Mich., I have stood in the supermarkets, I have personally stood in drugstores, I have done some of these things myself, and I have talked to people who have small children and I have said "Do you know what this thing is?" They say, "well, it looks like some kind of prescription container."

Then I say, "Do you have small children?"

And they say, "Yes."

Then I say, "Can you take the top off?"

And then they say, "No, I can't; how do you do it?"

And I teach them, and then their eyes light up. Anyone who gets the idea is "hung," so-to-speak, on this type of product.

I am not here as a salesman [laughter]. I am here in an attempt to see an industry which we believe in get off the ground. Thank you for the laughter anyway.

Now, a couple of other comments I might make. Yesterday there was some testimony by the Glass Manufacturers Institute which we were very interested in. They are concerned primarily about participation in the matter of setting standards.

We would like to submit that our work has been primarily in plastics, not in glass, and, therefore, we would hope that those of us in our company and other companies like ours would have an opportunity to participate in the setting of standards.

Finally, I would like to make one other comment. This product, Palm-N-Turn came to us as a result of an invention of Mr. Peter

Hedgewick of Windsor, Ontario, Canada. This product has been licensed to us in the United States and we are its sole licensee for distribution and manufacture in the United States.

But Palm-N-Turn is being manufactured and distributed in Canada; it is being manufactured and sold by companies in Europe, and literally all over the free world.

I would say that many of these countries, particularly in Canada, are far ahead in the area of legislation and the setting of standards. Therefore, I would like to suggest that we put you in touch with the people in Canada who have had their experience so that this committee might benefit from at least one other country's experience with this type of product.

Senator Moss. We appreciate that very much. We would like to correspond with them or perhaps if possible have someone come down and talk to us who has had experience in safety closures, safety packaging, and particularly of the type that you have been talking about here, Dr. Franklin.

(The full statement and attachments follow:)

STATEMENT OF DR. MURRAY F. FRANKLIN

Palm-N-Turn safety vials are the invention of Mr. Peter Hedgewick of International Tools, Limited in Windsor, Ontario, Canada.

In early 1967, Med-A-Safe was appointed exclusive United States distributor of Palm-N-Turn. At that time, Palm-N-Turn safety vials were imported from Canada in limited quantities and made available to the drug store trade in the United States. Shortly thereafter, Med-A-Safe Incorporated was licensed to manufacture and distribute in the United States. Product is currently manufactured in Los Angeles, California and Whitmore Lake, Michigan by the Med-A-Safe Division of Hayes Albion Corporation.

To date, approximately 86 million Palm-N-Turn vials have been distributed to the drug trade and to the United States Government for prescription use. The General Services Administration and Department of Defense usage of Palm-N-Turn is in excess of 35 million vials. Twelve thousands of the nation's 52,000 drugstores have purchased Palm-N-Turn safety vials, including the following chains: Arnolds, Crown, Cunningham, Daylin, Gray, Haag's, Hook, Katz, Longs, Muir, Osco, Peoples, Reed, Skaggs, Steinway-Ford-Hopkins, Super-X, Thrifty Drug of Illinois and Walgreens.

In addition to the aforementioned channels of distribution, over one-and-a-half million Palm-N-Turn vials have been supplied to various pharmaceutical associations, schools of pharmacy, as well as to regional and national meetings of the American Medical, the American Academy of Pediatrics, etc.

Palm-N-Turn has been under extensive testing by Madigan General Hospital in Tacoma, Washington. To date, over 660,000 Palm-N-Turn vials have been dispensed in the Tacoma, Washington area with a 97% reduction in the event of accidental child poisoning. Colonel Robert Scherz, M.D., Department of Pediatrics, Madigan General Hospital, has published the results of this testing in *Pediatrics Magazine* (official publication of the American Academy of Pediatrics) as well as in the *Journal of the American Medical Association*.

It is estimated that more than 2.5 million cases of accidental child poisonings will take place in the United States in 1969. Pending legislation is evidence of the seriousness of the problem. Five hundred and ten Poison Control Centers operating in the United States are further evidence of the gravity of the problem. The price tag on operating these Poison Control Centers and the cost of professional man hours and equipment in dealing with accidental poisoning is astronomical.

It is unlikely that there is a perfect panacea for the accidental poisoning problem. Palm-N-Turn prescription vials, as well as other types and brands of child-resistant packaging, are proving that the accidental poisoning of children can be very significantly reduced.

Palm-&-Turn prescription vials have found ready acceptance at both trade and consumer levels; however, the ultimate success of any child-safe packaging is contingent upon public education. The Med-A-Safe Division of Hayes-Albion Corporation, as well as other manufacturers of child-safe packaging, are diligently working on various educational programs aimed at both the consumer and the trade. These programs can be compared to consumer education related to seat belts and other safety devices.

We have found that the pharmaceutical industry is ready and willing to provide child-resistant safety packaging to the consumer if the safety packaging will meet the following criteria: (1) It must be competitively priced with current packaging, and (2) It must fit in with present packaging processes. Palm-N-Turn meets these criteria.

Palm-N-Turn is currently available in 4, 7, 12, 16 and 20 dram sizes in both clear and amber. Palm-N-Turn is priced competitively with standard "unsafe" prescription vials. The Palm-N-Turn vial consists of an injection molded polypropylene cap and lugs that mesh with notches in a special polystyrene vial. To open Palm-N-Turn, put cap in palm, press against it (approximately 8 pounds pressure) and turn slightly. These motions involves motor skills that are quite simple for adults, including arthritics and the elderly, but pose real barriers to children five years and under.

Numerous manufacturers of over-the-counter drug and household products that are potentially hazardous are working in concert with our Research and Development Department to utilize the Palm-N-Turn principal on their products. Among these are: Bristol-Myers, Hoffman LaRoche, Procter & Gamble, Boyle-Midway and Drackett. A major analgesic manufacturer is currently testing Palm-N-Turn and other safety packaging on a proprietary line.

If it is the purpose of this committee to ascertain whether the consumer and the trade require safety packaging and are ready for safety packaging, the answer is overwhelmingly affirmative, based on our experience in the introduction of Palm-N-Turn safety vials.

We've just made it harder for your children to poison themselves.

Until now, it was almost too easy.

Almost any youngster could open a prescription container to get at the dangerously pretty pills and capsules inside.

Lots do. Over 250,000 children are accidentally poisoned this way every year.

Now you can make sure that even if your youngster gets his hands on the container, it will be practically impossible for him to get at the pills. Simply by making sure all your prescriptions are in Palm-N-Turn containers.

They're new. So child-resistant they're commended by the National Safety Council.



The caps are notched on the inside to fit over and lock into specially designed projections on the container.

To open Palm-N-Turn you have to put the cap in your palm, press against it, and turn.

It's easy for adults, frustrating for children. Their hands aren't big enough. They can't apply enough pressure or the proper coordination. (In a hospital test by the United States Surgeon General's Department, 369 out of 270 children, ages 1 to 7, couldn't open Palm-N-Turn to get at the candy inside.)

Palm-N-Turn is an extra service of pharmacies that care: about you, and your child's safety.

For 10 cents, we'll send you a sample. Use it for the pills you keep in your handbag or on the kitchen counter. The ones you sometimes forget to hide. Or send for several containers.

After this, though, you'll have to count on your pharmacist for Palm-N-Turn. And if he isn't using them as yet, send us his name. We'll take it from there.

Always ask for Palm-N-Turn, the safety container that makes it harder for your children to poison themselves. And a little bit easier to be a parent.

Palm-N-Turn®

Look for the green arrow.
It points the way to safety.



See for yourself.

Palm-N-Turn
Med-A-Safe Division,
Hayes-Albion Corporation,
Route 2, Whitmore Lake, Michigan 48189

Please send me _____ sample (s) of your Palm-N-Turn
safety container, at 10 cents each. (Limit: 10 per coupon.)
Enclosed is _____

And here's my pharmacist's name, so I can count on this
protection for all my prescriptions in the future:

(Name of Pharmacy) _____

(Address of Pharmacy) _____

My name _____

Address _____

City _____

State _____

Zip _____

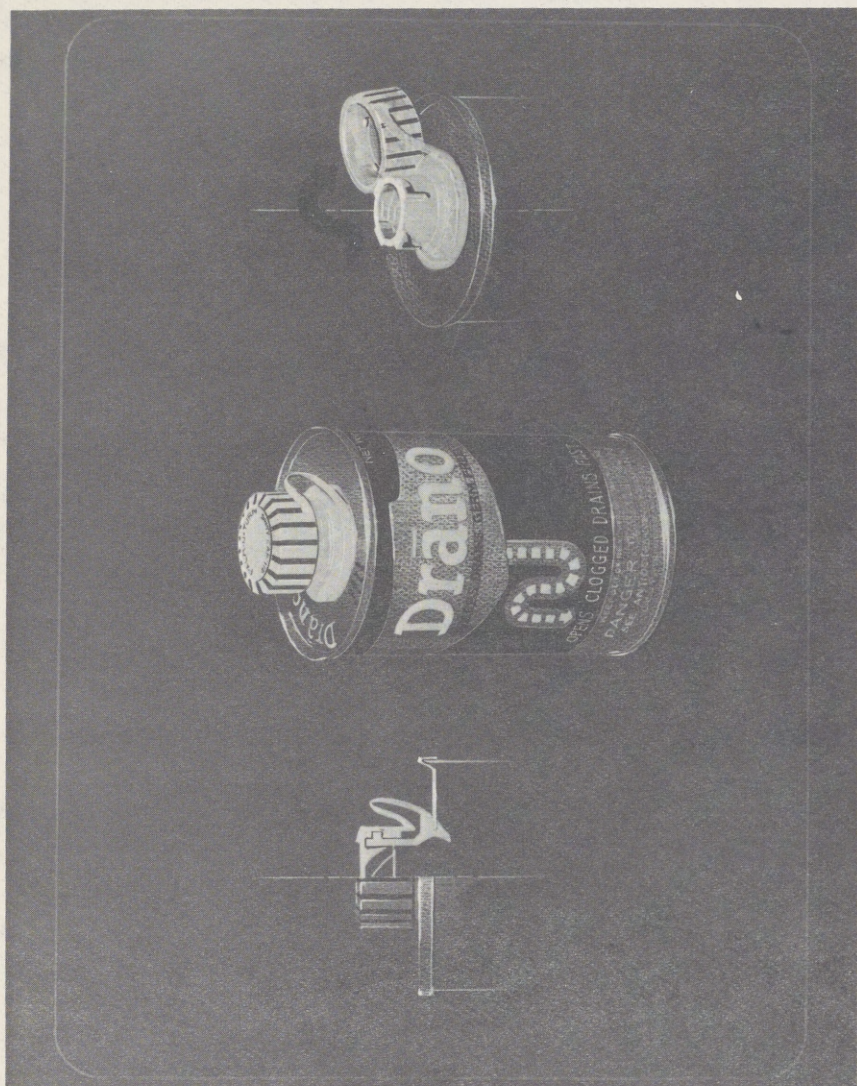
Check ☐

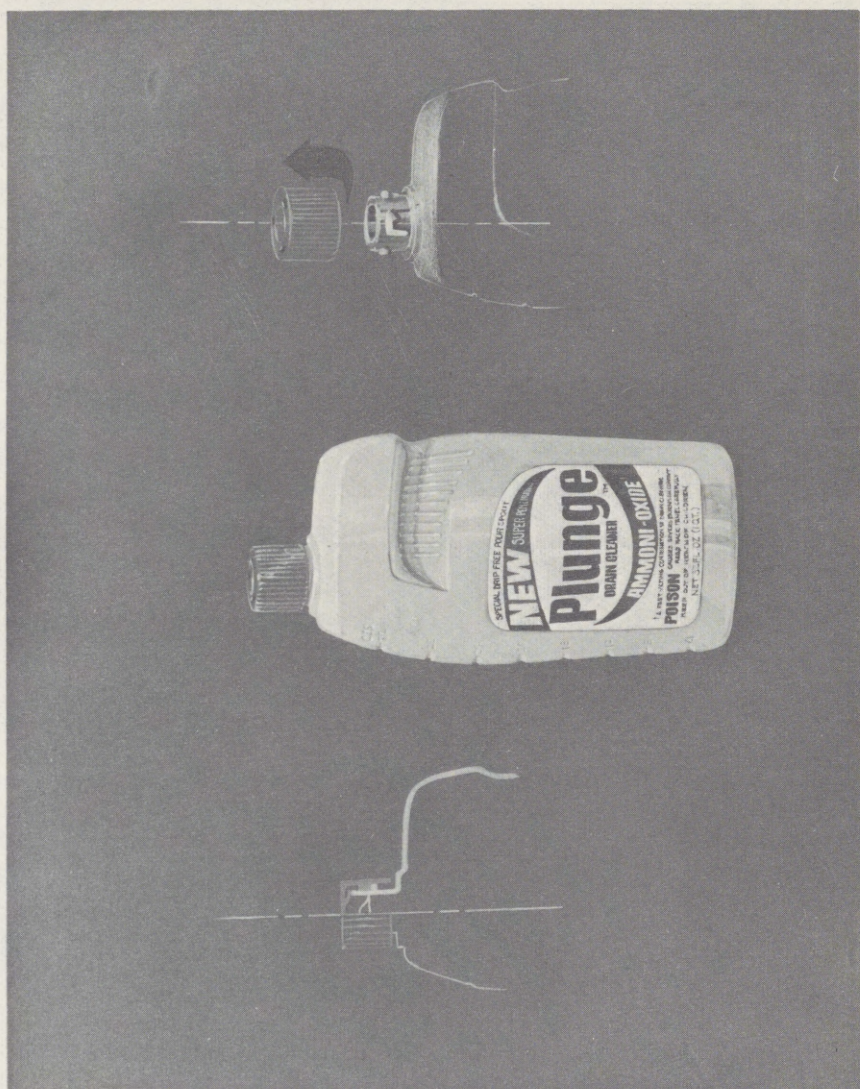
Cash ☐

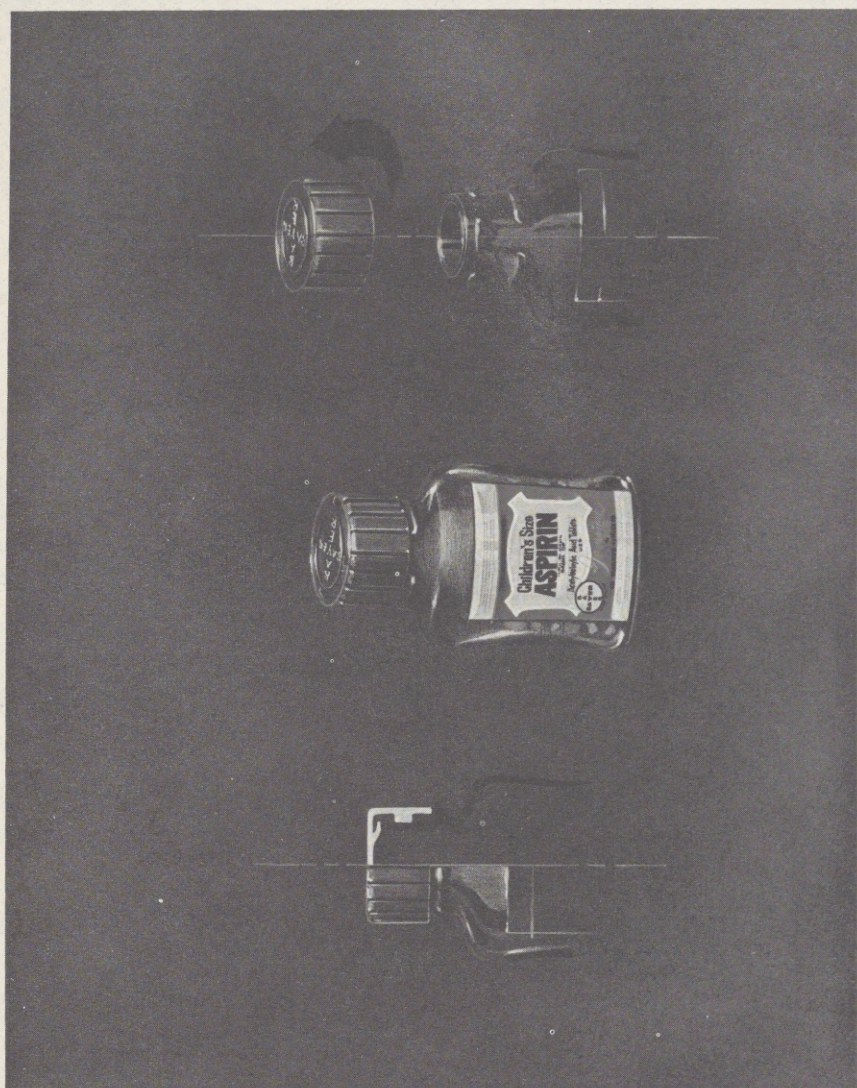
Money Order ☐

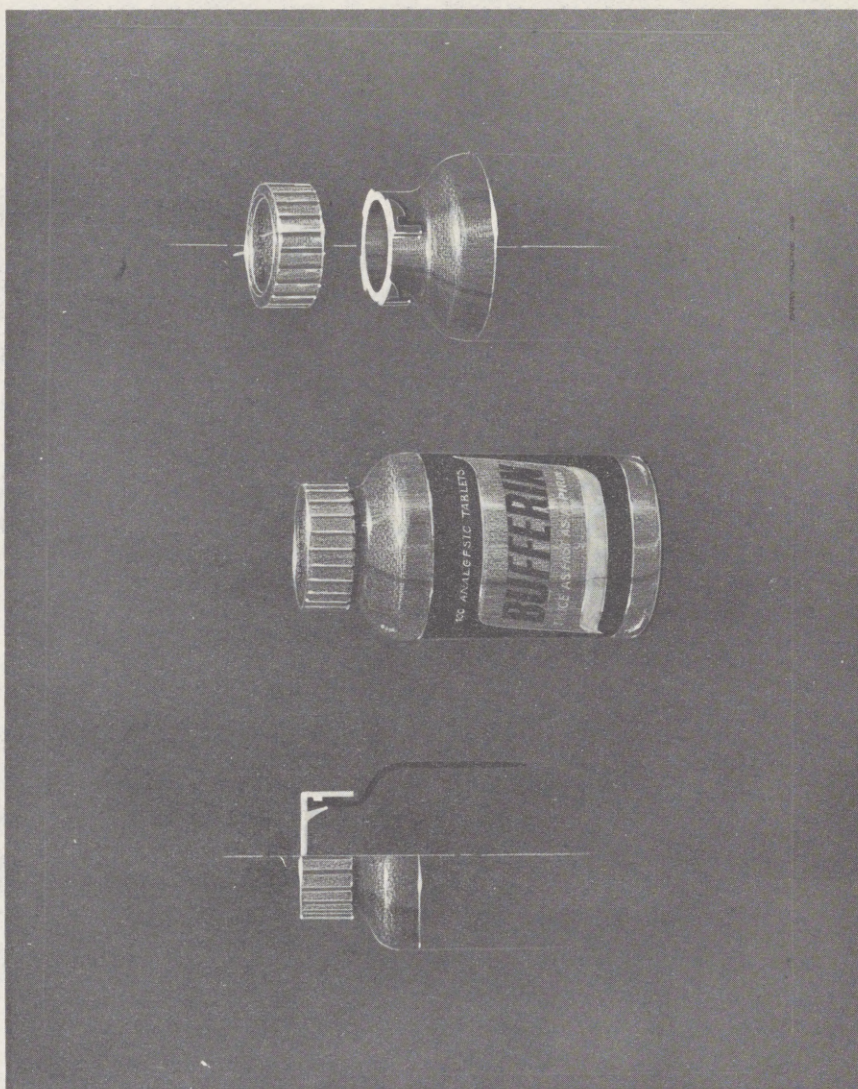
Ad. No. 8774 Full page
Parents Magazine Nov. 1969

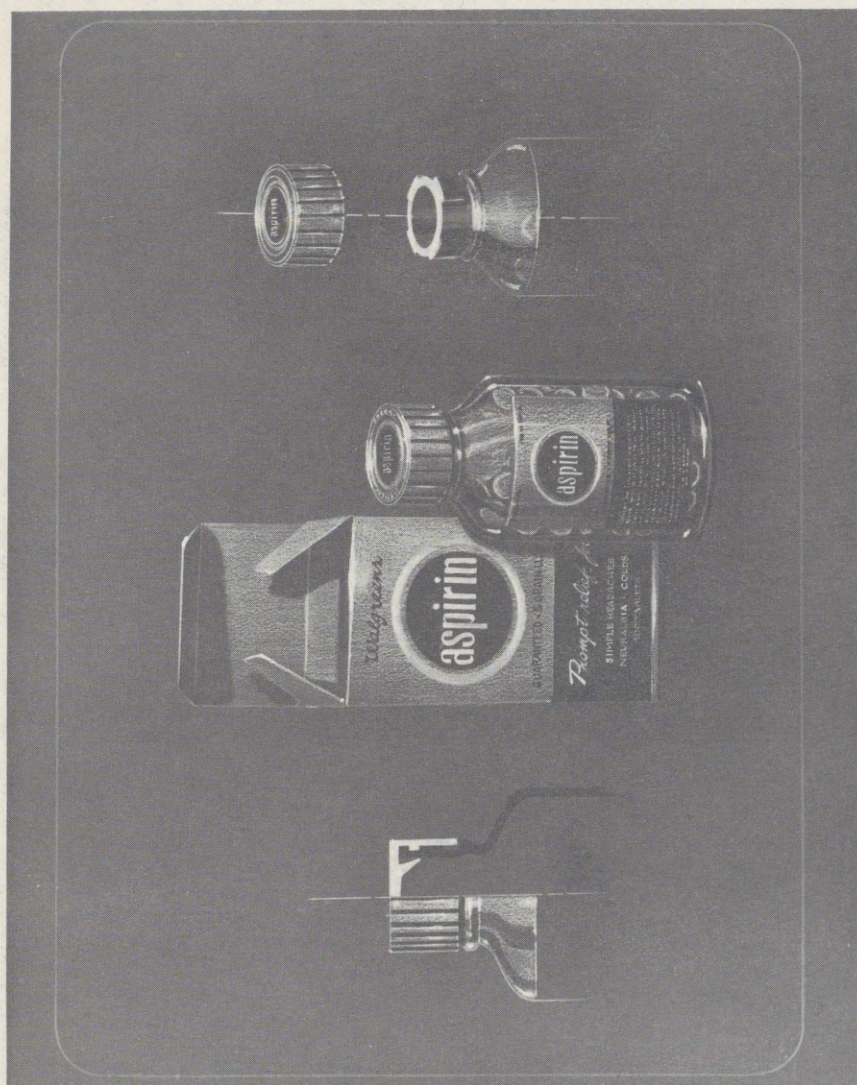
Prepared by
GUMPERT, BENTLEY & DOLAN
Advertising / Public Relations

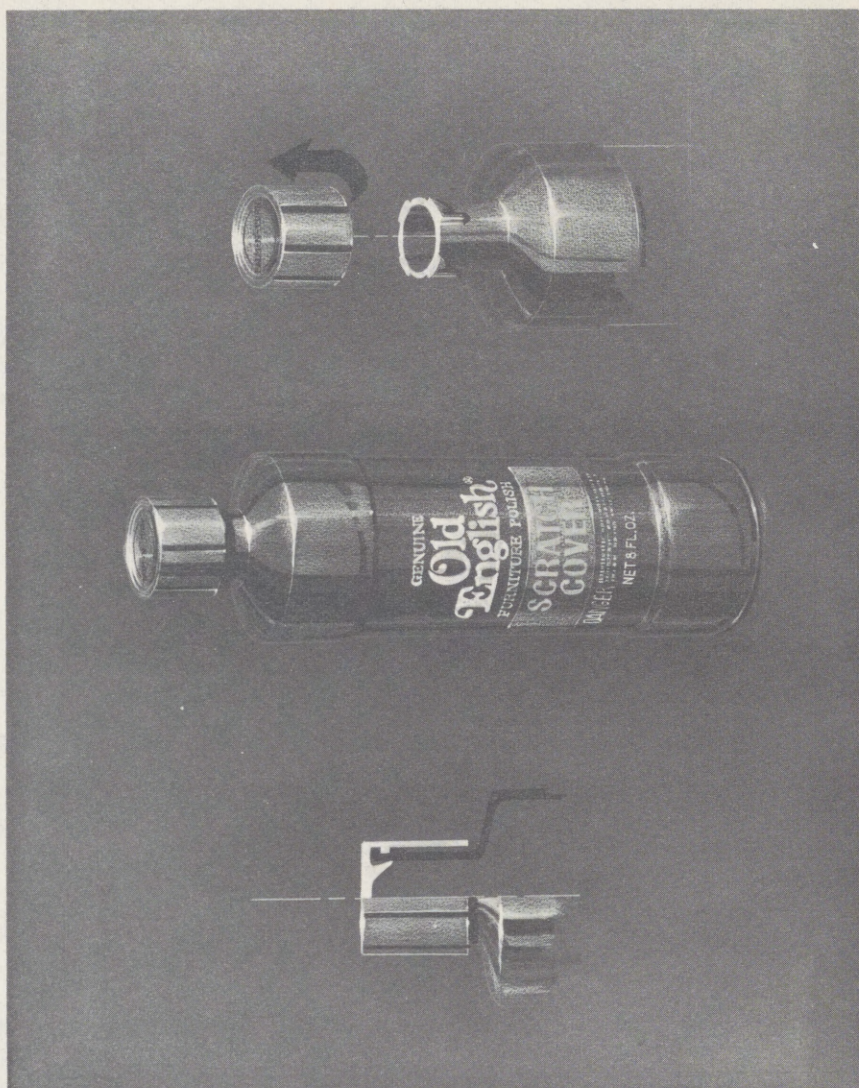


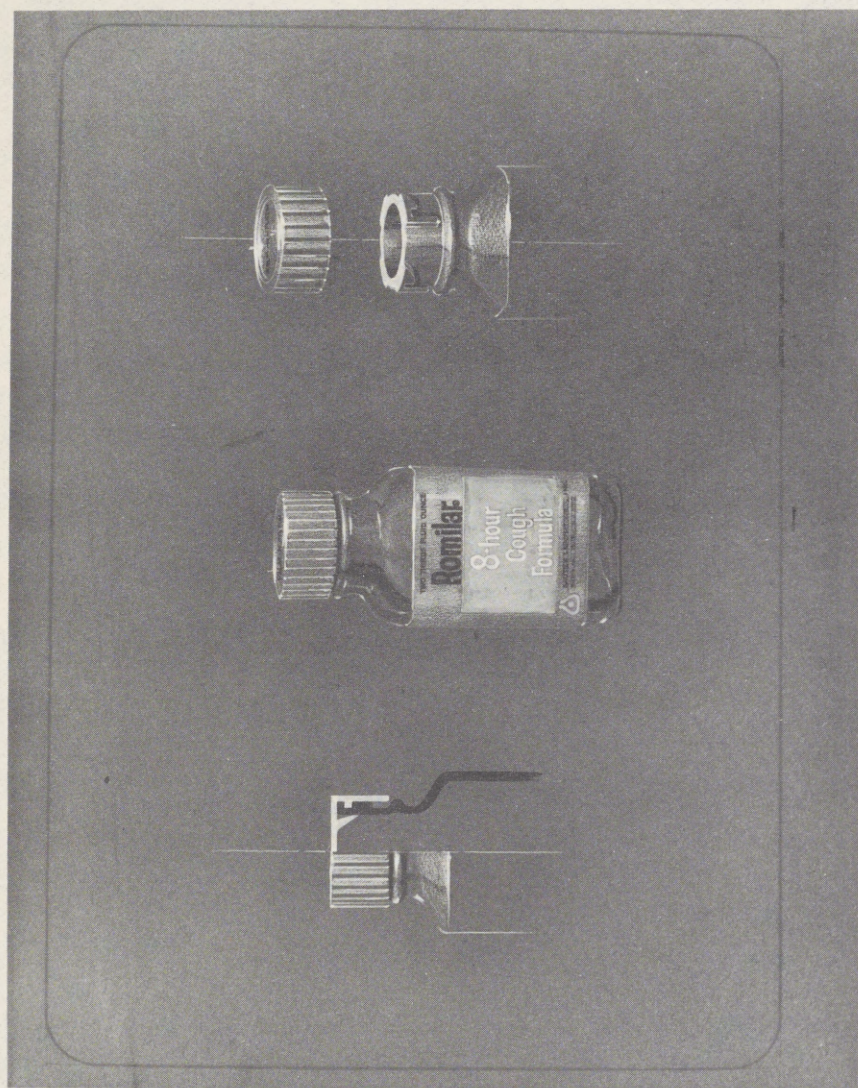




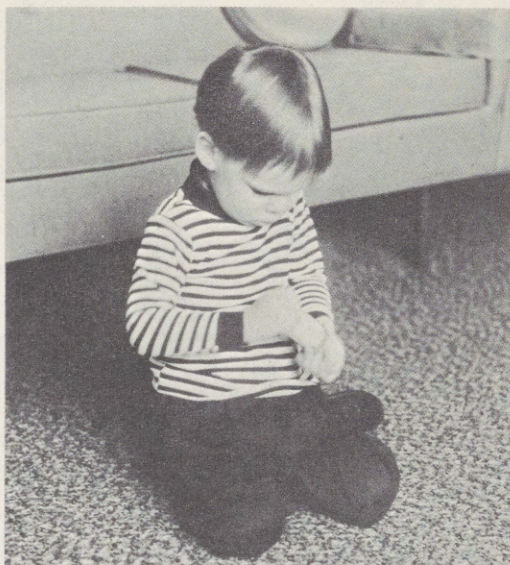








FOR ADULTS ONLY



*...The less kids knew about this
secret the healthier they were.*

We are accustomed to large doses of drama with our medical advances. Often cliff-hanging suspense grips the public when some new medical approach moves from the laboratory into the acid test of actual use—where statistics will tell us whether good results are due only to *chance* or can be generally expected.

One of the latest medical advances, in a sense, has been the reduction of accidental poisoning in the home, through the use of a new, unique child-resistant vial called Palm-N-Turn. Medical authorities estimate that some two million people each year are victims of accidental poisoning.

For generations the national toll of

fatal and non-fatal poisonings, especially among young children (accidental poisonings in the U. S. happens nine times out of ten to children under the age of five) has been a source of growing alarm and concern to doctors, especially pediatricians and other medical authorities.

It is a well-known fact that tots, fascinated with inviting pills left within their reach, gobble sedatives, stimulants, diet potions, etc. with the same zeal as they would eat gumdrops. Thus, a shocking number are killed each year by this commonplace accident. (The Los Angeles Herald-Examiner on May 4, 1966, quoted a leading authority that more children die from poison-

ing than from being hit by automobiles, or in swimming pool accidents. He said, across the nation about 500 children a day are given emergency treatment for poisoning!)

Apathy, coupled with the lack of excitement and awareness of the serious problem of child poisoning was, in fact, part of the reason the new prescription vial came into being. Although TV and other mass media contribute much time and space to airing the warnings, some get the message, but others don't . . . or think it unimportant.

One of the first medical authorities to take the bull by the horns and do something about it was Henri J. Breault, M.D., Medical Director

of the Windsor (Ontario) Poison Control Center, and a medical group in Ontario, who tried to get more results from the information method, mounting a very intense campaign in all media to build parental awareness. The campaign brought little or no reduction in accidental poisonings.

It was their efforts, after that disappointment, which led to development of the Palm-N-Turn vial through an international competition.

Tests utilizing the new vial resulted in a drastic reduction in accidental poisonings in a population of 275,000. During test periods in 1967 and 1968, there was only one failure of a Palm-N-Turn container for every 50,000 prescriptions filled.

The success of the Windsor, On-

tario tests prompted Lt. Colonel Robert G. Scherz, MC, USA, Chief of Obstetrics at Madigan General Hospital, Tacoma, Washington, to launch the first large scale U.S. trial on the new child-resistant container in May of 1967.

Madigan's first test was to be simple. Doctors decided to fill the child-resistant vials with candies and give them to 270 children ages one to seven, for 30 minutes. The result: 269 of the 270 children couldn't get at the goodies.

The real test, though, was actual usage. Records were set up and Madigan's pharmacy (which serves a community of 100,000 military people and their families) began dispensing every prescription in the vial.

The results were unbelievable!

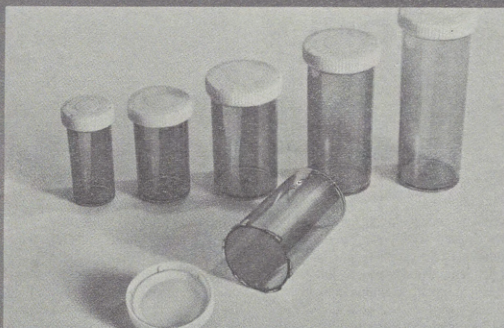
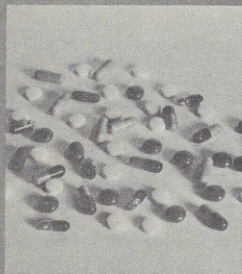
Childhood poisonings from prescription drugs were reduced by 92% during the period May 1, 1967 to October 1, 1968.

Poisonings from prescription drugs dropped from a 1966 rate of one for every 5,100 prescriptions filled to one for every 62,300 prescriptions.

Poisonings due to 1¼ grain flavored aspirin were reduced by 97% when the same Palm-N-Turn container was attached to packages of children's aspirin sold at the Post Exchange in the Ft. Lewis-McChord area, Tacoma, Wash.

In a progress report made by Lt. Col. Scherz and his associates the Army physicians made this statement: "No safety container will be a substitute for parental vigilance, however, it may give a parent a second chance, a chance the parent

"Taken as directed" these medications, prescribed and dispensed by competent professionals, can be life savers. Unfortunately they can also be deadly to curious tots if taken accidentally. It is estimated more than two million cases of accidental child poisoning will be treated this year.



Tests indicate that a significant reduction in the incidence of accidental child poisoning can be expected from the use of such containers as Palm-N-Turn containers, of course, with parental vigilance. Med-A-Safe Division now makes five sizes of vials and caps (above). Note the spring gasket and lugs on the cap, the notches in the vial.

is not afforded when the medication is dispensed in an obsolete, unsafe, easily opened container. It is our contention if child-resistant containers such as Palm-N-Turn were widely used we could expect an 80% reduction in childhood poisonings due to medication."

Plastic safety tops used on some children's aspirin bottles, Madigan physicians said, can be easily removed by children with teeth. (See part 2 of this story for progress in applying the new development to manufacturers' aspirin bottles.)

With Madigan results as a guide and other similarly favorable tests, the Defense Department is now utilizing this new vial in all military installations. The U.S. Public Health Service has also joined the fight for such safety packaging.



The secret of Palm-N-Turn: apply 12 pounds of pressure against the palmed cap and turn counterclockwise approximately 54 degrees. This sequence has proved frustrating to small children.

Palm-N-Turn is now spreading across the pharmaceutical world. And, its unique (patented) method of closure may shortly be used on other household products... even glass and metal containers for drain cleaners, furniture polishes, etc.

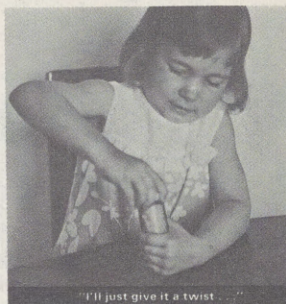
It is a standard FDA-approved styrene plastic vial with a polypropylene top. The Palm-N-Turn vial cannot be opened until two actions are taken together: the cap must be depressed with about 12 pounds of force (with the palm) while the cap is rotated counterclockwise.

The usual twisting or prying of which a child is capable will not open a Palm-N-Turn vial. The pliable plastic cap has lugs on it and when the cap is closed the lugs fit into the notches on the vial. Yet when you press the cap into the palm of your hand and turn it slightly it opens very easily and simply. By pressing it into your palm you depress a springy plastic disc inside the cap, freeing all lugs from the notches.

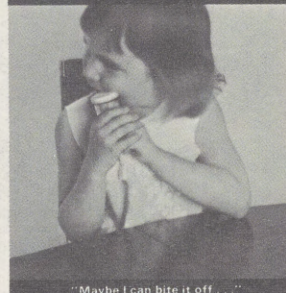
The simplicity is startling once the vial is examined and understood—but that only makes for practical manufacture and pricing.

It is strange that science, which generations ago invented bank vaults which could defy the most modern methods and equipment by professional burglars, only recently came up with a simple but unique prescription vial which a small child cannot open.

Palm-N-Turn is made by Med-A-Safe, which recently became a wholly-owned subsidiary of Hayes-Albion Corporation.



"I'll just give it a twist..."



"Maybe I can bite it off..."



"Can I smash it open?"

Palm-N-Turn not only stymies children, it also may present problems to un instructed adults. During testing, two adults were told to remove unmarked caps. After 30 minutes, the woman had resorted to sawing hers with an electric knife... the man had decided a hammer would do the job.



The new Med-A-Safe plant is located in Canoga Park, California. More manufacturing facilities are being planned to satisfy increasing demand.

Palm-N-Turn caps and vials are produced by rows of injection molding presses in California.

Just a few of the millions of Palm-N-Turn containers being shipped from Med-A-Safe's California warehouse. Shipments leave here in truckload or railroad carload lots.

AMERICA TAKES TO PALM-N-TURN TO FOIL TINY PILL TAKERS

When Carl Cooke and his staff at Med-A-Safe, now a subsidiary of Hayes-Albion Corporation, obtained an exclusive license from the Canadian developers of Palm-N-Turn vials to make and sell the safety container to the world's largest drug market—the U.S.—it was obvious the vial might save countless children's lives and drastically reduce the thousands of hours physicians spend yearly treating cases of accidental poisoning.

But it was easy to see that results would not be automatic.

Top manufacturing and automation capability would have to be developed, because if the container were ever to stand guard over all poten-

tially dangerous pills, it would mean producing hundreds of millions of containers each year . . . and cheaply enough to add little or nothing to present container cost.

Mass marketing and distribution techniques would have to be employed. It was obvious that demand by each level of the market would have to be created through education and sales promotion. Unlike a wonder drug, Palm-N-Turn's benefits must be projected to the consumer who in turn must demand that manufacturers of drugs and other potentially hazardous products utilize safety containers.

In the 20-odd months since Med-A-

Safe introduced Palm-N-Turn, the vial has received widespread acceptance from the medical profession as well as the public.

Today, Palm-N-Turn containers are being produced around the clock by high speed plastic molding machines in plants in California and Michigan. Efficiency is such that the vials are competitively priced with other conventional, easy-to-open plastic pill vials.

And marketing efforts have matched production in achievement, for a growing list of America's most important drug chains are dispensing their prescriptions in Palm-N-Turn vials, including: Crown-Shoprite, Cunninghams, Gray's,

Haag's, Hook's, Read's, Skagg's, Super-X, and Walgreen, as well as thousands of independent drug stores.

When success began to tax Med-A-Safe's manufacturing marketing and financial capacity, Carl Cooke and his staff might understandably have rested on their accomplishments. Instead they elected to link up with a strong company like Hayes-Albion, for many potential markets were still largely unserved.

At present a new facility is being constructed at Northfield, Michigan to add more capacity, and further plans for plants in other regions, later. The Northfield plant will be operated by Wolverine Plastics Division of Hayes-Albion and automated so that the vials are never touched from the time the huge plastic presses expel them until they are taken from the packages at the user's destination.

What about other products using the Palm-N-Turn principle? Med-A-Safe's research and development program includes working on the development of various glass, plastic and metal containers for proprietary drug and household products manufacturers. Currently, leading manufacturers of analgesics, cough syrup and household cleaners are testing Palm-N-Turn-type containers developed by Med-A-Safe for their potentially hazardous products.

Palm-N-Turn containers are now available in 4, 7, 12, 16 and 20-dram sizes, but the ultimate scope of the line is suggested by the fact that a bill presently in the U.S. Senate could make safety packaging a requirement for not only prescription drugs but a host of other potentially dangerous household products.

Observers say that an entire new field of safety packaging has been inspired by the introduction of the Palm-N-Turn safety vial.

March 15, 1969

Poison Prevention

Use of Child-Proof Drug Containers Urged In Military Pharmacies, PXs

Legislation Possible

Col. Scher suggested legislation to be introduced in the House of Representatives in January 1969.

Military pharmacies have been urged to use child-proof containers for the sale of over-the-counter drugs to the public. The use of child-proof containers is urged in military pharmacies, PXs and drug stores to reduce accidental poisonings in children's hands and to protect the health of the community.

The single vial of medicine is the most common cause of accidental poisoning in children.

New Medicine Containers Cut Child-Poisoning

Plastic Push-and-Turn Caps Help Keep Poisons Out of Youngsters' Reach

Recent studies have shown that the use of child-proof containers can reduce the number of accidental poisonings in children by as much as 50 percent.

The containers are designed to be used by children who are old enough to understand the danger of poisoning. They are designed to be used by children who are old enough to understand the danger of poisoning.

Poison Prevention Week in Progress

Many parents are encouraged to use child-proof containers for their children's medicine. The use of child-proof containers is urged in military pharmacies, PXs and drug stores to reduce accidental poisonings in children's hands and to protect the health of the community.

Child-Proof Bottles Seen Saving Lives From Threat of Poison

But the fight is whether doctors can prevent children from getting into the medicine bottles. The use of child-proof containers is urged in military pharmacies, PXs and drug stores to reduce accidental poisonings in children's hands and to protect the health of the community.

Palm-N-Turn Safety Vial Reduce Child Poison Cases

New bottles for medicine will reduce the number of accidental poisonings in children. The use of child-proof containers is urged in military pharmacies, PXs and drug stores to reduce accidental poisonings in children's hands and to protect the health of the community.

MEDICAL WORLD NEWS

"New Palm-N-Turn" Containers Bring Protection for Children

Containers in plastic, metal and glass will be used to hold medicine. The use of child-proof containers is urged in military pharmacies, PXs and drug stores to reduce accidental poisonings in children's hands and to protect the health of the community.

364-839 346

Senator Moss. Now, was your 3 cents just an illustration, or is that roughly in the area of the cost of this?

Dr. FRANKLIN. No, sir. That is simply an illustration. We could not possibly raise the price of the product that much nor have we any intention of doing so.

I would say that the added cost to the consumer might be something more like a cent or 2 cents.

We believe that the marketing of this type of product has to be done differently, or must be done differently.

Up until this point in time I think prescription containers have been simply packaging apparatus for the purpose of containing pills. We do not believe that we are selling packages to contain pills. We believe that we are selling safety and, therefore, we are marketing the product as if it were strictly a consumer product.

We are taking the view that this is like perfume or lipstick or a toothbrush or some other kind of consumer product. It is not simply something to contain pills.

Senator Moss. Is it suitable for a liquid, for instance, this type of closure?

Dr. FRANKLIN. We hope it will be shortly. It is not at this point in time.

Senator Moss. What about the question raised that, perhaps, elderly people or arthritics could not manipulate this Palm-N-Turn top?

Dr. FRANKLIN. Well, I would have to answer in this way: There are some people with extreme forms of arthritis. Such people will have difficulty with this type of product, whether it be ours or any other.

Senator Moss. Should such closures be mandatory?

Dr. FRANKLIN. We are not taking the point of view, and we do not believe the committee should take the point of view, that such closures be mandatory for every conceivable use. We simply take the point of view that these closures should be available or that this type of closure should be available so that a substantial portion of the consuming public can make use of them.

We do not want to suggest to any pharmacist that he be compelled in every single instance to use such a product. I think that would be a mistake.

Senator Moss. Has there been a rather general acceptance by pharmacists and others purchasing this kind of cap or is it still not widely accepted?

Dr. FRANKLIN. There has been some resistance. I think that it is a new product; it is a new concept. It takes some training and teaching, therefore it takes the time of a busy pharmacist to do the training and teaching.

We have reached the conclusion that we had to put the instructions right on the top of the container, as we are doing now. Originally we had a little piece of paper inside of the container which we found nobody bothered to read.

Senator Moss. They couldn't get into it to read it.

Dr. FRANKLIN. Well, there has been some of that; yes, sir. But I think this: That we have learned that it is a new product for us, a new industry for everybody. We have learned, as have our competitors, how to make the product better, and as time goes on, and the volume

increases, and we all benefit from each other, this product will be an even better one than it is today.

If I were to show you the earliest samples that we have, you might be surprised. What you saw this morning is commercially salable. I think all of our competitors would say the same thing.

Senator Moss. Well, thank you very much, Dr. Franklin. We appreciate your coming here and actually demonstrating before the committee the Palm-N-Turn type of closure. It is certainly one of the safer ones that ought to have the effect of deterring a good many children from getting into these bottles.

Thank you. You are excused.

It is now 5 or 4 minutes to 12 and I don't think we could adequately cover another witness, since we are going to have to go over into the afternoon anyway.

We have four very interesting witnesses yet to hear. So, the hearing will now stand in recess until 2 o'clock when we will hear the remaining witnesses.

(Whereupon, at 11:56 a.m., the hearing was adjourned to reconvene at 2 p.m., this same day.)

AFTERNOON SESSION

Senator PEARSON. The committee will come to order.
I believe our next witness is Mr. Cerny.

STATEMENT OF JOHN TALBOTT, EXECUTIVE VICE PRESIDENT, SAFETY PACKAGING CORP., HANOVER, N.J.; ACCOMPANIED BY S. HOWARD CERNY, COUNSEL FOR SAFETY PACKAGING CORP.; MARIO A. BENNETT, PRESIDENT; DR. EDWARD TOWNS, VICE PRESIDENT AND INVENTOR OF POP-LOK; WILLIAM PERKINS, VICE PRESIDENT, SAFETY PACKAGING CORP., HANOVER, N.J.

Mr. CERNY. Senator Pearson, my name is S. Howard Cerny. I am counsel for Safety Packaging Corp. of Hanover, N.J.

This company is exclusively concerned with safety packaging. It developed the safety package which was seen on the screen yesterday noon as Pop-Lok. It was also referred to yesterday by one of the witnesses as one of the two commercially feasible types of safety systems.

In the interest of brevity, we have condensed our testimony and will present only one witness, Mr. John Talbott, executive vice president.

Nevertheless, we have Mr. Mario Bennett, the president of the company, Dr. Edward J. Towns, who is the inventor of the Pop-Lok, and its vice president of engineering, and Mr. William Perkins, the vice president of marketing, here to answer any questions the committee might have.

I would like to introduce to you Mr. John Talbott.

Mr. TALBOTT. Mr. Chairman—

Senator PEARSON. Mr. Talbott, let me indicate to you, it is rather uncertain, but there may be a vote within the next hour, in which case we will be interrupted. But let's proceed.

Mr. TALBOTT. Thank you.

Yesterday there was a conflict in the testimony as to whether a safety

package in fact exists, and if so, whether the same is commercially feasible.

Gentlemen, I want to go on record here and now and state that a safety package does in fact exist and is not only commercially feasible, but is actually in production; that safety package is Pop-Lok.

I would like to hold it up and show it to you, sir. This closure was designed and perfected in the absence of any mandatory guidelines. However, we did take careful cognizance of Dr. Turk's 18 guidelines to safety which were presented at the 1966 committee hearings. After careful screening we retained a firm that we believed to be the most qualified to prove the efficacy of our product. This is the same firm referred to by Mr. Sullivan yesterday, namely, Foster D. Snell, Inc., a subsidiary of Booz, Allen and Hamilton. We retained them about a year ago for this purpose.

We have attached to our prepared statement the entire Foster D. Snell report, received August 29, 1969, which proves that Pop-Lok is 100 percent child-proof, based upon test procedures developed by Foster D. Snell, Inc., over a period of 1 year. Equally as important, the tests revealed 100 percent adult accessibility through age 60.

It will be of interest to the committee that even after being shown how to open the container, children could not do so—a truly 100 percent child-proof container. No instructions or demonstrations whatsoever were given to the adults other than printing on the container itself.

We also think noteworthy the fact that Bristol Meyers has selected Pop-Lok for a market test on Bufferin, one of this country's foremost analgesics.

The testimony yesterday established conclusively the need for safety closures for liquids as well as dry products.

Therefore, the committee should know that Safety Packaging Corp is currently testing a limited-dosage type of liquid safety closure, adaptable to household products like furniture polish, lye, bleach, and many other potentially dangerous products.

I would like to comment just briefly on price. It was said by a gentleman yesterday that the price on some safety closures are estimated to range from $\frac{1}{2}$ to $1\frac{1}{2}$ cents.

In our case, the prescription vial which is before you will be only fractionally higher than a nonsafety container of a similar nature. However, our liquid safety closure, in most cases, will be considerably less expensive than current closures which are nonsafety.

Figures were given to us this morning that indicate in the average household there are about 150 potentially dangerous products. Even if we take the middle cap cost estimate of 1 cent, it is evident that the American public could buy safety for their household for only \$1.50. We think this is a very significant factor.

In conclusion, we know of no reason to further delay the passage of the proposed legislation, and we offer our full cooperation to achieve this objective.

Senator PEARSON. Mr. Talbott, what is the lifespan or usage of this product?

Have your tests included not only the security of the top itself, but as to its period of usage?

Mr. TALBOTT. Sir, I would like to defer that to Dr. Towns, the head of our engineering department.

Dr. TOWNS. We tested that over a period of 250,000 bends and we have yet to get a failure.

Senator PEARSON. The safety mechanism on the liquid is similar to this? Would you like to describe it in its present form?

Dr. TOWNS. The present form of the liquid safety closure, sir, is a permanently attached closure to a bottle, which allows only the flap to be opened and a limited dose to be taken out of the bottle at a specific time.

We have a model of it here, sir.

(Showing model to Senator Pearson.)

Senator PEARSON. Mr. Talbott, we will keep this as an exhibit if it is your wish and in like manner insert this particular device. You made references in your testimony to the entire Foster D. Snell report. We will make that not a part of the record, but a part of the file.

Mr. TALBOTT. Thank you, Mr. Chairman.

We also have a model of our Pop-Lok, not on a prescription vial, but on a proprietary type package. I would like to submit that also.

Senator PEARSON. You made a reference to cost.

Would you like to enlarge on that point, as to these devices?

Mr. TALBOTT. You mean specific information?

Senator PEARSON. Yes.

Mr. TALBOT. I would like Dr. Towns to answer that again.

Dr. TOWNS. The liquid container closure that you have in front of you, on a nonremovable unit, is approximately .3 mils less than the normal snip-top closure found, in say, a bottle of liquid detergent. On an average it is within 2 to 4 mils across the board on our whole line of closures. Difference in price is sometimes above, sometimes below, the present costs of closures.

Senator PEARSON. You made some reference to the fact that children, when instructed as to their use, could not open this particular top. Not adults. And then I recall you said up to 60 years old.

Is there any problem for the elderly people?

Mr. TALBOTT. That was simply to demonstrate, sir, that the limits of accessibility go up to fairly elderly people, indicating that the great mass of people would have no difficulty in opening the closure, provided they can read.

Senator PEARSON. This has been very interesting.

We thank you, very much.

Mr. TALBOTT. I have omitted one thing I would like to have on the record.

When I said we are already in production, I neglected to state we have a firm, bona fide order in our possession for 25 million caps and vials. So, the business has actually started.

Senator PEARSON. Fine.

We are very pleased to have Lt. Col. Robert G. Scherz as our next witness.

Colonel, would you come forward.

Colonel Scherz is the Chief of the Pediatric Service at Madigan General Hospital, Tacoma, Wash. We are pleased to have you, sir. We have a copy of your statement and you may proceed as you desire.

STATEMENT OF LT. COL. ROBERT G. SCHERZ, CHIEF, PEDIATRIC SERVICE, MADIGAN GENERAL HOSPITAL, TACOMA, WASH.

Lieutenant Colonel SCHERZ. Thank you for inviting me here, Senator.

I must preface my remarks by saying although I am employed by the U.S. Army and have been for the last 15 years, I don't come as their representative nor does anything I say today have anything official in its connotation as an expression of official opinion or thought by the Department of the Army of Army Medical Corps.

I come to this hearing as a pediatrician who has been quite interested in problems of accidental poisoning, as a pediatrician for the last 13 years and most earnestly during the last 3 years, since being stationed at Madigan General Hospital.

(Slide.)

For a matter of orientation, to where Madigan General Hospital is for the Senator and staff, and also to be of some help in trying to understand what I will say a little later, I would like to let you know what our situation is there and what the circumstances are about it that make it an area suitable for study of poisoning and poisoning problems.

Madigan General Hospital is located a few miles out of Tacoma, Wash., as indicated on this map. That circle about the map encompasses a large population of servicemen and their dependents.

The number of patients that we serve in the total northwest area is approximately 100,000. Within a 6-mile radius live the majority of the patients served by Madigan General Hospital.

Madigan General Hospital itself sits in the middle of two large housing areas. In the housing areas are 4,500 families, Air Force and Army, within a 3-mile radius of the hospital.

If one extends the radius out another 3 miles it encompasses a larger number of lower ranking servicemen and their dependents, and a larger number of retired personnel, who live in civilian housing close to Fort Lewis and McChord Air Force Base.

Madigan General Hospital is the closest medical facility for the majority of the children we see in this area. Approximately 6 miles away is another hospital, approximately 12 to 14 miles away are two other hospitals, Tacoma General Hospital and St. Joseph Hospital.

Another hospital, again approximately 12 miles away, is the Children's Hospital. This seems a little redundant or superfluous to mention these distances, but it is important to us because in our experience when a mother has a child who has taken something poisonous, her tendency is to look toward the nearest medical facility, be it military or civilian to provide care for her child.

I also have extended myself into the community in a variety of ways. I am a member of the Pierce County Pediatric Society, and the liaison officer between the Pierce County Medical Society and the Pierce County Pharmaceutical Society. I am a member of the Pierce County Poison Information Committee. I also acted as an adviser in establishing the Pierce County Poison Information Center.

I have engaged in these activities primarily so I would have both a bird's-eye view and a very in-depth view at times of the poisoning situation in the civilian community surrounding Fort Lewis. Pierce

County, of which Tacoma is the center, encompasses a population of approximately 385,000 people. In that county at the present time are 14 practicing civilian pediatricians. I know each one on a first-name basis—they know of our studies at Madigan and are a source of information regarding military dependents who seek care from them for poisoning accidents. Madigan General Hospital provides complete medical care for the dependent child. We experience approximately 2,000 deliveries, 60,000 outpatient visits, and approximately 1,500 admissions to our hospital annually.

If one includes the pediatricians on the staff, the residents and interns, we have at varying times 15 to 20 physicians engaged in the practice of pediatrics at our hospital, caring for dependent children.

(Slide.)

During the 12-month period of May 1, 1966, to April 30, 1967, 382 children came to Madigan General Hospital for treatment of accidental poisoning.

We have no idea how many phone calls were made to the hospital and what kind of advice was given over the phone.

These figures represent bona fide visits to the hospital. Also during that time we had 48 hospital admissions for accidental childhood poisonings.

The majority of the poisonings that we saw at Madigan General Hospital during that 1-year period were from medications. Aspirin was at the head of the list (119), prescription items accounted for another large group of medicines (93), and other medicines which included proprietary products other than aspirin accounted for 49.

In addition to poisonings from medicines, we treated 97 children for poisonings from household products, petroleum products, and pesticides, with 34 children requiring treatment for poisonings from a variety of other things.

The problem of childhood poisoning at Madigan General Hospital made quite an impact on me. For a period of 5 years prior to going to Madigan General Hospital I was at Walter Reed General Hospital where the type of patients I saw was primarily a referral practice. There were fewer numbers of children with acute outpatient problems.

When I arrived at Madigan General Hospital in 1966 they were having 30, sometimes 40 and even more, childhood poisonings a month. My staff and I investigated a variety of pathways to see if we could find something that would be helpful in reducing the numbers of accidental poisonings.

I won't recount all of the things that we did, but I will say we did most of the traditional things, including public education through pamphlets, posters, and displays, conferences with the parents, and sending Army health nurses into the homes for consultation after a poisoning accident.

We also tried something else that one would not be able to try in a civilian community. For a period of time each poisoning involving a dependent of a serviceman was officially noted. A letter from the commanding general of Madigan General Hospital was sent to the serviceman's commanding officer in effect telling the commanding officer that he had among his troops a father who really was not a very capable person; that he allowed the child to become poisoned. (Sample of a letter is enclosed.) We didn't say that exactly, but that was the intent.

In addition to that, we invited the father and mother to make an appointment with the commanding general of the hospital. The commanding general would take the position of a stern father, and tell these two people, usually a young couple, that they were remiss, they should change their ways, and keep their children from becoming poisoned.

I might say that instead of poisoning rates decreasing with this technique, they actually increased.

(Slide.)

Senator PEARSON. Did they continue the practice thereafter?

Lieutenant Colonel SCHERZ. We discontinued that practice, because we found it was not effective.

I point that out because one of the questions that some critics have of our safety container study, is that the reason why we were having fewer poisonings was that the individuals were embarrassed to come to the hospital for care, and thus admit that their child had opened a safety container. They then, in effect, went someplace else. The extreme attempt we made to impress parents of the seriousness of allowing their children to be poisoned by contacting the serviceman's commanding officer and a subsequent interview with the hospital commanding general did not reduce poisonings. This situation would seem much more embarrassing than an admission that a child opened a safety container.

Along that line of reasoning, we have kept our finger on the pulse, you might say, of the medical community surrounding Madigan General Hospital. During the last 29 months not a single child has been admitted to a local civilian hospital or been treated by a Pierce County pediatrician for a poisoning from a pharmaceutical tablet or capsule dispensed by our pharmacies in a child-resistant container.

Senator PEARSON. Doctor, let me interrupt you. In the law there is a concept relating to the attractive nuisance. It imposes upon that person who may have a pool in their yard or some similar danger, proper and useful in all other regards, a greater burden to protect those who might be attracted to it. The pool in the yard being the best illustration.

Is there in the psychology of those who have been victims here, children particularly, something particularly attractive about the medicine cabinet as a forbidden place that attracts them there? Or the use of medicine that they see their parents take and, therefore, seek to imitate what they do? Is that part of the matter that has been studied by you?

Lieutenant Colonel SCHERZ. It hasn't been studied by us, but I think logic would tell us there are situations—I think a common thing is the sale, for instance, of little doctors' and nurses' kits that contain candy-coated pills. The child takes the candy-coated pills and might well transfer that thought about the candy-coated pills to what his parents might be taking.

How many times that resulted in poisoning, I can't tell you, but certainly there are attractivenesses about tablets, such as the coating, and color, that may in fact influence the number of childhood poisonings.

Senator PEARSON. And forbidden places?

Lieutenant Colonel SCHERZ. Yes, that may be part of it. I will say

most of our poisonings that we were able to tabulate, the poisons were not in a cabinet in the home, but were in another storage place. A very frequent place for medications was a high shelf in the kitchen.

Senator PEARSON. In those cases dealing with pesticides—and I have done a great deal of work on this some years ago with Senator Ribicoff—in those cases where poisoning resulted from pesticides, was it a misapplication of the pesticide, or was it a case where a particular pesticide had been left where a child could get hold of it?

Lieutenant Colonel SCHERZ. In those cases I am referring to here, sir, the child got into it, rather than situations where the pesticide was sprayed on the child. Our local experiences have been primarily with pesticides ingested by children.

I have excluded from our study situations such as a child who came in for treatment for inhalation of smoke or mercury vapors; things of that type.

In the fall of 1966 we thought that another approach to the problem should be taken. Pharmaceutical items over which we had greatest control were dispensed in containers that were easily opened by young children. In the fall of 1966 the containers in use by our pharmacy for tablets and capsules, were plastic vials with plastic caps that were easily removed.

We tested these containers. Since there were no standards, we developed our own standards for testing and found out of 120 children, 119 of them could not open containers of this type without any trouble. The age group we studied ranged from 9 months of age up to about 11 years of age. And the one exception out of 120 children tested was a 22-month old child who opened the unsafe container with no difficulty after one demonstration. This type of container was not a significant barrier to young children.

The children treated at Madigan during the pretest period were a relatively young age group. I selected 100 consecutive childhood poisonings taken at random from the records.

Two of the children were under the age of 1 year, 94 concentrated between the ages of 1 and 4 years, with four children over the age of 4 years.

So when we searched about for a child-resistant container, we were looking for one that would primarily resist the attempts of young children to open it; those who would be 4 years of age and under.

(Slide.)

We did a number of informal screening tests of safety closures available in commercial quantities. In 1966 we did not find more than five or six that were available in large quantities—or seemed suitable for further testing. One container seemed appropriate for further testing. This particular container was available only through Canadian markets, at that time.

(Slide.)

The types and methods for testing this container are detailed in the written statement. We have tested 500 children ranging from the age of 1 year to 11 years of age.

In summary, the children, particularly under the age of 4 years had a great deal of difficulty getting into this container. Once the child reached the age of 7 years, better than 50 percent of them could open it with very little prodding. This container was then used in two large

clinical studies—both studies are still in progress; the results thus far have been excellent.

What have been the results of the use of this particular container on our poisoning rates at Madigan General Hospital during the last 2 years? We started using the containers for pharmaceutical tablets and capsules in May of 1967 and are continuing to use them today. The total poisonings decreased in the first year period from a previous period of 382 down to 259 the first year, and in the second year, ended April 30, 1969 we had 162 poisonings from all causes. Total poisonings from medications decreased from 251 during the preceding year to 175—the first year of use—and 108 the second year of use.

Regarding poisonings from prescription drugs. We had 93 in the pretest year; after the first year of use, 49; and in the last 12 months of this study, 26. The most striking decrease in poisonings from pharmaceuticals were from those items that would be normally dispensed in the unsafe plastic snap-top closures. Sixty-seven poisonings occurred from medications dispensed in them during the pretest period.

We stopped using the plastic snap-top closure on May 1, 1967. However, that year we had 27 poisonings involving plastic snap-top closures.

I can explain this best by offering a brief analogy. If one has the hot water running, turns it off and turns on the cold water, it will be a short period of time while the water is in the spout, when there will be some warm water coming out. This is a fact of what we found. Eleven or 12 of the poisonings from pharmaceutical tablets and capsules during the first year of use, dispensed in plastic snap-top containers, were from containers that had been issued from Madigan pharmacies prior to the use of the child-resistant containers. They sat on shelves at home waiting for young children to ingest their contents. The others accounting for the total of 27 poisonings from plastic snap-top containers were from unsafe plastic snap-top vials dispensed either by civilian pharmacies, or from other military pharmacies. During the second year of use, there were only seven poisonings from plastic snap top containers. All of these were from other military or civilian pharmacies.

The first year of use we had five poisonings involving the child-resistant containers and in the second year of use we also had five poisonings involving child-resistant containers.

(Slide.)

Senator PEARSON. Was there an increase in cost in this child-resistant container?

Dr. SCHERZ. The cost to Government the first year we estimated an increase of \$200, that was for 270,000 containers. It was an increase in cost of approximately a tenth of a cent per container.

To bring you up to date to October 1, 1969, we have dispensed now 660,000 of these containers through our pharmacy. We have had 13 poisonings involving the child-resistant containers, with a poisoning/container ratio of 1 to 50,700. We were able to determine, based on numbers of poisonings treated at Madigan and the number of old style containers dispensed in the 1-year pretest period, that we could expect to treat one child for accidental poisoning from pharmaceutical tablets and capsules for each 5,100 containers of the older style dispensed.

The change in poisoning rate from pharmaceutical tablets and capsules has decreased 90 percent, or expressing it another way, we have had one-tenth the expected poisoning rate by using this particular container to dispense prescription tablets and capsules. [Slide.]

We have purposely biased our study against the value of child-resistant containers by our definition of failure of the container to prevent poisoning, by including all pharmaceutical tablet or capsule prescriptions dispensed in a child-resistant container and subsequently returned to our hospital in the form of accidental childhood poisoning "failures." We are not talking always about product failure. Out of the 13 containers involved in poisoning to date, only five children actually opened the container. One was trained by the mother to open the container, one child was old enough to read, read the instructions, and opened it. A 2-year-old opened it by random trial and error. And two children pried off the top with their teeth. On the other hand, eight of the 13 poisonings occurred because somebody along the way had violated the safety factor built into the container. The average age of the children who got into the containers under these circumstances was the same as the average age of children involved in poisonings from other causes (2 years, 5 months).

The average age of children who opened the containers was over 4 years (4 years, 3 months). However, in spite of the parents or adult usually who did not properly use the safety container and involvement of that container in the poisoning, there still has been a 90 percent decrease in the total poisoning rate. It is our opinion that if we were able to influence parents to use this container properly; helped with certain changes in design which we have suggested to the manufacturers, we would expect to see an even lower number of "failures," failures of the product and proper use by adults. [Slide.]

I might say also that this is not a clinical study unique to this country. There is another study that has been going on in Canada; it preceded ours by approximately 3 months. This is a study done in Essex County, Ontario, headed by Dr. Henri Breault. Dr. Breault has been quite active in poison prevention work. He works on a full-time basis in this area. There are many contrasting differences between Dr. Breault's study and our own. We have a military population, young families, primarily, with some retired personnel and their dependents. Dr. Breault's study involves a civilian population of approximately 300,000, in Essex County, Ontario.

We are dealing with only four major pharmacies who dispense prescription items and in a rather arbitrary way we told them this is how you will dispense your tablets and capsules during the test period. Dr. Breault, on the other hand, was dealing with a group of civilian pharmacists, approximately 60, who had to be encouraged through a great deal of persuasion on his part to cooperate in the study of this type. I recently received a letter from Dr. Breault on the 24th of September, 1969, and I would like to read a portion of it.

In Essex County we are now at the 33 month mark, two and three-fourths years with approximately two million Palm-N'-Turn vials used in this area. We are just as pleased as ever with our results. We have no prescription drug poisonings except those brought in from the outside, or perhaps one a month where the parent is at fault. Apparently we are dispensing from the civilian pharmacists in this area approximately 60,000 prescriptions a month. In all there have been 43 safety vials involved in poisoning as follows: 9 where the containers

were opened by children and 34 containers that had the safety feature violated by somebody else.

Poisonings decreased 50% in the first two years. We have had a 25% decrease in poisonings during the first 9 months of this year compared to 1968. [Slide.]

If I can combine then the results of our two studies, we now have some experience with 2,700,000 containers, with a total number of failures of 56, with a ratio of ingestion to container of one poisoning for 48,000 containers. When one looks closely at the reasons for failure, Dr. Breault's experience has been similar to ours. In a high percentage of the ones that are opened by small children, they are in fact opened with the teeth. If we look just at the product failure of 14 and put that into a figure of 2,700,000, it gives us something in the range of one child opening a container, becoming involved in a poisoning, for every 200,000 prescriptions. In both studies, despite product failures and failures of some adults to use the safety containers properly, there have been highly significant reductions in accidental poisonings.

Senator PEARSON. Are these the only two studies you know of underway now?

Dr. SCHERZ. Studies of closures of various kinds will usually fall into two phases. Phase 1—and this has been talked about previously—is the phase of attempting to develop a standard of some kind for a child-resistant package. I would liken it to a college entrance exam, trying to do in a short period of time an evaluation of a prospective student and then predicting from the results of the exam how he will do in the future. The real test of a phase 1 exam, that is, its reliability to predict success, is the phase 2 study. The studies that we are doing at Madigan General Hospital, and also in Essex County are phase 2 type studies at this time. We have selected out a container for mass use in large populations. These are the only two studies of this kind that I know have been done and well documented.

Senator PEARSON. I note that you have written an article for publication in Pediatrics setting forth some of your findings. It is also noted that you speak in your individual capacity. But I want to inquire as to whether or not your findings and your study have been reported also to the Surgeon General?

Dr. SCHERZ. Yes, sir. I will come to that in a few minutes, if I might, about that and what effect it has had throughout the Federal governmental hospitals. To continue, a second phase study was designed to see if we could produce some control over the numbers of aspirin poisonings we were experiencing. During a 1-year period, February 1, 1967, to January 31, 1968, we had 91 poisonings from aspirin. I am talking specifically about children's aspirin. We asked a simple question of the parents when they brought the child in, where did you get the aspirin involved in this poisoning? Fifty-eight of the 91 stated with certainty that they purchased the aspirin from the Fort Lewis or McChord Air Force Base post exchanges. Other sources included civilian pharmacies, drugstores, grocery stores and so on. And the few we couldn't determine because they had left the area were placed in an unknown group. By very simply findings out how many boxes of aspirin were sold during that 1 year and using this as a denominator, we determined the ratio of poisonings per boxes sold. We found that during this 1-year period we could expect one child to be treated for aspirin poisoning at our hospital for each 220 boxes of aspirin sold in the local post exchanges. [Slide.]

The aspirin was sold in the post exchanges packaged in what was called a safety-capped bottle containing 36 $1\frac{1}{4}$ -grain aspirin tablets. I show here one brand (St. Josephs). We also had another popular brand (Bayer). There was no significant difference in the number of sales, nor in the number of children involved in poisoning in one versus the other. In my opinion this particular type of closure should not be labeled child-resistant, it is opened far too easily by small children, and if you look at the top of the cap there, you can see perhaps how they opened it. They opened it with their teeth more frequently than by any other method.

Senator PEARSON. Doctor, let me ask you this, and I ask it in relation to the Canadian study: What was the consumer reaction to the child-resistant cap, both as to its use and as to any increased cost?

Dr. SCHERZ. You see again we are talking about a population that in general is not given a choice of containers to package pharmaceutical items. Here is your prescription in this container, if you don't like it, you can complain. Some did complain and quite loudly at first.

Senator PEARSON. That is your study group.

Dr. SCHERZ. Yes, indeed. Some of them did complain. When they complained, we listened, however, we persisted in the use of the containers. We tried to avoid a lot of complaints by helping people learn to open the closures. But we did have numerous circumstances in the beginning where the parents did have trouble opening the containers, individuals who had no physical disability, yet had problems in reading the directions or interpreting instructions or understanding the purpose of the new containers. Some of the individuals with handicaps of the hands had great difficulty opening this particular closure. We didn't quibble with that group. The number was quite small, much less than 1 percent who could not be trained. If they had trouble with this closure, then we gave them their prescriptions in another type of container. Our pharmacist states that fewer than 1 per 1,000 complain about the containers now. Most arthritics can open the containers albeit with some trouble at times when their hand joints are bothering them.

In general there was an acceptance of this type of closure within several months after starting its use. And in talking to the pharmacists now, they rarely get any comments one way or the other.

Senator PEARSON. I think there would be less resistance within your group than there would be in the Canadian group. Do you know what your colleague in the other study found as to customer resistance?

Dr. SCHERZ. I am sorry, I can't give you what his thoughts were except to say they did have trouble too. I can't be much more specific than that. He expressed his greatest problem in trying to convince the pharmacists that they had a responsibility to dispense pharmaceutical tablets and capsules in a safer container. This is where his problem seemed to be primarily.

Senator PEARSON. Why did they resist?

Dr. SCHERZ. Complacency, perhaps. It is something new; some have stated that it is not their responsibility. There are a number of expressions one could use that would seem to typify the attitude. Most just don't want to be bothered using them, explaining to customers why they are used, or facing occasional complaints. It's easier to maintain the status quo.

Senator PEARSON. But cost was not a factor?

Dr. SHERZ. No, In our own Pierce County area, I would say that 10 percent or less of the pharmacists use this container, even though I have made some personal effort and so have other physicians in the community to influence them to use them. There is no legal requirement for them to use them. It is kind of a bothersome thing for the pharmacists to spend an extra few moments to put the medication in a container of this kind. It is more convenient to put the medication in another type of container. Our pharmacists at Madigan have actually developed callouses on their left hands from opening thousands of the containers—yet they have an excellent attitude and feel personally involved in the safety program.

Senator PEARSON. How about the pharmaceutical companies as distinguished from the druggists and retailers?

Dr. SCHERZ. Are you thinking in terms of the companies that produce proprietary products.

Senator PEARSON. Yes.

Dr. SCHERZ. I have had correspondence with several of them and I would say the correspondence has been favorable in the sense of their interest in closures of this kind. But in the beginning it was sort of a warm interest and lately it has been a little more than warm, they seem quite interested in doing something.

Senator PEARSON. I want to note that the Chairman of this Subcommittee, Senator Moss, is here now and I was sitting in his place. Do you have any questions, Senator?

Senator Moss. Well, had you finished, Colonel?

Dr. SCHERZ. I would like to say a few more things about our aspirin study to point out that child-resistant containers can prevent aspirin poisonings. I think it is worth while to give you some detail here because the Proprietary Association or others might be interested in knowing what happened to sales and the preferences of the individual in at least the post exchanges when they came up against a situation of buying a package with one of the test containers attached versus one without.

In the first year the preference for a box of one of these attached test containers by the consumers was approximately three to one. If they were given a choice, they would buy the box with the attached test container. [Slide.]

In actual figures, I believe they are in the statement I handed in. The only instruction we gave the parents about what to do with the test container were little signs put up in four post exchanges that read like this, "Recommended that the contents be transferred to the safer container." When we summarized that study, 15 months experience, from February 1, 1968 to May 1, 1969, there were total sales with a test container of 13,285. There are another approximately 4,000 or 5,000 that were sold without a test container. Of those sold with the test container, we had five poisonings. Three of these were from the original container, because the parents did not transfer the aspirin. And two were from containers that children actually opened.

The poisoning rate, based on numbers of children coming to our hospital, versus sales, changed from 1 to 220 to a rate of 1 to 2,700. And this again is a drop of greater than 90 percent. Again this study pointed out that despite product failure and failure of adults to use the containers properly, there was a highly significant decrease in

accidental childhood poisoning, using an effective child-resistant container. (Slide.)

I would like now to summarize the current status of safety containers used in Federal governmental pharmacies at this time. We made inquiries and suggestions to the Surgeon General's Office in I believe it was the fall of 1967 suggesting that it might be useful to use child-resistant containers in other Federal hospitals. In a survey performed in March of 1969 of 178 Army, Navy, Air Force, and Public Health hospitals in the United States that provide care to children, 176 responded. Out of that group, 73 percent were using child-resistant containers in their pharmacies. In a second survey, started in September of 1969, incomplete at this time, the numbers using the containers of those who have responded so far, has increased to 85 percent. I have tabulated the first 103 responders who are using the containers. Those that have been using them for over 2 years are only 11. But out of that group, 10 of the 11 report a decrease in childhood poisonings, particularly poisonings due to tablet and capsule medications. Of those that have been using the containers less than a year, 49 believed it was too early to say whether there has been a change in poisoning rates. However, 18 were able to commit themselves at this time to a feeling that there has been a decrease in the number of poisonings in their hospitals.

I think it is quite significant to point out that in none of the studies, none of the reports thus far, has there been an increase in poisonings from medications or from anything else by use of the safety containers. The number of Federal hospitals able to give us hard data on poisoning rates are quite few. Yet those that have been able to provide reliable data, uniformly report decreases in poisonings. We are accumulating that data now and it should be available for presentation at the American Academy of Pediatrics meeting in October of this year.

(The statement follows:)

STATEMENT OF ROBERT G. SCHERZ, LTC, MC, CHIEF, PEDIATRIC SERVICE,
MADIGAN GENERAL HOSPITAL, TACOMA, WASHINGTON

Accidental childhood poisonings are common occurrences, particularly among children five years and under. Education programs for prevention of poisoning directed at parents are at most an indirect deterrent to the small child who cannot or does not comprehend the effects of his impulsive actions. Most accidental poisonings are from ingested solids and liquids. During the period 1963 through 1966, substances in four categories (medicines, household products, pesticides, and petroleum products) were implicated in 89.8% to 90.8% of poisonings of all causes among children under the age of five years. In almost all instances, the toxic substances were packaged in containers easily opened by small children. A sensible approach to the problem of accidental poisoning would seem to be to package toxic and potentially toxic consumer products in containers opened easily by most adults and with difficulty by small children.

In the fall of 1966, we began a search for a medicine container for prescription items that would be a more effective barrier to small children than containers in common use. A test container was evaluated in the winter of 66-67 and selected for use in two clinical studies. Prescription tablet and capsule medications have been dispensed to a population of 100,000 in the Fort Lewis-McChord area since May 1967. The first year results have been reported (Enclosure 1). From February 1968 to date, test containers have been attached to boxes of commercial $\frac{1}{4}$ grain flavored aspirin sold in the Post Exchange outlets in the Fort Lewis-McChord area. The first year study has been tabulated (Enclosure 2). The direct results of both of these projects are summarized in Tables I and II. The test container has produced significant reductions in childhood poisonings. Any child "poisoned" by medication for any reason whatsoever, if the medication was originally dispensed in a test container, was termed a "failure". The "failures" from tablet and capsule prescriptions are summarized in Table III. In 8 of the 13 failures, the safety factor of the container was bypassed. Five children actually opened the container. However, only two developed signs of toxicity and required hospitalization. There were no fatalities. The test container is a standard item for Federal Governmental pharmacies. In a recent survey, of 124 Army, Air Force, Navy and Public Health hospitals in the U.S., 106 were dispensing prescription items in the test containers (85%) as of September 1969.

SUMMARY AND SPECULATION. A decrease of greater than 90% in poisoning rates from prescription tablets and capsules and from $\frac{1}{4}$ grain flavored aspirin has occurred through the use of the test container. If this and other child-resistant containers could be developed and used generally throughout the United States to package all consumer medicines, household products, pesticides, and petroleum products, a reduction of accidental childhood poisonings of over 80% would be a conservative reasonable expectation. If the annual number of childhood poisonings is 2,000,000, this would mean a reduction of 1,600,000 accidental childhood poisonings with concurrent decrease in morbidity and death. There is a scripture that would seem appropriate here (I Thes. 5:21) "Make sure of all things; hold fast to what is fine". We have proven that child-resistant containers do protect children from harm. Now is the time to hold fast to that concept.

TABLE I

MADIGAN GENERAL HOSPITAL
ACCIDENTAL CHILDHOOD POISONINGS
DUE TO PRESCRIPTION TABLETS AND CAPSULES
1 May 1966 - 1 Oct 1969

No. of child-resistant containers dispensed (1 May 1967 - 1 Oct 1969)	660,000
No. of containers involved in poisonings	13
Current poisoning/container ratio	1/50,700
Previous poisoning/container ratio (1 May 1966 - 30 Apr 1967)	1/5,100
% change in poisoning rate	↓ 90%

TABLE II

ACCIDENTAL CHILDHOOD POISONINGS
FROM 1½ GRAIN ORANGE FLAVORED
ASPIRIN SOLD IN THE FORT LEWIS-
McCHORD AIR FORCE BASE EXCHANGES

1 Feb 1967 - 31 Jan 1968	
Total sales without test container	12,800
No. of children treated for poisoning	58
Ratio poisonings/sales	1/220
1 Feb 1968 - 1 May 1969 (15 months)	
Total sales with test container	13,285
No. of children treated for poisoning	5*
Ratio poisonings/sales	1/2,700
* 1) 3 were from the original container, parents did not transfer aspirin to the test container.	
2) 2 children opened the test container.	

TABLE III

ACCIDENTAL CHILDHOOD POISONINGS
DUE TO PRESCRIPTION TABLETS AND CAPSULES
DISPENSED IN 660,000 CHILD-RESISTANT CONTAINERS
1 May 1967 - 1 October 1969 (29 months)

REASON FOR FAILURE	MEDICATION	AGE OF CHILD	SEX
1. Child opened container (5)			
a. Trained unintentionally by mother	Tofranil	4 y**	Fe
b. Read instructions	1½ gr flavored aspirin	7 y	M
c. Random trial and error	Valium	2 y*	M
d. Used teeth to pry off cap	Dexamyl	4 y**	M
e. Used teeth	Penicillin	4 y	Fe
2. Violation of safety factor (8)			
a. Medication stored without top	Dexamyl	2 y*	M
b. Medication loose in purse	Darvon	2 y	M
c. Open container in trash can	Phenobarbital	3 y	Fe
d. Top loose	Ornade	2 y	Fe
e. Spilled on floor	Tofranil	4 y*	Fe
f. Top loose	Reserpine	2 y	M
g. Top loose	Ferrous sulfate	2 y**	M
h. Top off	Darvon	2 y	Fe

* Ingestion suspected, but not proven.

** Hospitalized for 24 hours.

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 tab-

let 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.

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

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

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 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

<i>Data</i>	1966- 1967	1967- 1968	<i>Change</i>	<i>% Change</i>
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

<i>Container Type</i>	<i>Madigan Pharmacies</i>		<i>Other Civilian and Military Pharmacies</i>	<i>Totals</i>
	<i>Dispensed Before May 1</i>	<i>Dispensed During Test Period</i>		
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 PRE-
SCRIPTION TABLETS AND CAPSULES DISPENSED IN
270,000 CHILD-RESISTANT CONTAINERS, MAY 1, 1967,
TO APRIL 30, 1968

<i>Cause of Failure</i>	<i>Number</i>	<i>Age (yr)</i>	<i>Sex</i>
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 con- tainer	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 con-

tainers—a reminder each time a child-resistant container is opened, that accidental childhood poisonings are an ever present threat.

REFERENCES

1. Statistical Bulletin, Metropolitan Life Insurance Company. Vol. 48, p. 9, 1968.
2. Stracener, C. E., Scherz, R. G., Crone, R. I.: Results of testing a child-resistant medicine container. *PEDIATRICS*, 40:286, 1967.

Reprinted from *Pediatrics*, Vol. 43, No. 1

January, 1969

© All rights reserved

PREVENTION OF CHILDHOOD ASPIRIN POISONING

Author

LTC Robert G. Scherz, M. C., M. D., F. A. A. P.

Associate Clinical Professor of Pediatrics
University of Washington School of Medicine
Chief, Pediatric Service, Madigan General Hospital
Tacoma, Washington 98431

ABSTRACT

PREVENTION OF CHILDHOOD ASPIRIN POISONING

During a pretest period of one year, 58 children were treated at Madigan General Hospital for ingestion of $1\frac{1}{2}$ grain orange flavored aspirin tablets from sales of 12,800 units of aspirin packaged in containers with friction cap closures. The ingestion/sales ratio was 1/220. During a second 12-month period, parents were instructed to repackage purchased aspirin in an attached test press-lug closure. There was a 93% decrease in ingestion/sales ratio to 1/3,168. These studies demonstrate that an effective safety closure can significantly reduce childhood aspirin ingestions and poisonings.

PREVENTION OF CHILDHOOD ASPIRIN POISONING

Introduction

Accidental childhood poisoning due to aspirin is a very common problem. From 1963-1967 accidental ingestions of aspirin among children under 5 years of age reported to the National Clearinghouse for Poison Control Centers ranged from 23.0% to 25.8% of all poisonings.¹ The toll from aspirin poisoning continues despite local and national efforts by a variety of safety conscious groups to meet the problem with mass education techniques. Educational programs which emphasize the hazards of aspirin and the importance of careful storage would seem to be an effective approach. However, two studies, well conceived, demonstrate that this 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 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 is to make containers less vulnerable. An investigation was designed to evaluate the relative effectiveness of child-resistant containers to prevent ingestions of orange flavored 1½ grain aspirin - 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 5 years to open 3 different types of closures.

2. A clinical study to evaluate the most effective container in the comparative study.

Comparative Study of Medicine Container

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 children⁴. A subsequent clinical test demonstrated a significant reduction in accidental poisonings due to prescription tablets and capsules when the test container was used in a large scale study involving a semi-closed population of 105,000 servicemen and their dependents⁵. 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 5 years in a laboratory setting. The technique for evaluation has been reported⁴. 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% of the 2 year old and 100% of the 4 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 1 child opened the closure within 3 minutes without help. An additional 7 children opened the press-lug closure after visual demonstrations.

Evaluation of a child-resistant closure 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 $1\frac{1}{4}$ 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. (See photo) 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 is summarized in Table II. During a 12 month pre-test period, 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 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.

Eight of the 11 poisonings were from aspirin sold without a test container (1 per 485 boxes sold). Three were from aspirin sold with an attached test container (1 per 3,168 boxes sold). On further questioning, two of the three ingestions were from the original containers, because the parents had not made the transfers to the test containers. Only one of the ingestions was due to a child actually opening the test container.

Observations

There was a marked reduction in ingestion rates that can be best explained by having available an effective child-resistant container. It is apparent from this study that children's aspirin should be packaged originally in an effective child-resistant container. Relying on parents to consistently transfer aspirin to a safer container will lead to unnecessary poisonings when they fail.

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. In several specific instances parents purchased one or more boxes of aspirin without a test container and reused a test container from an earlier purchase. The extent of this practice was not determined.

Implications

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 5 years.

Summary and Conclusions

A child-resistant container evaluated in both a laboratory and clinical setting was found to be significantly more effective than the common friction cap "safety" closures in preventing accidental childhood poisoning due to $1\frac{1}{2}$ grain flavored aspirin. The clinical use of the test containers during a 12 month study period was accompanied by a 93% decrease in poisoning rates due to flavored aspirin.

REFERENCES

1. Bulletin - Statistical Analysis of Ingestion Experience Reported to the National Clearinghouse, 1966.

National Clearinghouse for Poison Control Centers Bulletin, July-August 1967.

2. Baltimore, C. L.; and Meyer, R. J.: A Study of Storage, Child Behavioral Traits, and Mothers Knowledge of Toxicology in 52 Poisoned Families and 52 Comparison Families; Pediatrics, Vol. 42, No. 2, page 312, 1968.

3. Sobel, Raymond: Traditional Safety Measures and Accidental Poisoning in Childhood, National Childhood Research Symposium, Charlottesville, Va., 1968.

4. Stracener et al; Results of Testing a Child-Resistant Medicine Container, Pediatrics, Vol. 40, No. 2, Aug 1967.

5. Scherz et al; Child-Resistant Containers can Prevent Poisoning, Pediatrics, Vol. 43, No. 1, Jan 1969.

TABLE I

MADIGAN GENERAL HOSPITAL
COMPARATIVE ABILITY OF 200 CHILDREN
TO OPEN THREE TYPES OF CONTAINERS

SUMMARY

Age	No. studied	Opened successfully								
		Screw cap ¹			Friction cap ²			Press cap ³		
		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			8		
					(63 opened with the aid of the teeth)			(5 opened with aid of the teeth)		

- 1 2 oz glass bottle with standard screw cap.
- 2 New Bayer or St. Joseph pink plastic friction cap on 36 tablet bottle of 1½ grain orange flavored aspirin.
- 3 Palm-N'-Turn plastic press-lug cap on 7 dram plastic container.

TRIAL

3 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 1 or 2 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 3 minutes with no demonstration, 3 minutes after both the 1st and 2nd demonstrations.

Conclusion: The press-cap closure is superior to the screw-cap and friction cap closures as a barrier to children under age 5 years.

Recommendations:

- 1) The screw caps and friction caps tested should not be considered "child-resistant".
- 2) 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.

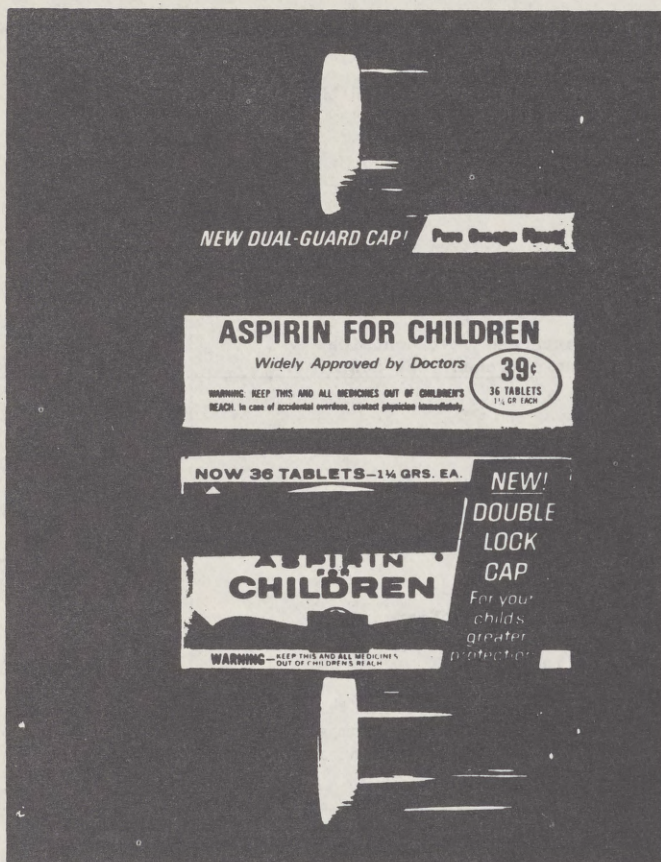
TABLE II

ACCIDENTAL CHILDHOOD POISONINGS
FROM 1½ 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
% change in ratios of ingestions/sales without test container 1967-68 compared to ingestions/sales with test container 1968-69 ↓ 93%		

*Estimated to nearest 100.

** 19 m.o. female opened container with random motion, took 6 aspirin.



Test containers taped to 9,505 boxes
of commercial aspirin
sold in local Post Exchanges
1 Feb 1968 - 31 Jan 1969

DEPARTMENT OF THE ARMY,
HEADQUARTERS MADIGAN GENERAL HOSPITAL,
Tacoma, Wash., 1 December 1966.

Subject: Accidental poisoning.

To Commanding General, attention Surgeon, Fort Lewis, Wash.

1. Incidents of accidental poisoning of young children have been increasing in recent months. In the interest of preventing future incidents, or at least reducing the possibility of occurrence, the following is reported to your office:

- (a) Name: Barry K. Phillips, Relationship, dependent son.
- (b) Sponsor: SGT Melvin L. Phillips, DOB, 1963.
- (c) Station and unit of assignment: E Co., 4th Bn, 1st Bde, USATC, Fort Lewis, Washington.

(d) Date of admission or treatment: 19 November 1966.

(e) Circumstances: Patient ingested Sulfadimethoxine (5 - 12). While Mother was sleeping, the child climbed up to the kitchen cabinet. Incident occurred at Quarters 5918, Fort Lewis, Washington.

2. The above is furnished for any action you may deem appropriate or necessary.

RICHARD I. CRONE,
Brigadier General, Medical Corps, Commanding.

"Failures" child-resistant containers for prescription tablets and capsules combined experience Essex County, Canada, Madigan General Hospital, September 1969

Total number of containers	2,700,000
Total number of "failures"	56
Ratio ingestions/containers	1:48,000
Reasons for "failure":	
1. Child opened container	14
2. Violation of safety factor	42
Ratio—child opened container/number of containers dispensed	1:200,000

Senator Moss. Thank you very much, Dr. Scherz. That was a most interesting and helpful tabulation and information you have brought us from your studies. And a rather dramatic result I would say in the drop of poisonings that have been effected by simply having a child-resistant closure. It isn't absolute, of course, you said two of them got into it. But it is child-resistant and therefore difficult for them to open. I am sorry that I wasn't here to follow the entire testimony that you gave, but I am sure that it is most significant and should be very helpful to us in this committee as we consider the legislation that we have before us now.

Did you indicate earlier in your testimony whether you approved the bill now? Do you recommend it be approved?

Dr. SCHERZ. I do not feel qualified to understand or interpret the bill properly. But if it is a bill that will in fact require the general use of child-resistant containers for a variety of products that go into the home, yes, I am for the bill. If it also will allow enough leeway so that the occasional individual who has handicaps, particularly inability or problems with their hands in opening safety closures, will not be ignored, then again I am for that bill.

Senator Moss. Would you think the ideal or the best situation would be to have the hazardous products normally packaged in a package that was resistant to child opening, but with a separate stock that could be utilized by adults with handicaps, by asking for it? Would that seem reasonable?

Dr. SCHERZ. This to me would seem to be a very reasonable approach. I don't know what it would involve as far as the manufacturers are concerned, but it would seem a reasonable way of handling the

problem. In any instance, the bulk of the packaging should be safety packaging.

Senator Moss. I appreciate having your opinion and knowing that you at least endorse the objective of the bill, even though we must work it through of course carefully to make sure we are attaining the objective, which is the maximum degree of protection without placing handicaps in the way of those who need to open those containers and do not have the physical facilities to do so. Thank you very much.

Senator PEARSON. Doctor, I understand the drug companies say we don't know when we have a resistant or safe package or container. Yet you made a statement in your summary that if you utilize these child-resistant type container caps, on household products, pesticides, petroleum products, and medicines, that a conservative and reasonable expectation would be a reduction of some 80 percent in poisonings throughout the country. So you don't have any trouble making a judgment as to what is a safety cap or what is a child-resistant mechanism.

Dr. SCHERZ. I think the quibbling has revolved principally around phase 1 testing to determine how resistant a specific closure is to the attempts of a young child to open it. I believe one could carry on the quibbling for a long period of time; is it 70 percent or 80 percent or 90 percent effective? By using various study groups and various techniques, one can come up with a variety of reports on the same container. However, the true effectiveness of a given container will be determined by field trials. If you will, phase 2 testing. If legislation offers leeway for the testing and for determining the requirements for a child-resistant container as it relates to classes of specific hazardous products, then initial regulations for minimum standards could be modified and refined based on actual experience with proposed child-resistant containers used in field trials. (Phase 2 testing.) In my opinion, the Secretary of HEW should be required to evaluate proposed containers and closures with both phase 1 and 2 tests. During study periods, containers could be tentatively approved for use, subject to modifications based on field use.

Senator PEARSON. At what point in time, if you know, was there any use whatsoever of safety precautions or child-resistant caps? Was it in the last year or last 2 years? How long have we really touched on this subject through efforts such as yours?

Dr. SCHERZ. Certainly there has been preamble work done for many years. Dr. Jay Arena is one of the well known people who worked on this many years ago. Yet I would say the concerted interest has only been in the last 2 or 3 years in developing truly effective closures for pharmaceutical products that are practical, effective, and can be used in large numbers.

Senator PEARSON. Well, I continue to be puzzled and have a sense of frustration about the priorities of what we seek to do in this country. Just as a personal observation, it seems to me that something along this line would have been an active endeavor for many, many years. I commend you on your efforts and your study. It is only one of two in the United States or in the world, perhaps. You have made a very valuable contribution to these hearings, I believe.

Senator Moss. I agree. I thank you very much, Dr. Scherz, for your testimony and the information you brought us for our record.

Senator Moss. Our next witness is Dr. Maurice L. Tainter, vice president of the Sterling Drug, Inc., New York. I think he will be accompanied by James L. Luther, vice president, legal affairs.

We are pleased to have you gentlemen here. You may proceed.

The rather full statement will be placed in the record in full. You may present it in such a way as you care to.

**STATEMENT OF DR. MAURICE L. TAINTER, VICE PRESIDENT,
STERLING DRUG, INC.; ACCOMPANIED BY JAMES L. LUTHER,
VICE PRESIDENT, LEGAL AFFAIRS, STERLING DRUG, INC.**

Dr. TAINTER. Gentlemen, I would like to introduce Mr. James Luther, my associate, who is a vice president of Sterling Drug and an attorney, in whom I will rely for any questions which involve legal or regulatory matters.

I am Dr. Maurice L. Tainter, appearing for Sterling Drug, Inc. I am a physician, licensed to practice medicine in California and New York, and a pharmacologist. I was on the teaching faculty of Stanford University School of Medicine for about 20 years, during which time I became a professor of pharmacology, the subject which deals with the actions and uses of medicines and the treatment of their adverse effects. Subsequently, I became the director for research for Sterling Drug, Inc., which position I held for 26 years until my retirement this year.

Sterling Drug, Inc., markets several thousand medicinal products throughout the world through its various divisions and subsidiary companies. Many of these are the major products in their therapeutic class, well known to either physicians or lay individuals. One of these, aspirin, is the most widely used medicine of all time. Under our name, Bayer aspirin, its use has been pioneered here and abroad for about 70 years. It is safe to say that aspirin in some one of its many forms is readily available in substantially all households and its use is familiar to even small children. Possibly because of this widespread familiarity, aspirin-containing products are involved in more accidental ingestion or alleged poisoning episodes than any other individual drug or group of products, and are therefore of special interest in these present hearings.

I propose to discuss some of the factors needed to understand the epidemiology of such overdosage and to draw conclusions from these as to how best the problem may be ameliorated. These factors are ambiguous in that much of the reported data does not differentiate between aspirin and all other salicylate preparations, including the highly toxic methylsalicylate or oil of wintergreen commonly used as a household liniment, of which one teaspoonful may be a fatal dose for a small child. My remarks will bear mainly on household poisoning. Much of what I will say specifically about salicylates is also applicable at least in part to other drugs. Therefore my remarks will bear on household poisoning in general although using mainly salicylate statistics for illustration.

I believe that our analysis of the facts surrounding salicylate overdosage in the preschool child will show that the problem is quite different from what might be assumed without investigation, and that as a result the remedy proposed in the pending legislation is not timely

nor likely to be really effective nor to promote public welfare. I also will attempt to be constructive by pointing out alternative routes for progress which should be utilized.

Senate bill 2162 would amend the Federal Hazardous Substances Act to provide for, and by implication require, the use of child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting any product found in or around households. Since this bill is intended as a child-protection measure, we will concentrate our attention on the preschool child who is involved in the great majority of all child poisoning episodes.

Sterling joins all others in being completely in favor of maximal safety in the home and with more particular reference to substances which might be ingested, such as medicines.

The remedy proposed of putting potentially hazardous substances in child-proof packages seems a very simple, direct and supposedly efficacious one. Our company has explored this approach to greater safety for many years in trying to make our packaging of aspirin as safe as possible. Various steps we have taken in more recent years are summarized in chart 1. You will see continuous steps in modifications in our packaging.

Sterling's Efforts to Improve the Safety of BAYER ASPIRIN FOR CHILDREN'S Packages

- Feb. 1955 : FDA-Medicine-Industry Conference on Children's Aspirin.
- May 1956 : "WARNING" Added to Package & Label and Size Changed to 1¼ grains, from 2½ grs.
- May 1959 : "Tamper Proof" Safety Cap Introduced.
- Apr. 1960 : "Grip Tight" Safety Cap Introduced.
- July 1961 : Mothers' Reactions Studied to "Strip Pack" vs. "Grip Tight"
- Aug. 1965 : Child Testing of "Mira-Pack" (Blister Pack) vs. "Grip Tight" Cap.
- Aug. 1965 : Mothers' Reaction Test of Mira-Pack vs. "Grip Tight".
- 1966 : Financial Support through the Proprietary Association of the Syracuse Accident Study Program.
- Apr. 1966 : Child Testing of "Double Lock" Cap vs. "Grip Tight".
- Apr. 1966 : Financial Support for International Symposium on Childhood Accidental Injuries
- Apr. 1966 : Sterling Took Lead in Organizing the Council on Family Health.
- May 1966 : Mothers' Reaction Test of "Double Lock" vs. "Grip Tight".
- Jun-Sep 1966 : Hearings before the Subcommittee on Public Health & Welfare on Child Safety Act H.R. 13886.
- Nov. 21, 1966 : FDA Conference on Prevention of Accidental Ingestion of Salicylate Products by Children.
- Nov. 1966 : Sterling representative appointed by Dr. Goddard to FDA Committee to Study Safety Closures.

This chart starts in 1955. It could have been earlier. During this period of time we have introduced one improved safety cap after another. We have carried out extensive tests of various kinds of caps, trying to find one that would be an improvement over previous ones.

We explored the mother's reactions to see whether they would be willing to use bottles closed with different kinds of caps, which is essential to their use.

We have also taken part in Government conferences on the prevention of this kind of childhood poisoning.

- Nov. 1966 : Mothers' Reaction Test of "Modified Double Lock" vs. "Grip Tight".
- Nov. 1966 : "Double Lock" Safety Cap Introduced.
- Dec. 1966 : Proprietary Association Research & Scientific Development Conference:
"Safety in the Use of Home Medicines", N.Y.
- Apr. 1967 : New "Warning" Added to Labels.
- Apr. 1967 : Hearings before the Connecticut Public Health & Safety Committee on S.B. 983.
- May 1967 : Tablet Count Dropped to 36 from 50.
- Jun. 1967 : Child Testing Studies by Dr. Alan Done (Univ. of Utah) : Double Lock ;
Oct. 1968 } Grip Tight ; Blister Pack ; Strip Pack ; Screw Cap ; Palm-N'-Turn ;
Child Guard.
- Jun. 1967 : Mothers' Reaction Test of "Super Lock" vs. Blister Pack 36's & 24's vs.
"Double Lock".
- Sept. 1967 : • Child Testing of "Super Lock" vs. "Double Lock." • Mothers' Reaction
Test of "Super Lock" or "Double Lock" vs. "Grip Tight".
- Nov. 1968 : • Child Testing of "Child Guard" Cap.
• Mothers' Reaction Testing of "Child Guard" Cap.
• Adult Testing and Preference Study of "Child Guard"
vs. "Grip Tight" vs. Snap Top vs. Screw Cap vs. Blister Foil.
- Jan. 1969 : "Child-Guard" cap introduced on Adult 75's
- Feb. 1969 : "Child-Guard" cap introduced on Children's Aspirin

On chart 2 you will see a continuation of this tabulation which carries us to the present day.

In January 1969 we introduced the latest new safety cap, which is an improvement on the Palm-N-Turn which you heard about today. We put this first on an adult size tablet bottle, so that adults would have this available and then in February we put it on the children's aspirin tablet bottles as well. These are being tested right now in Arizona.

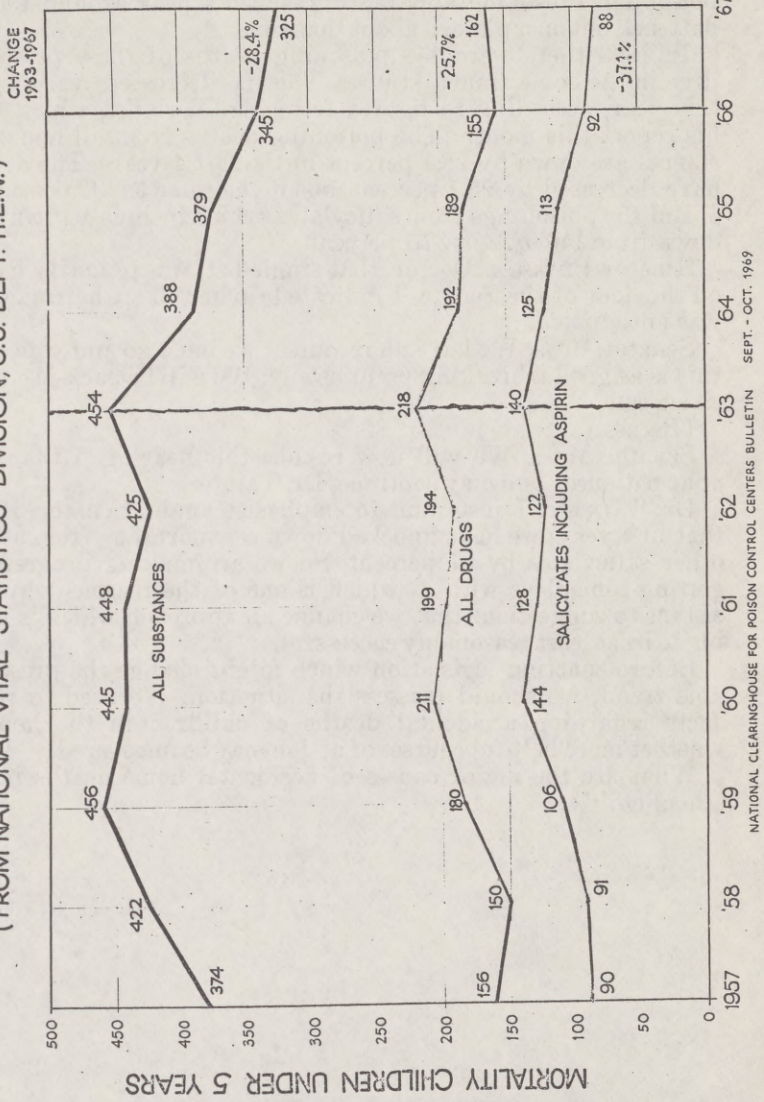
So, I think you will agree we have a record here of very continuous awareness and concern with this problem and attempts to do something about it.

The question was asked today whether these studies of safety closures had only started within the last year or two. This obviously is not correct. Historically these studies have been going on for many years, not only by our company, but by others as well. Other companies have had similar programs, so that today, by voluntary action, all children's aspirin is packaged only in bottles of 36 tablets, closed with the most child-resistant closures so far developed that are suitable for such use.

Although these efforts have not succeeded in completely eliminating serious poisoning in children from salicylates they apparently have decreased it appreciably in the last 4 years as shown in chart 3.

POISONING DEATHS IN CHILDREN UNDER 5 YEARS OF AGE 1957-1967

(FROM NATIONAL VITAL STATISTICS DIVISION, U.S. DEPT. H.E.W.)



This chart might surprise you in view of the statements made only a few minutes ago that there has been no serious increase in childhood poisoning. Poisoning apparently reached a peak around 1963, or had flattened out on a plateau about that time.

In 1963 there were 454 poisoning deaths of these preschool children in the home from all causes. This has decreased year by year until this year, according to figures from Mr. Verhulst, which will be in his report this month. The poisoning deaths from all household substances are down by 28.4 percent in the last 4 years. The drug deaths have decreased by 25.7 percent, about the same as all poisonings.

But the poisonings from salicylates, which include aspirin have gone down from 140 to 88 or 37.1 percent.

Senator PEARSON. Doctor, that single bell was to notify us of a vote on the floor of the Senate. I indicated earlier, Mr. Chairman, that this was anticipated.

Senator MOSS. We have no recourse; we must go and vote. I suppose this is as good a breaking point as any. We will be back just as quickly as we can.

(Recess.)

Senator MOSS. We will now resume this hearing. I thank you for your patience. You may continue, Dr. Tainter.

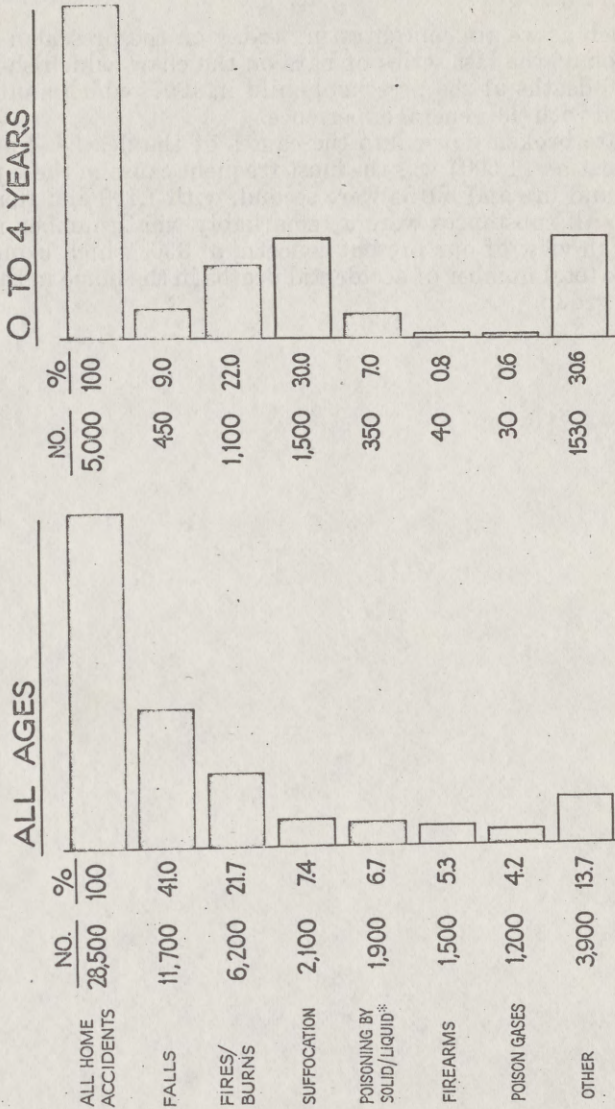
Dr. TAINTER. I just want to emphasize again, Senator, if I might, that in 4 years we have knocked down the mortality from aspirin and other salicylates by 37 percent. So we are making progress; we are getting someplace with it, which is one of the reasons why I am resistant to suggestions that we change an approach which is now proving to be at least reasonably successful.

Before enacting legislation which might change the present favorable trend, we should reassess the situation. We need to review the facts regarding accidental deaths of children in the home to see whether more helpful courses of action may be uncovered.

What are the major causes of accidental home deaths in the preschool child?

DEATHS FROM HOME ACCIDENTS -1967

Source: National Safety Council, Based on Data from National Vital Statistics Division & State Health Departments



* Includes deaths from medicines and commonly recognized poisons. Mushrooms and Shellfish poisoning deaths are included but fatal poisoning from spoiled foods are not.
Accident Facts 1968, Natl. Safety Council, pp. 80-84.

The next chart shows that in 1967, the last year for which we have official Government data, there were 28,500 deaths in the homes of all ages.

Inasmuch as we are concentrating today on the preschool child, we should look at the last series of bars on the chart which shows there were 5,000 deaths of the preschool child in 1967, which annual figure is in accord with the general experience.

These are broken down into the causes of the deaths. You can see that suffocation (1,500) was the most frequent cause in these preschool children, and fire and burns were second, with 1,100 and that poisonings from all substances were a remarkably small number relatively speaking, in view of our present concern, of 350, which is only 7 percent of the total number of accidental deaths in the home in this particular age group.

INCIDENCE OF ACCIDENTAL INGESTIONS IN CHILDREN UNDER 5 IN 1968

TYPE OF SUBSTANCE	CASES REPORTED ALL AGES	CASES REPORTED UNDER 5
Medicines	60,021	38,354
Aspirin (Group?)	18,560	15,523
Other Internal	35,522	16,477
External	5,939	4,596
Cleaning, Polishing Agents	13,110	10,349
Petroleum Products	4,363	3,573
Cosmetics	4,924	4,286
Pesticides	5,739	3,965
Gases and Vapors	630	64
Plants	3,798	2,740
Turpentine, Paint, etc.	4,991	3,947
Miscellaneous	6,081	3,688
Not Specified	1,521	597
<i>Total</i>	<u>105,178</u>	<u>71,563</u>

The next chart shows you the official figures on the incidence of accidental ingestion episodes in the children in this preschool age group. These are the 1968 figures which came from Mr. Verhulst of the National Clearinghouse of Poison Control Centers. They will be published in his bulletin of September-October.

You can see that for children under five, there were 38,354 reported accidental ingestion cases last year with medicines, and 71,563 from all products combined. So medicines make up approximately half of the total. Again the aspirin and salicylate group make up almost half of the medicine group or 22 percent of the total accidental ingestion cases.

What is the explanation of this number of 71,563 cases reported here? It should be remembered that every phone call and every case seen in a poison control center is recorded as a poisoning incident and appears in this tabulation. But in many of these it is uncertain whether any or how much of the product may have been taken. As an example, some observers have reported that in about 90 percent of the aspirin incidents that get into the records there are no symptoms at all.

The first disturbing fact about the proposed bill is that this legislation would not affect in any way by far the most important cause of serious and fatal poisonings from salicylates, which is therapeutic overdosage. This is a remarkable situation which no safe packaging measure can modify.

CONTRIBUTION OF THERAPEUTIC OVERDOSAGE TO POISONING BY SALICYLATES IN PRE-SCHOOL CHILDREN

Source	No. Pts.	CASES			DEATHS	
		ACCIDENTAL No.	ACCIDENTAL %	THERAPEUTIC No.	ACCIDENTAL No.	THERAPEUTIC No.
CRAIG, ET AL. ¹	78	67	85.9	11	2	6
SEGAR & HOLLIDAY ²	43	11	25.6	32	0	5
RILEY & WORLEY ³	42	13	31	29	0	5
WINTERS ⁴	25	18	72.0	7	0	1
DRIVER ⁵	24	21	87.5	3	0	1
ILL DEPT. PH. ⁶	8	3	37.5	4	1	3
CRICHTON & ELLIOTT ⁷	41	27	65.9	14	1	2
LEIKEN & EMMANOUILIDE ⁸	7	6	85.7	1	1	0
KALLEN, ET AL. ⁹	13	7	53.8	6	1	1
HEYMANN ET AL. ¹⁰	107	68	63.6	39	1	11
CELANDER & HAGLUND ¹¹	20	7	35.0	12	0	0
ERGANIAN ET AL. ¹²	13	2	15.4	11	0	1
DIETRICK ET AL. ¹³	6	3	50.0	3	0	1
BARNETT ET AL. ¹⁴	5	1	20.0	4	0	0
KELLEY & DONE ¹⁵	19	6	31.6	12	Not Stated	Not Stated
POIRIER & CORBET ¹⁶	6	4	66.7	2	0	0
BEATLEY ¹⁷	6	3	50.0	3	Not Stated	Not Stated
TOTAL 17	463	267	58%	193	7	37
					15%	84%

References - Chart 6

CONTRIBUTION OF THERAPEUTIC OVERDOSAGE TO POISONING BY SALICYLATES
IN PRE-SCHOOL CHILDREN

1. Craig, J.O., Ferguson, Isabel C. and Syme, J.: Infants, toddlers and aspirin, Brit. Med. J. 1:757, Mar. 1966.
2. Segar, W.E. and Holliday, M.A.: Physiological abnormalities of salicylate intoxication, New Eng. J. Med. 258:1191, Dec. 1958.
3. Riley, H.D., Jr. and Worley, L.: Salicylate intoxication, Pediat. 18:578, Oct. 1956.
4. Winters, R.W., White, J.S., Hughes, M.C. and Ordway, N.K.: Disturbances of acid-base equilibrium, Pediat. 23:260, Feb. 1959.
5. Driver, Rachel A.: Aspirin poisoning in children, J. Kans. Med. Soc. 59:278, June 1958.
6. Rose, N.J.: State of Illinois Department of Public Health Communication to Poison Control Centers, September 24, 1965.
7. Crichton, J.U. and Elliott, G.B.: Salicylate - A dangerous drug to infancy and childhood, Canad. Med. J. 83:1144, Nov. 1960.
8. Leikin, S.L. and Emmanouilides, G.C.: The use of exchange transfusion in salicylate intoxication, J. Pediat. 57:715, Nov. 1960.
9. Kallen, R.J., Zaltzman, S., Coe, F.L. and Metcoff, J.: Hemodialysis in children, Medicine 45:1, Jan. 1966.
10. Heymann, S., Javett, S.N. and Rudolph, A.M.: Salicylate overdosage and intoxication in infants and young children, So. Afr. Med. J. 28:1092, Dec. 1954.
11. Celander, O. and Haglund, G.: Neuromuscular block and respirator treatment in the management of severe salicylate intoxications, Acta. Anesth. Scand. 2:123, Sept. 1958.
12. Erganian, J.A., Forbes, G.B. and Case, D.M.: Salicylate intoxication in the infant and young child, J. Pediat. 30:129, Feb. 1947.
13. Dietrick, A.C., Guard, H.L. and Geppert, L.J.: Salicylate intoxication in children, U.S. Armed Forces Med. J. 3:149, Jan. 1952.

References - Chart 6 - page 2

14. Barnett, H.L., Powers, J.R., Benward, J.H. and Hartmann, A.F.: Salicylate intoxication in infants and children, J. Pediat. 24:214, Aug. 1942.
15. Kelley, V.C. and Done, A.K.: Poisoning in childhood, Rocky Mountain Med. J. 53:291, Mar. 1956.
16. Poirier, R. and Corbet, R.: Acute salicylate poisoning in children, Canad. Med. Assoc. J. 67:117, Aug. 1952.
17. Beatley, R.: Death due to synthetic analgesics, Medico-Legal Bull. 150:1, Oct. 1965.

In the next chart I have analyzed 17 scientific reports in the medical literature where all of the cases of aspirin and salicylate ingestion are recorded, from which I could get the statistics on this phenomenon. In the 463 cases recorded here, you will note 193 of the 463, or 42 percent, were caused by therapeutic overdosage. In other words, these were overdosage cases where the parents or doctors gave the child too much aspirin and where the child had nothing to do with it. Therefore, almost half of the cases seen of aspirin overdosage are due to the therapeutic overdosage administered by adults. And the other amazing, and to me very disturbing feature, is that in these 463 cases, there were 44 deaths and 37 of them, or 84 percent, were in therapeutic series.

Thus it is therapeutic overdosage which is most serious, rather than a child helping himself to aspirin tablets. It follows from these figures that in about six out of every seven deaths from aspirin and the salicylate group, even a completely safe package, if one existed, would make no difference at all.

In the attempt to reduce this type of serious overdosage, I have just written a book on aspirin for physicians, copies of which are here for you.

Senator Moss. We have them, sir.

Dr. TAINTER. I brought enough copies along for each of the committee. This is a monograph on how physicians should use aspirin, how they should treat overdosage, and all of the other factors about it which would improve its safe therapeutic use. I may say that in this book I achieved instantaneous best seller-list status, because this book will be distributed to over 100,000 doctors in this country, in fact to every doctor who has any reason to use aspirin in his practice. In addition, it will be put in every medical and hospital library, so it will have a maximum impact in trying to improve the use of aspirin.

In that half of the children, where the child takes the medicine himself as a truly accidental episode, special behavior patterns seem to be important. We heard this morning that some children are excessively active, they restlessly get into things every time a mother's back is turned. Some perversely swallow tablets to create parental confusion or to demand attention. Many of these children are "Dennis the Menace" of the comic strip type. Such children are well known to the psychologist, psychiatrist, or pediatrician. They are not uncommon.

References - Chart 7

THE REPEATER PROBLEM IN CHILDHOOD ACCIDENTAL POISONING
FROM ALL SUBSTANCES

1. Jensen, G.D. and Wilson, W.W.: Preventive implications of a study of 100 poisonings in childhood, Pediat. 25:490, Mar. 1960.
2. Corsa, L. and Stallones, R.A.: Epidemiologic study of childhood poisonings in two California counties, Pediat. 28:480, Sep. 1961.
3. Meyer, R.J.: Acetylsalicylic acid (aspirin) poisoning, Am. J. Dis. Child. 102:47, July, 1961.
4. Griffith, J.F. and Carter, R.O.: Participation of industry in poison control, Arch. Environ. Health 11:678, Nov. 1965.
5. Wehrle, P.F., DeFreest, L., Penhollow, J. and Harris, Virginia G.: Epidemiology of accidental poisoning in an urban population. 3. The repeater problem in accidental poisoning, Pediat. 27:614, Apr. 1961.
6. Koumans, A.J.R.: A new aspect of "accidental" poisoning in childhood, Pediat. 25:1067, June 1960.
7. McIntire, M.S. and Simmons, D.L.: Poison control in Nebraska, Nebraska Med. J. 45:112, Mar. 1960.
8. Sobel, R. and Margolis, J.A.: Repetitive poisoning in children: A psychosocial study, Pediat. 25:641, Apr. 1965.

I have summarized in chart 7 eight published scientific articles on these repeater children. You will see that in the 1,465 children who are summarized in these papers, repeaters were very common, going up to as high as 25 percent in the Jensen series at the top of the chart. Sobel had an astounding experience where he had 20 children who poisoned themselves 151 times during the period of time he was writing about.

The repeater child is a real phenomena. The child learns to take the medicine to get attention, and for the excitement of the trip to the hospital. They will search out something to take, because they have a psychological drive that requires this outlet.

The opportunity for a child to get into trouble is greatly increased if the parent is careless in the storage of the household product. Storage in a place the child could not get into would eliminate all cases of true accidental poisoning of this type. But what do we find? Chart 8 summarizes the data from two reports where the storage place is indicated on the right side of the chart. You can see from these studies that in about three-quarters of the time, or even more frequently the material was stored in what was not a normal storage place for medicine.

References - Chart 8

STORAGE PRACTICES FOR VARIOUS SUBSTANCES
ACCIDENTALLY INGESTED

1. Corsa, L. and Stallones, R.A.: Epidemiologic study of childhood poisonings in two California counties, Pediat. 28:480, Sep. 1961.
2. Verhulst, H.L. and Crotty, J.J.: National Clearinghouse for Poison Control Centers Bulletin, Sept.-Oct. 1964.
3. Jacobziner, H. and Raybin, H.W.: Accidental poisonings in childhood and their prevention, J. Pediat. 49:592, Nov. 1956.

Also, there is a surprisingly large number where, as you will see on the left side of the chart, it was not kept in the original container. They didn't like the container, perhaps the top was hard to get off or on, and they changed the material into another container which would be more convenient.

Petroleum products we have talked about today. Kerosene is commonly stored in pop bottles under the kitchen sink and is a serious cause of poisoning and fatal pneumonia in such children. In other reports from 46 to 80 percent of the cases, the products involved in accidental poisoning have been found to be in visible or easily accessible places and not in the usual storage place.

In the remaining small group of children, where the material was voluntarily ingested by the child himself from a properly closed original container, the use of a "child-proof package," if one existed, would save some but unfortunately only a very few lives.

Over the years we have considered at least 50 allegedly child-proof closures for aspirin. The problem to be solved is a very difficult one. I am convinced from my own experience with my 10 children and grandchildren that in situations like this a child is apt to be as smart as or smarter than his parents. We must realize that through experience, usage and education, what we conceive of as a "safety closure" today will inevitably become less than safe to future generations. This fact of historical development lies at the root of our problem and will not yield to, or be repealed by, legislation.

It is not impossible to make a bottle cap that a child cannot get off. But then many adults will not be able to get it off either. And the very difficult cap is more apt not be put back on tight, or the medicine may be transferred to a conventional bottle. As an illustration we learned this morning that Dr. Scherz and his colleague in this kind of study in Ontario, Dr. Breault, are enthusiastic about the Palm-N-Turn closure.

References - Chart 2

LOCATION OF ALL SUBSTANCES ACCIDENTALLY INGESTED
EXPRESSED AS PER CENT OF TOTAL CASES

1. Cann, H.M., Iskrent, A.P. and Neyman, D.S.: Epidemiologic aspects of poisoning accidents, Am. J. Pub. Health 50:1914, Dec. 1960.
Cann, H.M., Neyman, D.S. and Verhulst, H.L.: Control of accidental poisoning - A progress report, J.A.M.A. 168:717, Oct. 1958.
2. Mellins, R.B., Christian, J.R. and Bundesen, H.N.: The natural history of poisoning in childhood, Pediat. 17:314, Mar. 1956
3. Jensen, G.D. and Wilson, W.W.: Preventive implications of a study of 100 poisonings in children, Pediat. 25:490, Mar. 1960.
4. Corsa, L. and Stallones, R.A.: Epidemiologic study of childhood poisonings in two California counties, Pediat. 28:480, Sep. 1961.
5. Wehrle, P.F., DeFreest, L., Penhollow, J. and Harris, Virginia G.: Epidemiology of accidental poisoning in an urban population. 3. The repeater problem in accidental poisoning, Pediat. 27:614, Apr. 1961.
6. Middlekamp, J.N.: Poison control centers in St. Louis, Missouri Med. 56:149, Feb. 1959.
7. Jacobziner, H.: Public Health Reports 81:31, Jan. 1966.
8. McIntire, M.S. and Simmons, D.L.: Poison control in Nebraska, Nebraska Med. J. 45:112, Mar. 1960.

In the next chart from articles which are earlier than reported today (but the order of magnitude of the figures still carries the lesson I believe) are combined the details of 25 cases between the two groups, where there was a failure of the safety container. It is interesting to analyze that in these 25 cases the container top was left loose in four; and it was left off altogether in six. So, there are 10 cases where the Palm-N-Turn container was not kept closed. In eight others the material was transferred to another container, possibly because it was too hard to manipulate this pressure-top. In only seven out of the 25 cases of failure did the child open it himself. This is one of the difficulties of making it too difficult to open. You can create a failure to use the package properly by many of the adults.

In addition, unfortunately, the Palm-N-Turn closure doesn't do everything it should, which is one reason why we have not embraced it enthusiastically. Aspirin, unfortunately for us, is a very sensitive chemical compound. It breaks down if it gets moist or if it is exposed to too much heat. We must have for acceptable commercial distribution a container which keeps the aspirin free from moisture for up to 3 to 5 years.

Many containers, except perhaps those with properly sealed screw caps breathe, as we say. As the atmospheric pressure rises and falls with the warmth of the day and the coolness of the night, a vacuum is created inside of the container and air is sucked in. If you are in a humid area of the country, you suck in moisture.

The tablets you have in front of you in Palm-N-Turn vials are commercial aspirin tablets which have been exposed to a warm humid atmosphere for only 2 weeks. This atmosphere is similar to that of the Gulf States in the summertime. Tablets in a package that would meet our standards have to stand up under these conditions for at least 3 years.

You notice these tablets are discolored and matted together. If you pull the cotton out, you see salicylic acid crystals in the bottle, showing they are decomposed. Both the adult and the children's tablets I am showing you are unsalable after only 2 weeks and should not be used.

This is the reason why we cannot use the Palm-N-Turn on these aspirin products, nor could it be used on any other product that is sensitive to moisture.

Another top which was talked about in the presentation here yesterday is this one. (Demonstrating.)

This came to my office just a few days ago. I dropped it in a glass of water overnight to see whether the top was tight. I didn't try to force water in. But see what happened. You can see water inside. Obviously this cap is not going to be usable for aspirin tablets.

Another closure which was shown to you here in these hearings—I won't embarrass anybody by mentioning the name—was sent to me. I filled it with water, dried off the outside carefully and shook it. You could shake water out of it.

Obviously these kinds of safety closures, while they may be all right for certain products and for short periods, are not generally applicable.

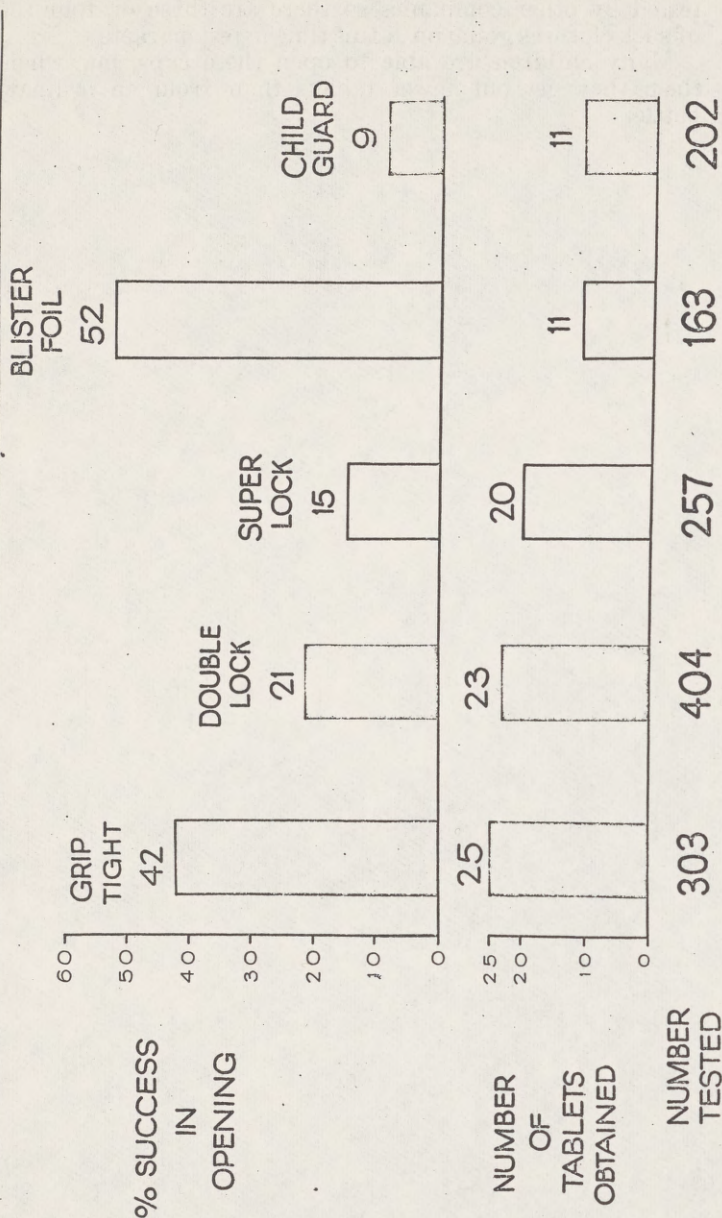
A company has tried to improve on the Palm-N-Turn principle by making a tighter fit on a glass bottle. This is called the "Screw Lock"

or "Child Guard" cap. This is being tested by us in the test markets in Arizona as I mentioned before. Similar caps to this are being tested by other companies so there are three or four separate tests of such closures going on at this time in test markets.

Many children are able to open these caps, but when they open them they get out fewer tablets than from an ordinary screwcap bottle.

COMPARISON IN FOUR PAIRED TESTS OF FIVE SAFETY CLOSURES

Children 2 to 6 years of age 140, 163, 521 and 202 Children in each group=(1026)
and 10-15 minute duration, (Sterling data)



Here in chart 10 is a study for example we carried out on over a thousand children. You can see that for the grip-tight cap, which is a plastic one we have used before, 42 percent of the children could get them open. For the punch-out type (blister-foil) which Dr. Done showed you this morning, 52 percent could open them. And in this new cap, "Child Guard," 9 percent could get them open.

But you see from the bottom bars that the children got on the average only 11 tablets out of a "Child Guard" bottle as compared to 25, 23, 20, and 11 with the other closures.

We think that this is an improvement; however, I will tell you frankly that I am not confident at the present moment that it is tight enough in its seal so we can market a children's aspirin successfully with this cap in Southern climates where humidity and temperature are very adverse.

However, we have an obligation to make our tablets available not only to the parents of the preschool child but also to other adults, including the aged, the infirm, the patient with tremors, the one whose hands are crippled by arthritis, et cetera. Tests of the "Screw Lock" or "Child Guard" improvement with such individuals are therefore being carried on by several groups of workers.

OBSERVED DIFFICULTY IN OPENING

	Number - (600) Total Women	(281) Arthritis	(119) Over 55 years
"CHILD- GUARD"	66%	68%	77%
SCREW CAP	1%	2%	1%
SNAP TOP	19%	29%	35%
GRIP TIGHT	44%	58%	71%
BLISTER FOIL	23%	26%	32%

We have tested this in 600 adults, of whom 281 had arthritis of varying degrees, as shown in chart 11. Sixty-eight percent of the arthritic people had difficulty in opening this modification of the "Palm-N-Turn closure." We also broke the figures down according to age, and arthritis is more common in the aged than in the young. Of the 119 over 55, 77 percent had difficulty in opening this closure, whereas for the screwcap, snap top and blister foil, there was some difficulty but not anywhere near as much.

UNABLE TO OPEN

	Number- (600) Total Women	(281) Arthritis	(119) Over 55 years
"CHILD- GUARD"	10%	18%	22%
SCREW CAP	1%	1%	1%
SNAP TOP	2%	6%	8%
GRIP TIGHT	5%	13%	13%
BLISTER FOIL	1%	1%	1%

In the next chart we have a continuation of these observations, where in the same patients, 18 percent of the arthritics couldn't open it at all, and 22 percent of those over 55 years of age could not open this modification of the Palm-N-Turn. It seems to us that in the attempt to make this container completely safe for the preschool child we may have made it impossible to use for an important part of the adult population, who cannot get along well without aspirin or related medication.

Test marketing of the child-guard type of cap under various names is now going on in a half dozen communities. When the results of these tests under practical use conditions are evaluated, the industry will be able to judge whether we have now made it too difficult to open to be acceptable, and if so will have to search for better alternatives.

As a possible hint of the outcome, I understand several of the chain drugstores which began regularly dispensing Palm-N-Turn on prescriptions have received substantial objections from their customers, particularly the aged and arthritic, because of the difficulty of removing these caps. As a result of these complaints these chains now only dispense Palm-N-Turn caps on a special request basis.

We hope that ultimately we can achieve greater safety by packaging children's aspirin in some form of safer container, one which is not necessarily developed or under test at this time. But because it seems probable that a desirable degree of safety for a child will require a closure which will be unacceptable to, or too difficult for, many adults, we are now testing the child-guard on not only the children's aspirin but also on one size bottle of adult aspirin tablets. This permits purchase of adult tablets in the safety closure bottle for the small proportion of homes where there are young children, and still makes available to other families, and particularly to the elderly or infirm, a more easily opened bottle in homes where no hazard to children exists.

In the conference on children's aspirin held under FDA auspices in November 1966, it was agreed that a pressing need was to have a thorough investigation of standards and performance of safety closures carried out by a representative committee of Government scientists, pediatricians, and industrial experts. Dr. Goddard appointed such a committee, on which I serve, under the chairmanship of Dr. Edward Press, State Health Officer of Oregon. The committee has completed the first phase of its assignment by devising and validating by test an experimental protocol for determining the efficacy of safety closures. As described by Mr. Sullivan today this committee is now proceeding to test a variety of proposed safety packages on an adequate number of children and adults, in the expectation of being able to establish performance standards, by which such packages can be judged as safe. Until these standards are created by this committee, or by others, there are no bases from which the Secretary of HEW or anyone else could draft regulations purporting to set safety performance requirements for packages or closures.

You will remember that Dr. Done made the same observation here. He just didn't know what proper standards should be. Clearly such legislation or regulations cannot be soundly drafted at this time.

We will not know for some months how these tests are coming out. It is therefore vitally necessary that our freedom of action be maintained to test, to adapt, discard, and to finally adopt the best solution

which modern pharmaceutical science brings forward. Any legislation at this time which would permit or virtually require regulations to be issued restricting such freedom to move ahead will choke off experimentation and delay progress.

There is another phase of this problem which over the long pull in our opinion is going to be much more important than modifications in the packaging. This was brought forward in the joint recommendations of the FDA, medical profession, and industry conference of 1955. The recommendations of that conference are summarized in Chart 13.

1955 FDA - Medicine - Industry - Pharmacy Conference on Salicylates
Washington Feb. 14, 1955

185

Recommendations:

1. Labels to bear "WARNING: Keep out of reach of children."
2. Dosage: "For children under three years of age, consult your physician."
3. $1\frac{1}{4}$ grain strength for Children's Aspirin tablets.
4. No more than 50 $1\frac{1}{4}$ grain tablets of Children's Aspirin per package.
5. Encourage development of safer packaging.
6. Continue flavored tablets.
7. Stress public education on prevention of accidental poisoning.

You notice they said that there should be a warning to keep out of reach of children, to consult your physician for dosage under 3 years of age, to use one and a quarter grain strength for the children's aspirin tablet, and restrict the size of the bottle to 50 tablets. Also, the last line is the important one for today, to stress public education on prevention of accidental poisoning.

FDA Conference on Prevention Accidental Ingestion of
Salicylate Products by Children (Arlington, Va., Nov. 21, 1966)

Major Conclusions:

- 1 Children's aspirin tablets continue grains $1\frac{1}{4}$.
- 2 Did not prohibit flavoring Children's Aspirin.
- 3 36 tablets maximum per bottle.
- 4 New Warning: *"In case of accidental overdose,
contact a physician immediately."*
5. Appointed committee to continue study safer closures.
6. Stressed need for better educational safety programs.

There was also a conference held under Dr. Goddard's auspices in November 1966 over which Dr. Harry Shirkey presided and Mr. Luther and I attended. The conclusions have been summarized in chart 14 which reiterate much of what was recommended in 1955. But notice that among the conclusions they stressed again the need for better educational safety programs. Better education comes out repeatedly.

Sterling has adopted this need for education as part of its formal policy regarding aspirin.

STERLING'S POLICY ON SAFETY FOR ASPIRIN

1. To market all children's aspirin in the safest practical package.
2. To test the value and acceptability of a safety closure on an adult size bottle for families where there are young children.
3. To continue search for improved safety packaging.
4. To vigorously continue educational programs on safety.

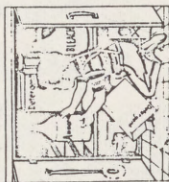
Here for your information is what I have chosen to call Sterling's official policy on safety for aspirin. In the first place, we will market all of our children's aspirin in the safest practical package. It has to be a package that works, and keeps the product without deterioration. Second, we will test the value and acceptability of a safety closure on an adult size tablet bottle for families where there are young children. We will continue the search for improved safety packaging. Last, but not least, we will vigorously continue educational programs on safety.

Now to implement this policy, may I point out first that we are using or testing the safest practical closures we can find, on both children's and adult tablets and we will continue to do so if we are not prevented by new regulations.

Second, we pack all of our bottles of aspirin in cardboard cartons, which are pasted shut to make them difficult for a small child to open. I think we are unique in the industry with this particular safety feature.

NEW! Child-Guard CAP on adult Bayer 75-Tablet
Size just for families with young children!

So, to help families with little children, Bayer Children's Aspirin now has an improved protective cap — the new CHILD-GUARD CAP. This protective CHILD-GUARD CAP is also available in a new size of adult Bayer aspirin.



a 75-tablet bottle. This means that if you have little children, you can get this special protective cap on both Bayer products...the orange flavored Bayer that you give to your children and the adult Bayer that you use yourself. Bayer gives you the extra protection and reassurance you want.

But maximum safety still depends on you. As a concerned parent, you can guard against trouble by always keeping potentially dangerous household items securely capped, and by immediately returning them to a safe storage place well out of children's reach.

Here's why:

It's the tablet size doctors recommend. Each tablet contains 1 1/4 grains (1/4 adult dose) of the exact tablet size doctors prescribe for youngsters for fast, effective, gentle pain relief.

It's the highest quality aspirin you can buy for your child—genuine Bayer Aspirin. So reliable. So effective and gentle. Its orange flavor is smooth and pleasant. Tasting all the way through, so children accept it readily.

DOOSAGE

Is to be administered only under adult supervision.

Under 3 years	consult physician
3 years	1 tablet
4 years	2 tablets
5 to 7 years	2 or 3 tablets
8 to 12 years	3 or 4 tablets
Over 12 years	4 tablets

Indicated dosage may be repeated every

three hours up to but not more than five times a day. Larger dosage may be prescribed by your physician.

DIRECTIONS FOR USE

FEVER FROM MINOR AILMENTS: To reduce fever and relieve pain resulting from minor ailments, give according to age as stated.

PAIN FOLLOWING INOCULATIONS: To relieve the painful discomfort of "shots",

TEETHING PAINS: To relieve pain, consult

SLEEPLESSNESS: To relieve discomfort

may come naturally. Give according to age as listed.

COLDS-FLU: To relieve painful discomforts and reduce fever, give according to

HEADACHE: To relieve headache and other minor aches and pains. Just accord-

SORE THROAT: To relieve sore throat; due to age as listed.

to colds, minor throat irritations, or follow-
ing removal of tonsils. Give according to
directions listed. Let tablets dissolve in

Do not rinse mouth. Tablets also may be dissolved in a small amount of

In case of high or continued fever, severe or persistent sore throat especially when accom-

panied by high fever, headache, nausea or vomiting, consult your physician.

WAYS TO ADMINISTER

Orange flavored Bayer Children's Aspirin Tablets may be administered in any of these four easy ways, with or followed by a drink of water, milk or fruit juice chewed, swallowed whole, dissolved on tongue, or dissolved in a glassful of water. Tablets may be easily powdered and mixed with foods for administering to infants when directed by a physician.

PARENTS—IMPORTANT!

Your child's safety depends on you. Never let your child confuse any medicine with candy.

WARNING: Keep this and all medicines out of children's reach. In case of accidental overdose, contact a physician immediately.

THE BAYER COMPANY

●●●●●

**MOTHERS! Try these
other fine products**

ZBT.
Baby Powder

**Fletcher's
CASTORIA**
A natural vegetable
lubricant for the
intimate life of
men and women.

1.59

Third, inside each package we put an illustrated leaflet which emphasizes safety precautions. That for the children's size, which I have shown here in the chart shows how to open the child-guard cap. It points out the danger of materials under the sink, and gives other information required for using aspirin safely. This is the children's package.

1969: CHILD-GUARD CAP ON
BAYER ADULT 75's

**SPECIAL ADULT BAYER PACKAGE FOR
FAMILIES WITH YOUNG CHILDREN!**

**Bayer helps protect
your child from
his own curiosity**

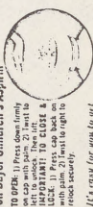
A small child is one of nature's most inquisitive creatures. One minute he's playing peacefully. The next, he's in your sewing box, or your make-up kit, or your medicine chest. No matter how closely you watch him, he has a way of getting into things he's not supposed to. A child's curiosity knows no bounds.

To help families with little children in the house, Bayer Aspirin now makes available this special protective package: a new 75-tablet package of *adult* Bayer Aspirin with a protective CHILD-GUARD Cap on the bottle. The cap is designed for you to get it, but

This protective CHILD-GUARD CAP is also available on Bayer Children's Aspirin. This means that if you have little children, you can get this special cap on both Bayer products...the Adult Bayer that you buy for your own use and the orange flavored Bayer that you buy for your children. Bayer gives you

the extra protection and reassurance you want. But maximum safety still depends on you. As a concerned parent, you can guard against trouble by always keeping potentially dangerous household items securely capped, and by immediately returning them to a safe storage place well out of children's reach.

New! Protective CHILD-GUARD CAP
on adult Bayer Aspirin and
on Bayer Children's Aspirin



It's easy for you to get off, but not for your child. Cap is designed just to come off when you press down with your firmly before turning.

DIRECTIONS for ADULTS (5 GRAIN TABLETS)

in the following conditions:

MENSTRUUAL PAIN—For relief of functional menstrual pain, headache and pain due to cramps, take 1 or 2 tablets with half a glass of water every 4 hours, as necessary, up to 12 tablets a day.

HAZARD 330433—When caused by minor paintless stress or discomfort, take 1 or 2 tablets with half a glass of water at bedtime.

DIRECTIONS for CHILDREN

To be administered only under adult supervision
For relief of Hives, Itches, Aches and Pains and the pain-
ful effects and some skin eruptions.

Under 3 years . . .	consult your physician
3 to 4 years . . .	1 to 2 tablets
5 to 7 years . . .	2 to 3 tablets
8 to 12 years . . .	3 to 4 tablets

Over 12.....same as adult

IMPORTANT NOTICE!

distinctions are appropriate for the actors and parts that may be treated by some mechanisms. If these changes do not bring relief and the pain persists, it is an indication that this particular person is a patient that requires the attention of a physician. After these distinctions about

equivalent with any other fusion atom. A single fusion atom is the only one equivalent to the others. The cause of the fusion atom is not the fusion atom itself, but the fusion atom itself.

for various conditions, when needed.
In accidental emergencies, contact a physician immediately.

ALING DRUG INC., NEW YORK, N.Y. 10014
C7 103 09

HEADACHES—Take 1 or 2 tablets with half a glass of water every 4 hours, as necessary, up to 12 tablets a day.

COLDS—FLU—To relieve painful discomforts and reduce the fever, take 1 or 2 tablets with half a glass of water (or fruit juice) every 4 hours, as necessary, up to 12 tablets a day.

MUSCULAR ACHES AND PAINS—Take 1 or 2 tablets with half a glass of water every 4 hours, as necessary, up to 12 tablets a day.

TOOTHACHE—EXTRACTIONS—or for relief of other pains following dental work, take 1 or 2 tablets with half a glass of water every 4 hours, as necessary, up to 12 tablets a day.

ARTHRITIS AND RHEUMATISM—For the temporary relief of minor pains, take 1 or 2 tablets with half a glass of water every 4 hours, as necessary, up to 12 tablets a day.

more than a day. 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.

MUSCIS—LUMBAGO—SCIATICA—For the temporary relief of muscle pains, take 1 or 2 tablets with half a glass of water every 4 hours, as necessary, up to 12 tablets a day.

SORE THROAT DUE TO A COLD AND FOR RELIEF OF MINOR THROAT IRRITATIONS—REMOVAL OF TONSILS—(TONSILLECTOMY)—To relieve pain and swell-

WARM water every 2 hours, as necessary for best results, let a little trickle down throat and do not rinse mouth. In severe or persistent sore throat, especially when accompanied by high fever, head,

NOTE: Your physician may prescribe larger doses if you experience severe vomiting, which may indicate a severe infection, consult physician

Printed in U. S. A.

1

The next chart shows you a similar leaflet for the adult size, where the same basic safety precautions are summarized. Clear and conspicuous statements regarding the proper handling of these products appear also on the outside of the carton along with a reference to the fuller discussion in the leaflet.

In the fourth place, we are making special efforts to alert physicians to proper dosage and treatment of any overdosage incidents by means of broad distribution of the monograph I have just shown you on the therapeutic uses of aspirin.

In the fifth place, in addition, to help alert parents we are making available in doctors' waiting rooms the children's aspirin picture book, a "Mother Knows", which I am now showing you, which tells how to use aspirin. In the center you can see it has a double page spread on the safety cap and how to put it back on. It says "the mother replaces the double lock cap and makes sure aspirin is safely stored." This booklet, you will be interested to know, we have made into a television program. It has been shown on the air in the last year 215 times, or about two and a half times every week. From estimates of the audience, this has been seen by roughly one and a half billion people, one and a half billion exposures to this safety message.

Finally, realizing that these measures, while important, may not provide for the full needs of the situation, we have collaborated in establishing the tremendously promising Council on Family Health, which by massive educational efforts will strike at the roots of the problem: Mother's inadequate awareness of safety requirements in the home over which she presides.

COUNCIL ON FAMILY HEALTH

(Established April 1, 1966)

First Chairman of the Board of Directors... Dr. J. Mark Hiebert

WHAT IT IS...

- a non-profit public service educational organization sponsored by members of drug industry to promote home safety and family health.

ITS OBJECTIVES...

- to make mother a more knowledgeable guardian of the family health.
- to reduce home accidents, including accidental poisonings, by educating mother to causes and prevention of home accidents.
- to alert mother to benefits available through medical progress.

In the next chart I have summarized the activities of the Council on Family Health. It is a nonprofit public service educational organization sponsored by, I think, now 58 different companies in the drug industry. Its objective is to make Mother a more knowledgeable guardian of the family health. It also aims to reduce home accidents, including accidental poisonings, by educating Mother to the causes and prevention of home accidents and to alert Mother to the benefits of medical progress, that is protective inoculation and other public health precautions.

COUNCIL ON FAMILY HEALTH

WHAT IT DOES...

- Carries on a nation-wide educational safety program directed mainly to mother, traditional guardian of the family health.
- Utilizes all available educational media including newspapers, periodicals, radio, TV, club meetings, parent-teacher associations, schools and county home extension organizations, etc.
- Cooperates with public and private organizations including Am. Acad. of Ped., Am. Med. Assoc., Am. Assoc. of Poison Control Centers, U.S. Public Health Service, FDA, Am. Assoc. of Retired Persons, state and municipal health departments, in producing and/or distributing material.

How does it go about this? What does it do? It carries on a nationwide educational safety program directed mainly to the mother, who is the traditional guardian of the family health. It utilizes all available educational media, including newspapers, periodicals, radio, television, club meetings, parent-teacher associations, schools and county home extension organizations, et cetera. It cooperates with public and private organizations who are also interested in safety, including the American Academy of Pediatrics, American Medical Association, American Association of Poison Control Centers, U.S. Public Health Service, Food and Drug Administration, the American Association of Retired Persons, because the geriatric patient is concerned with safety, State and municipal health departments, and it produces and distributes educational material.

Is this just a paper organization? Does it really function effectively?

COUNCIL ON FAMILY HEALTH

ACTIVITIES IN 1968...

1. Produced over 100 news and feature stories, scripts and cartoons for newspapers, periodicals and radio.
2. Distributed recordings and tapes on "Home Safety" featuring movie stars which had over 10,000 broadcasts on individual stations.
3. Issued three 30-second TV spots on Home Safety run on over 300 stations approximately 10,000 times.
4. Distributed 3,000 Women's Club speaking kits entitled "Mother, Key to Safety in the Home." With these went 40,000 illustrations of home hazards.
5. With U.S. Public Health Service, prepared and distributed 2,000 speaker kits on home safety for retiree groups.
6. Cooperated with Canadian Council on Family Health in their similar activities.
7. Responded to over 5,000 inquiries and requests for more information and materials.

Last year (1968) this Council on Family Health produced over 100 news and feature stories, scripts and cartoons for newspapers, periodicals and radio. It distributed recordings and tapes on home safety, featured movie stars which had over 10,000 broadcasts on individual stations. It issued three 30-second TV spots on home safety run on over 300 stations approximately 10,000 times. It distributed 3,000 women's club speaking kits entitled "Mother, Key to Safety in the Home." With these went 40,000 illustrations of home hazards.

With the U.S. Public Health Service, the Council on Family Health prepared and distributed 2,000 speaker kits on home safety for the geriatric group of individuals. It also reached across the border to cooperate with the Canadian Council on Family Health, which is sponsored by the drug industry in Canada.

In addition, its full-time staff responded to over 5,000 inquiries and requests for more information and safety materials. These educational activities of the Council on Family Health are impressive in scope and coverage. They are continuing at a constantly increasing rate.

Senator Magnuson, Chairman of the Commerce Committee, has honored the council by endorsing its philosophy and program in the Congressional Record of July 11, 1968. He states:

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 two 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 . . .

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.

We believe the material presented in my remarks today establish the following facts:

1. Greater safety in the home for the preschool child is an objective desired by all.
2. Poisoning in the home is responsible for only one out of every 15 accidental deaths of preschool children.
3. Among the relatively smaller proportion of these deaths due to salicylates six out of every seven are the result of overdosage by the parent or physician where the kind of package or closure would have made no difference in the unfortunate result.
4. Therefore, a completely safe closure or package, if one existed, would be able to make only a disappointingly small improvement in home safety as reflected by such childhood mortality.
5. The best safety closures presently being used or proposed still can be opened by some preschool children, and yet are so difficult that many infirm adults cannot open them and are thus led to leave the bottles open or to transfer the contents to other less safe containers.
6. This leads to the conclusion that these medicines should be made available in both safety and conventional containers so that the safety package could be used for homes with young children.
7. The most important cause of home poisoning is carelessness in storing and handling hazardous materials.

8. Education of the mother to such home hazards strikes at the root causes of all home accidents, including poisoning by medicines.

9. The Council on Family Health, organized and financed by the pharmaceutical industry, is vigorously creating home safety appreciation in mothers by every available medium of public communication.

10. These total influences have progressively reduced home poisoning mortality each year since 1963 and give promise of still further reductions if the present trend is not interfered with.

Therefore, we are confident that if we are not restrained or inhibited by well intended but premature legislation, we will continue to make conspicuous gains in the years ahead. So much effort is being put at this time by industry into attempts to make the home a safer place for the preschool child that legislation or regulation would be unwise while the present programs are producing progressive improvement. It should be reiterated that the latest statistics released by the National Clearing House for Poison Control Centers, which I showed today, demonstrate that the reported incidence of children's aspirin ingestion cases has been decreasing steadily in the last 4 years, and that deaths in this category have already dropped by about 37 percent. Therefore, we respectfully urge that this is not the time for new legislation or regulation which well might have the adverse effect of checking the valuable progress now being made.

(The statement follows:)

OCTOBER 1, 1969.

I am Dr. Maurice L. Tainter, appearing for Sterling Drug Inc. I am a physician licensed to practice medicine in California and New York, and a pharmacologist. I was on the teaching faculty of Stanford University School of Medicine for about 20 years during which time I became Professor of Pharmacology, a subject which deals with the actions and uses of medicines and the treatment of their adverse effects. Subsequently, I became the Vice President for research for Sterling Drug Inc., which position I held for 26 years until my retirement this year.

Sterling Drug Inc. markets several thousand medicinal products throughout the world through its various divisions and subsidiary companies. Many of these are the major products in their therapeutic class, well known to either physicians or lay individuals. One of these, aspirin, is the most widely used medicine of all time. Under our name, Bayer aspirin, its use has been pioneered here and abroad for about 70 years. It is safe to say that aspirin in some one of its many forms is readily available in substantially all households and its use is familiar to even small children. Possibly because of this widespread familiarity, aspirin-containing products are involved in more accidental ingestion or alleged poisoning episodes than any other individual drug or group of products, and are therefore of special interest in these present hearings.

I propose to discuss some of the factors needed to understand the epidemiology of such overdosage and to draw conclusions from these as to how best the problem may be ameliorated. These factors are ambiguous in that much of the reported data does not differentiate between aspirin and all other salicylate preparations, including the highly toxic methylsalicylate or oil of wintergreen commonly used as a household liniment. Much of what I will say specifically about salicylates is also applicable at least in part to other drugs. Therefore my remarks will bear on household poisoning in general although using mainly salicylate statistics for illustration.

I believe that our analysis of the facts surrounding salicylate overdosage in the preschool child will show that the problem is quite different from what might be assumed without investigation, and that as a result the remedy proposed in the pending legislation is not timely nor likely to be really effective or to promote public welfare. I also will attempt to be constructive by pointing out alternative routes for progress which should be utilized.

Senate Bill 2162 would amend the Federal Hazardous Substances Act to provide for and require the use of child-resistant packaging to protect children from serious personal injury or serious illness resulting from handling, using or in-

gesting any product found in or around households. The objectives of the bill as stated I am sure will be unanimously praised by all the witnesses in the hearings. Sterling joins all others in being completely in favor of maximal safety in the home and with more particular reference to substances which might be ingested, such as medicines.

The remedy proposed of putting potentially hazardous substances in child-proof packages seems a very simple, direct and supposedly efficacious one. Our company has explored this approach to greater safety for many years in trying to make our packaging of aspirin as safe as possible. The various steps we have taken in more recent years are summarized in Charts 1 and 2.

CHARTS 1 AND 2—STERLING'S EFFORTS TO IMPROVE THE SAFETY OF BAYER ASPIRIN FOR CHILDREN'S PACKAGES

Other companies have had similar programs, so that today by voluntary action all children's aspirin is packaged only in bottles of 36 tablets, closed with the most child-resistant closure so far developed that is suitable for such use. Although these efforts have not succeeded in completely eliminating serious poisoning in children from salicylates they apparently have decreased it appreciably in the last four years as shown in Chart 3. It is striking that the chart shows that deaths from the salicylate group have been decreasing faster than those from drugs or all substances combined.

CHART 3—POISONING DEATHS IN CHILDREN UNDER 5 YEARS OF AGE—1957-67

Before enacting legislation which might change the present favorable trend, we should reassess the situation. We need to review the facts regarding accidental deaths of children in the home to see whether more helpful courses of action may be uncovered.

What are the major causes of accidental home deaths in the preschool child?

CHART 4—DEATHS FROM HOME ACCIDENTS—1967

Chart 4 shows that there were 5,000 accidental home deaths of these children in 1967 of which burns and suffocation accounted for over half and poisoning from all substances only 7% of the total. Naturally many more accidental ingestion cases are reported (71,563) in 1968 to the Poison Control Centers. These are of widely varying degrees of seriousness.

CHART 5—INCIDENCE OF ACCIDENTAL INGESTIONS IN CHILDREN UNDER 5 IN 1968

Chart 5 shows that medicines make up about half the preschool child cases (38,354/71,563) and the aspirin group about 40% of these medicinal episodes or 22% of the total (15,523/71,563).

Is information available explaining the causes of the apparently high frequency of reported accidental ingestions in these children? Each phone call and case seen in a Poison Control Center is recorded as a "poisoning incident". In many it is uncertain whether any or how much of the product may have been taken. As an example, some observers have reported that in about 90% of the aspirin incidents that get into the records there are no symptoms at all.

The proposed legislation would not affect in any way by far the most important cause of serious and fatal poisoning from aspirin or salicylates which is therapeutic overdosage. This is a remarkable situation which no "safe packaging" measures are going to modify.

CHART 6—CONTRIBUTION OF THERAPEUTIC OVERDOSAGE TO POISONING BY SALICYLATES IN PRESCHOOL CHILDREN

In Chart 6 it will be seen that in 17 studies of large groups of poisoning cases 193 out of 463 salicylate cases or 42% were caused by the administration of overdoses by either physician or parent. There were 44 deaths in these 463 cases. Thirty-seven of them, or 84% of the total, were therapeutic where the children were given the medicine by an adult. Therefore in 6 out of every 7 deaths even a completely safe package, if one existed, would have made no difference. In the attempt to overcome this type of serious overdosage we have just published a monograph on the proper therapeutic uses of aspirin, including dosage, which is being distributed by Sterling Drug Inc. to virtually all doctors who use this medicine. Copies of it are supplied herewith for your own information.

In the remaining cases where the child took the medicine himself, interesting behavioral patterns seem to be important. We all know that some children are excessively active, restlessly getting into things every time the mother's back is turned. Some perversely swallow tablets to create parental confusion or to demand attention. Many of these children are "Dennis the Menace" of the comic strip type. Such children are well known to the psychologist, psychiatrist or pediatrician. They are not uncommon.

CHART 7—THE REPEATER PROBLEM IN CHILDHOOD ACCIDENTAL POISONING FROM ALL SUBSTANCES

In Chart 7 summarizing 8 published scientific papers on this phenomenon, up to one-fourth of the 1465 children studied repeated the so-called "accidental" ingestion episode one or more times, often within a year.

The opportunity for the child to get into trouble is greatly increased if the parent is careless in the storage of the household product. Storage in a place the child could not get into would eliminate *all* cases of true accidental poisoning of this type. But what do we find? Chart 8 summarizes the data from three reports arranged by type of product and Chart 9 gives information from 8 studies according to the location of the product.

CHART 8—STORAGE PRACTICES FOR VARIOUS SUBSTANCES ACCIDENTALLY INGESTED

CHART 9—LOCATION OF ALL SUBSTANCES ACCIDENTALLY INGESTED EXPRESSED AS PERCENT OF TOTAL CASES

In from 46 to 87% of these cases, according to the two charts, the product was in a visible or easily accessible place or not in its usual storage place. In many cases the material had been transferred out of the original container to a probably less safe one. This is evidence of parental carelessness or more probably lack of understanding of the dangers of careless storage or handling.

In the relatively small remaining group where the material was truly accidentally ingested by a child from a properly closed original container, the use of a "child-proof package", if one existed, would save some but only a very few lives. Over the years we have considered at least 50 allegedly child-proof bottles for aspirin. The problem to be solved is a very difficult one. I am convinced from my own experience with my 10 children and grandchildren that in situations like this a child is apt to be as smart or smarter than his parents. Seriously, we must realize that through experience, usage and education, what we conceive of as a "safety closure" today will inevitably become less than safe to future generations. This fact of historical development lies at the root of our problem and will not yield to, or be repealed by, legislation.

It is not difficult to make a bottle cap that a child cannot get off. But then many adults will not be able to get it off either. And the very difficult cap is more apt not to be put back on tight, or the medicine may be transferred to a conventional bottle. For example in a test of 223 preschool children Scherz and Crone found that only a negligible proportion of these children could open one of the latest so-called safety closures, the Palm-N-Turn, as compared to another safety cap, as shown in Chart 10.

CHART 10—NON-CROSSOVER STUDY—2 CLOSURES

However, Dr. Scherz at the Madigan Army Base in Tacoma and his colleague in similar studies, Dr. Breault in Windsor, Ontario, who are enthusiastic about the Palm-N-Turn, also have reported the details of failures in 25 cases with it.

CHART 11—CAUSES OF FAILURES OF "CHILD RESISTANT" CONTAINERS

Chart 11 shows that in 10 of these the top was not closed properly or was left off, in 8 of the tablets were transferred to a different bottle, and in only 7 of the 25 the child opened it.

The commercial Palm-N-Turn cap is designed to fit on a plastic vial and has inadequate sealing power to exclude air and moisture. One of the glass companies has improved this basic idea by adapting it to a moisture-impervious glass bottle they call the "Screw-Lock". This is being tested by our company under the name "Child-Guard" and by others under their own names with possibly encouraging results. Nearly all children are unable to open this type of bottle and cap, and

when they do the number of tablets they get out is smaller than with other packages as is shown in the more extensive studies summarized in Charts 12 and 13.

CHART 12—CONTROLLED CROSSOVER STUDIES OF 6 CLOSURES

CHART 13—COMPARISON IN FOUR PAIRED TESTS OF FIVE SAFETY CLOSURES

However, we have an obligation to make our tablets available not only to the parents of the preschool child but also to other adults, including the aged, the infirm, the patient with tremors, the one whose hands are crippled by arthritis, etc. Tests of the Screw-Lock or "Child-Guard" improvement with such individuals are therefore being carried on by several groups of workers. In our own group of 600 patients in 8 typical American cities 68% of 281 women with arthritis had difficulty in opening this bottle and 77% of those over 55 years also had difficulty as shown in Chart 14.

CHART 14—OBSERVED DIFFICULTY IN OPENING

Among these, 18% of the arthritics and 22% of the "over 55" group could not open them at all as shown in Chart 15.

CHART 15—UNABLE TO OPEN

In contrast, much less difficulty was encountered with other earlier versions of safety closures.

It seems to us that in the attempt to make this completely safe for the preschool child we may have made it impossible to use for an important part of the adult population who cannot get along well without aspirin or related medication. Test-marketing of the Child-Guard type of cap under various names is now going on in a half-dozen communities. When the results of these tests under practical use conditions are evaluated, the industry will be able to judge whether we have now made it too difficult to open to be acceptable, and if so will have to search for better alternatives. Although the figures are not available to me, I understand that several of the leading chain drugstores which began dispensing Palm-N-Turn caps on prescriptions have received very substantial objections from consumers—particularly the aged and the arthritic—based upon the difficulty of removing these caps. As a result of these complaints, these chains now dispense Palm-N-Turn caps only on a selected request basis.

We hope that ultimately we can achieve greater safety by packaging children's aspirin in some form of safer container, one which is not necessarily developed or under test at this time. But because it seem probable that a desirable degree of safety for a child will require a closure which will be unacceptable to, or too difficult for, many adults, we are now testing the Child-Guard on not only the children's aspirin but also on one size bottle of adult aspirin tablets. This permits purchase of adult tablets in the safety closure bottle for the small proportion of homes where there are young children, and still makes available to other families, and particularly to the elderly or infirm a more easily opened bottle where no hazard to children exists.

In the conference on children's aspirin held under FDA auspices in November 1966 it was agreed that a pressing need was to have a thorough investigation of standards and performances of safety closures carried out by a representative committee of government scientists, pediatricians and industrial experts. Dr. Goddard appointed such a committee, on which I serve, under the Chairmanship of Dr. Edward Press, State Health Officer of Oregon. The Committee has completed the first phase of its assignment by devising and validating by test an experimental protocol for determining the efficacy of safety closures.

This Committee is now proceeding to test a variety of proposed safety packages on an adequate number of children and adults, in the expectation of being able to establish performance standards, by which such packages can be judged as safe. Until these standards are created by this Committee or by others there are no bases from which the Secretary of H.E.W. or anyone else could draft regulations purporting to set safety performance requirements for packages or closures. Clearly such legislation or regulations cannot be soundly drafted at this time.

We will not know for some months how these tests are coming out. It is therefore vitally necessary that our freedom of action be maintained to test, to adapt, discard and to finally adopt the best solutions which modern pharmaceu-

tical science brings forward. Any legislation at this time which would permit, and with respect to some categories, virtually require, regulations to be issued restricting such freedom to move ahead will choke off experimentation and delay progress.

There is another phase of this problem which over the long pull in our opinion is going to be much more important than modifications in the packaging. This was brought forward in the joint recommendations of the F.D.A., medical profession and industry conference of 1955. The recommendations of that conference are summarized in Chart 16.

CHART 16—1955 FDA-MEDICINE-INDUSTRY-PHARMACY CONFERENCE ON SALICYLATES

You will note in these the admonition to "stress public education". This was reiterated in the November 1966 conference convened by Dr. Goddard under the Chairmanship of Dr. Harry Shirkey, when the "need was stressed for better educational safety programs" as shown in Chart 17.

CHART 17—FDA CONFERENCE ON PREVENTION OF ACCIDENTAL INGESTION OF SALICYLATE PRODUCTS BY CHILDREN—1966

Education is an important element in Sterling Drug's formal statement of policy on aspirin safety, presented in Chart 18.

CHART 18—STERLING'S POLICY ON SAFETY FOR ASPIRIN

In accord with this stated policy, first, we are using or testing the safest practical closures we can find in both children's and adult tablets and will continue to do so. Secondly, we are packing all our bottles of aspirin in cardboard cartons which are pasted shut to make them difficult for the preschool child to open. Thirdly, we are putting inside each package an illustrated leaflet which emphasizes safety precautions in both the children's (shown in Chart 19).

CHART 19—1969: CHILD-GUARD CAP

and the adult sizes (in Chart 20).

CHART 20—1969: CHILD-GUARD CAP ON BAYER ADULT 75'S

Clear and conspicuous statements concerning the proper handling of these products appear on the outside of the carton along with a reference to the fuller discussion in the leaflet.

In the fourth place, we are making special efforts to alert physicians to proper dosage and treatment of any over-dosage incidents by means of broad distribution of the monograph on the therapeutic uses of aspirin referred to above.

In the fifth place, in addition, to help alert parents we are making available in doctors' waiting rooms the children's aspirin picture book, which I am now showing you, which graphically teaches safe use of aspirin in the home. This book has also been used widely as the text of television presentations.

Finally, realizing that these measures, while important, are unlikely to provide for the full needs of the situation, we have collaborated in establishing the tremendously promising Council on Family Health which by massive educational efforts will strike at the roots of the problem: Mother's inadequate awareness of safety requirements in the home over which she presides. In Charts 21 and 22 we have summarized what the Council is, its objectives and how it goes about to achieve them.

CHART 21—COUNCIL ON FAMILY HEALTH, WHAT IT IS

CHART 22—COUNCIL ON FAMILY HEALTH, WHAT IT DOES

The Council in three years has achieved great momentum. It is actively functioning with a full time staff on funds supplied by 58 pharmaceutical companies.

CHART 23—COUNCIL ON FAMILY HEALTH, ACTIVITIES IN 1968

Chart 23 shows that in 1968 its educational activities were impressive in scope and breadth of coverage. They are continuing at a constantly increasing rate.

Senator Magnuson has honored the Council by endorsing its philosophy and program in the pages of the Congressional Record for July 11, 1968 as follows:

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.

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.

We believe the material presented in these Hearings and in my remarks today establish the following facts:

(1) Greater safety in the home for the preschool child is an objective desired by all.

(2) Poisoning in the home is responsible for only one out of every fifteen accidental deaths of preschool children.

(3) Among the still smaller proportion of these deaths due to salicylates six out of every seven are the result of overdosage by the parent or physician where the kind of package or closure would have made no difference in the unfortunate result.

(4) Therefore, a completely safe closure or package, if one existed, would be able to make only a disappointingly small improvement in home safety as reflected by such childhood mortality.

(5) The best safety closures presently being used or proposed still can be opened by some preschool children, and yet are so difficult that many infirm adults cannot open them and are thus led to leave the bottles open or to transfer the contents to other less safe containers.

(6) This leads to the conclusion that these medicines should be made available in both safety and conventional containers so that the safety package could be used for homes with young children.

(7) The most important cause of home poisoning is carelessness in storing and handling hazardous materials.

(8) Education of the mother to such home hazards strikes at the root causes of all home accidents, including poisoning by medicines.

(9) The Council on Family Health, organized and financed by the pharmaceutical industry, is vigorously creating home safety appreciation in mothers by every available medium of public communication.

(10) These total influences have progressively reduced home poisoning mortality each year since 1963 and give promise of still further reductions if the present trend is not interfered with.

Therefore we are confident that if we are not restrained or inhibited by well intended but premature legislation, we will continue to make conspicuous gains in the years ahead. So much effort is being put by industry at this time into attempts to make the home a safer place for the preschool child that legislation or regulation would be unwise while the present programs are producing progressive improvement. It should be remembered that the latest statistics released by the National Clearing House for Poison Control Centers, which I showed today, demonstrate that the reported incidence of children's aspirin ingestion cases has been decreasing steadily in the last 4 years, and that deaths in this category have already dropped by about 37%. Therefore we respectfully urge that this is not the time for new legislation or regulation which well might have the adverse effect of checking the valuable progress now being made.

M. L. TANTER, M.D.

Senator Moss. Thank you, Dr. Tainter. That is a very full and complete statement and contains a lot of good data and information. But I don't see where your last sentence respectfully urging that this is not the time for new legislation or regulation which might have the adverse effect of checking the valuable progress now being made,

follows on the basis of all this. Can you tell me how it would check the progress now being made?

Dr. TAINTER. This is I think a matter of practical human experience. If you establish standards which say that a safety closure has to meet a certain performance standard, and we succeed in producing such a safety closure, we will use that closure to fulfill the law and the requirements. Then our attempts to develop better closures will probably stop or will be minimal from there on.

Senator Moss. But why? If the closure is not satisfactory, either if it doesn't stop the children from getting in, or if it lets the product deteriorate, or if it is too difficult, you mean to say you won't go on and try to do something still better, even though you have met a standard?

Dr. TAINTER. Unfortunately, Senator Moss, once the Government establishes a standard it is almost impossible to get it changed. We would be faced with the situation that unless these standards were drawn so loosely that they were not restrictive, in which case they wouldn't be very effective, that in order to use a different kind of a closure which would do something else, or do it better, we would have to get a new standard issued. It is so hard to get this done in the regulatory atmosphere that exists today, that I can tell you as a matter of practical judgment that such a restriction would be met by all companies and that is where the thing would stay.

Senator Moss. Perhaps you and I don't understand the standard to mean the same thing. A standard is a level below which you cannot fall. Now I don't understand a standard to put a ceiling on and say you can't go beyond that and do better, so long as you meet certain minimum requirements. That is the standard.

Dr. TAINTER. But the temptation would be very strong that having adopted something which meets the standards and therefore is in accord with what the Government says you should do, the tendency on the part of everyone would be to go to other problems that are more pressing, and not to go through all of the work of trying to change the standard or to get a higher standard set than is required.

Senator Moss. You have told me at some length about what Sterling has done in this area of trying to get a better container or closure, child resistant and so on. Does this include all other companies that make aspirin?

Dr. TAINTER. All of the major companies are engaged in the same kind of studies we have.

Senator Moss. How about all of them? You said all of the major ones.

Dr. TAINTER. There are five or six major companies that sell aspirin type products. Then there is a large number of small companies which are what we call private label houses, who characteristically buy their aspirin tablets in bulk and put them in a bottle with their own label. I can't answer for those, because of course there are literally hundreds of them. I can't answer for all their policies and activities.

Senator Moss. I can tell you—

Dr. TAINTER. In the children's aspirin, every one of these companies are now voluntarily complying with the recommendations of the conference of November 1966 held by Dr. Goddard. Every one of them fell in line as soon as these suggestions were made, and by voluntary action.

Senator Moss. How long has Bayer been putting its adult-type aspirin in this container?

Dr. TAINTER. Since January of this year, as an experiment.

Senator Moss. I have purchased aspirin of another brand since then that has nothing of this sort, the plain old screw top on it. I don't see any—

Dr. TAINTER. We are not sure yet that this will be a successful closure. This is why we have introduced its first in what we call a test market. We have saturated that area with information regarding the safety closure, trying to get adults, where there are small children in the home, to use this closure. We are out in the field now trying to get statistics to see how many people will buy this kind of closure, to see whether this will work and whether it will be successful. We can't predict that it will be. When we get the final information, then of course we will carry on in whatever seems to be appropriate.

Senator Moss. Suppose this legislation, this bill became legislation, became law, and the Secretary in conjunction with the Bureau of Standards, and whatever else, got out a set of standards and said, now for all hazardous products that are found in or around or stored in the home, not only aspirin but everything, these are certain requirements. It may be labeling, it may be caps, maybe packages, whatever it is. Do you think that Sterling would at that point simply put out whatever that standard was and stop all of this effort you are making to improve?

Dr. TAINTER. Well, I hate to be dogmatic about it, because there are so many "ifs" in the question as you put it. If the standards were realistic, which we could live with, if they set a reasonable, compromise standard which created an acceptable safety for children and yet did not produce too much difficulty in the infirm adult, we would be tempted to say, "Now this is what the Government wants us to do, all right, we are part of the Government, we will do what the Government wants."

I would be very reluctant, if we found a safety closure which outperformed the standard one, but which did not comply with the regulations, to try to get the regulations changed, based on our experience.

Senator Moss. Again you and I don't see the same on that. If it is better than the requirement, I don't think it is going to be barred by any regulations or statute.

Dr. TAINTER. This depends on how the regulations are stated.

Senator Moss. The thing that is rather disappointing to me about it is that I believe you when you say that you and your company are genuinely concerned about the life and health of children and you have done a great educational job trying to teach parents not to give overdoses and poison children in that way. You are spending money trying to find an ideal closure so that children can't get into it themselves and yet you say to me, well, if the Government comes along and sets a standard, no matter how the thing is, we will take it and we will just forget about whether children are dying, whether they are being poisoned, we will just abandon all of that, because the Government moved in and tried to put a standard that people at least must meet to put out their products on the market.

Dr. TAINTER. As I say, our reaction will depend on what the standard is, whether it is a high standard or low standard. Suppose we

have a safety closure that gives you 95-percent protection, just to use a figure. But at the same time it produces 20 percent of difficulty with the aged and infirm, they just can't use it, they won't use it, they complain, they are very unhappy. Now if we got another closure that came along that gave us 96- or 97-percent protection and we knew this would give us a 30- or 40-percent complaints from the infirm adults, and the Government said the first one is all right, it is satisfactory, we would be strongly tempted, I am sure, to stay with the one that the Government says meets what they think the closure should do.

Senator Moss. But if the Government wasn't in there, you wouldn't stay with it, even though you had 30- or 40-percent complaints.

Dr. TAINTER. We would work very hard and continue to work to try to improve the situation, because we would hope to have a competitive advantage over everybody else. If we could develop a closure of our own which was better than others, so we could make some mileage out of it in promotion and in customer acceptance, you can be very sure we would try to use it, if it was unique to us.

Senator Moss. In this whole consumer field, my experience is that the great majority of the manufacturers and suppliers want to put out the best product, the most safe product, they want to do all of these things, but that there is always a marginal group who do not come up to what is good practice for various reasons. One is competitive perhaps, trying to get a competitive advantage at a lower price. And this is the reason we have meat inspection, poultry inspection, fish inspection, all of the various standards we have. And the Federal Government tries to make a realistic standard that all must meet in order to ship their products in interstate commerce which is the measure for Federal regulation, and this is done for protection of the consumer.

Now you have told me at great length that you are trying to protect the consumer. I honor you for it. I think you have done a tremendous job, your company is doing a great job. But it utterly escapes me to have you make from that the conclusion that if the Federal Government comes in and says, "OK, some of you other guys that aren't making that same effort have to come up to a level now, that some way or other that makes you sit down and say OK, the ball game is over, we don't need to worry any more." I just can't believe that.

Dr. TAINTER. When the Government tells us what is needed and when we meet that requirement, meet it in a way which seems to us to meet it fully, then there certainly would be a tendency not to try to go beyond the Government's standards, particularly if in this case improving it beyond the Government standards might get us into additional difficulty with the other segment of our population, where we already have real problems. I showed that there was roughly 20 percent of the adults who have to use aspirin who couldn't get the Palm-N-Turn open.

Senator Moss. But that is going to affect you anyway. You say you have pressure on the other side of making it too difficult. And, therefore, you have to make a judgment right now as to whether you have raised it so far that you have gone marginally into the other side. Well, it isn't going to make any difference to you then if you are above the Government standard in getting the pressure or whether

you are just making your own standard and getting the pressure. It will have the same effect.

Dr. TAINTER. I can tell you as one who has been in this industry for 26 years that we will innovate, experiment, will do creative work more freely if we are not tied to a standard around which we have to revolve. In other words, the freedom to experiment, to try to get a jump on your competitors, is a tremendous stimulus. If you get the Government in there telling you you have to do it at this level as a minimum, it takes away a lot of that competitive urge.

Senator Moss. Even though you have a representative on the advisory council to confer with the Secretary in trying to find a reasonable and adequate standard, you think nevertheless you will just quit because the Secretary is bringing out the standards?

Dr. TAINTER. I don't know that. My judgment is that it would restrict our freedom to research, to innovate, to create new closures. The fact that there is no effective Government regulation exerts no restrictive influence. If there were Government regulations there would be perhaps a psychological and irrational influence, but a real one.

Mr. LUTHER. May I have a word on that? We have told you of our experiments and test marketing. Dr. Done has indicated this morning he is constantly surprised at what he learns from these tests. We are too in a marketing sense. Without the Government regulation, we presently have the freedom to move as our intelligence and experience shows in a limited way. I will tell you these (pointing to box of Bayer aspirin 78's) are almost handmade. These caps are almost on a piece basis. That is all right, because we are learning with them. When the situation develops that the Government imposes the standard we then have to convert our entire automated high volume operation, purchase equipment and all of the rest—I am not complaining about cost, but this is what will happen—into a method of operation and production which will comply with that standard, obviously. Once having done that, there is a natural reaction to resist further change, to maintain the status quo. Whereas now if we find this doesn't do what we hope it does, or if someone else comes around with good basis to believe he has something better, we can move, we move in a hurry, we get no resistance along the line and we can ultimately hope to find, which I think everyone said no one has yet found, and that is the perfect closure. That is the freedom which will be inhibited, we feel, if our entire business is subject to a standard.

Senator Moss. Well, I think you have made your point, and it is in the record. It is just that I can't quite see it. Now the Federal Government has a standard for automobile tires. They can't fall below that. It has not prevented those rubber companies 1 minute from trying to get out a radial tire, a polyglass tire, or some other kind of tire, always saying it is better, ours is better. And this is the way they compete. I don't see that the fact that there is a standard they can't fall below because of the safety factor has put a lid on them at all. That is the same feeling I have here on this packaging and closure thing we have been talking about.

Now, I would hope we would continue to have the widest amount of freedom in experimenting—in fact if you were here the first day, my questions very often went to that, as to whether this was going to in-

hibit companies from continuing to seek better ways and perhaps using that as a sales tool and saying "Our product is not only good for this reason, but it has this kind of a package, which is better for you." If it could be presented in an appealing way, maybe that would sell more of the product, because in the kind of competitive market that we have, certainly the best assurance for the consumer is to have competition remain, always finding a better product and producing it at a reasonable price.

There is nothing that can overcome that sort of competition. I am the last one that would want to put any inhibition on that. But the thing I can't quite accept in the position you have stated—I am glad you stated it, because it may convince my colleagues who read it in the record—is that if there is a standard set up, a minimum standard, suddenly everything will stop right there and not move on.

Mr. LUTHER. I don't think really we said that. I think we did say—we will never give up our obligation to our customers, we will always do our best. But we did say that there would be additional restrictions on us, and motives from many quarters not to continue at the rate and in the manner which we have. I am not familiar with the tire situation, in any aspect, but part of what we are saying here concerning this legislation is our position that it is "premature." We are greatly concerned that the state of engineering art and the psychological art of why children get into these things, and how best to handle this problem, contains so many unknowns at this time, in those areas, that we just don't feel it is time to legislate.

And we feel that any standard set in that lack of knowledge, any standard that comes out may be incorrect and by calling into play these built-in reasons to defend the status quo, may stop the pace of research and change which is currently going on.

Senator Moss. Well, I understand what you say, but I, of course, can see no reason, even if the Secretary, within a year's time, came out with some standards and the industry then had a year thereafter to comply and come up to the standards, I do not see why this research on children and what attracts them, how they can open things, should not continue to go forward. As a matter of fact, it might be stimulated to some degree. But I appreciate your testimony, you people are in the field, you deserve great credit for the leadership you have taken in trying to find better containers and closures in the product of which you are I guess the largest manufacturer of aspirin in the country. And I know you have spent vast amounts of money in trying to find answers. We are glad to have you come and share them with us. We will try to keep them in mind as we work on this legislation. We might even put it aside, we don't know.

Thank you.

Senator Moss. Now, Mr. James F. Hoge, who is the general counsel of the Proprietary Association, is our cleanup witness and I apologize at the great length that the hearing has assumed, Mr. Hoge.

I appreciate your patience in staying with us for 2 long hours.

Your statement which appears to be a very full and complete one will be placed in the record in full and you may proceed in the manner you would like to bring it to our attention.

STATEMENT OF JAMES F. HOGE, ON BEHALF OF THE PROPRIETARY ASSOCIATION; ACCOMPANIED BY RALPH H. THOMAS, DIRECTOR OF PACKAGING RESEARCH, BRISTOL MYERS CO.; DANIEL F. O'KEEFE, JR., VICE PRESIDENT AND SECRETARY, THE PROPRIETARY ASSOCIATION; AND E. CARRINGTON BOGGAN, ROGERS, HOGE & HILLS

MR. HOGE. Mr. Chairman, I thank you very much. Before I sit down, let me say you have no occasion to apologize to me at all. I have great sympathy for the schedule that you gentlemen keep up here. In fact, there is a constitutional guarantee against cruel and unusual punishment. I am afraid we may be subjecting you to that. I personally don't want to be guilty. So I will cut mine down to the bone. I have been trying to mark out parts of my written statement. I did want some of my people to sit with me here. They won't take any time.

Senator Moss. We would be glad to have them come and sit with you.

MR. HOGE. Mr. Ralph H. Thomas, director of packaging research, Bristol Myers, Mr. Daniel F. O'Keefe, Jr., vice president and secretary of the Proprietary Association, and Mr. E. Carrington Boggan, who is an associate of mine.

MR. CHAIRMAN, I understood you to say that the whole statement will appear in the record, so I won't read that.

Senator Moss. That is true, sir.

MR. HOGE. The Proprietary Association consists of the manufacturers of what we call over-the-counter medicines: Vicks Vaporub, Listerine, Bayer Aspirin, St. Joseph Aspirin, Bufferin, Anacin, Milk of Magnesia, Alka-Seltzer, Castoria, and so on. I would like for my first reference to be one of appreciation, to express thanks on behalf of my client and on behalf of myself, the General Counsel of this Association since October 1934. As you see, I am at my 35th anniversary this month—I do express appreciation for myself and for my client for the opportunity to be here and to hear the testimony that has gone on these 2 days, and now to have a part in it.

I have a very deep interest in the subject of foods, drugs, and cosmetics, particularly drugs.

I don't think a man can give 35 years of his life to something without developing a very deep interest. Perhaps I should say I have a proprietary interest in these products.

Senator Moss. Well said.

MR. HOGE. Now, promotion of child safety is an undertaking with which we want to be involved. And, I think we are deeply involved. It is a subject to which we have a very sensitive relationship. There is, and there can be, no question as to the virtue of the declared purpose of this 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.

MR. CHAIRMAN, I hope we may raise questions about the bill, and advise against passage of it at this time without being classed as opponents of safety packaging. So often in this work I have almost had

to apologize—even to give an affidavit—to committees, and sometimes to courts, if I dared to oppose measures of this sort. I must aver that I really do have the public interest at heart, and that my clients do too. So, I realize the risk in opposing a bill like this. It is not easy to articulate our position clearly without running the risk of being classed as opponents of the idea, or at least of being misunderstood. We insist—and I respectfully ask agreement at this point—that being opposed to the bill under the circumstances in which we are opposing it is not synonymous with being opposed to child safety and to necessary disciplines for accomplishing it.

Senator Moss. We will so stipulate.

Mr. Hoge. Thank you, sir.

It is in this framework that we say, for the reasons which are set forth in my paper, that this particular bill, at this particular time, should not be enacted. We think the legislative requirements contemplated by this bill would better come at a later time when studies and experimentation now in process have advanced further.

You have heard that from the witness just before me, and from others. But I reiterate it with great sincerity. The sweep of this legislation is immeasurable. 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." The classes of products affected are many. The number of products is legion.

Now, perhaps some of our difficulty, Mr. Chairman, is in our not understanding just what the bill does, or would, do. Perhaps I may say that the bill does not tell us, or that—at least—it needs clarification. If there is anything we can do to help in these areas, then out of our interest in the subject, we stand ready to do it.

Let me ask a question—a rhetorical question: Does this authorization mean that the Secretary will formulate standards in the nature of guidelines, criteria or specifications, or does it mean that he will actually regulate the packaging of soaps, cleaners, 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?

The first question which confronts us, and I pass it on respectfully to you, 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"? Shall medicines be caught up with kerosene, lighter fluid, floor polishes, and detergents?

Most of the testimony has gone on here with respect to drugs. Yet, I think it has been made rather definite that the drug industry has been the forward one in trying to work out voluntary improvements in this field and in giving of itself and its money, time, and earnest interest.

I think the answer to this question, whether we should be classed with detergents, should have regard to the fact that drug products are now regulated in this country to an extent and a degree not applicable to any other products.

Mr. Chairman, I had the great privilege to be engaged in this work

during the 5 years it took to pass the 1938 act, which replaced the 1906 act. From June of 1933 to June of 1938 that bill was in these two Houses of Congress. It was a great privilege. I shall remember, all my life, that I had some part in a great law—in the formulation of a great law—because I think we lawyers do have a part, even when we are cast in adverse positions. That is the system we have in this country, of course.

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 U.S.C. 352) defines a drug as misbranded unless its labeling bears adequate directions for use and adequate warnings against misuse. The regulations, attached to my written statement 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: I counted 33 suggested warnings with respect to children which appear in the appendix to my statement.

I had a little concern whether to put that appendix in, Mr. Chairman. But it seemed to me that it did show the extent of the regulation that goes on with respect to drugs. I was delighted that I put it in when I heard Mr. Wolfstone yesterday say so much about labeling. In fact I thought his statement was really about labeling, rather than closures and packaging. So I was glad in view of that statement that I put here for your ready reference a full copy from the Federal regulations of the warnings, particularly those pertaining to children. Twenty-seven of the warnings in appendix I to my statement are against unsafe dosage, and they of course are very pertinent with respect to children.

Also in the appendix are warnings as to 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, and warnings as to 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 to my statement indicates some of the many and specific requirements of the Federal Food, Drug and Cosmetic Act as to the packaging of drug products. For instance, if a drug is liable to deterioration, it is misbranded unless it is packaged and labeled according to the regulations of the Secretary. If the drug is listed in the Pharmacopoeia, or the National Formulary, then it is misbranded unless it is packaged and labeled as the Formulary or Pharmacopoeia requires. These are just illustrations of the lengths to which these regulations go with respect to drugs. Then Senator Hart's bill, which be-

came the "Fair Packaging and Labeling Act," required the relabeling just last year of most drug products.

Mr. Chairman, I won't tarry long on my statement references to the 1966 developments except to say that bills relating to safety packaging were introduced in the Congress in 1966. H.R. 13886 came close to what we are talking about here in that it had a requirement specifically for safety closures on containers of all drug products. It also was greatly involved with the number of tablets of aspirin in children's packages. That is children's aspirin: The number of tablets in the package and the number of grains in the tablet.

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."

That conference was held at the Food and Drug Administration in Arlington, Va., in November 1966. The conference reported what it called 13 "significant decisions" with respect to contents of children's aspirin, flavoring thereof, number of tablets to be packaged in a retail container, bottle closures, and warnings to appear in the labeling. These decisions were contained in a summary of the conference dated November 21, 1966. A copy of it is attached to my statement 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 to the statement 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. It was appointed by the Food and Drug Administration, and the committee is in no respect responsible to the Proprietary Association.

The 1966 conference also took this decision:

"10. Educational programs should point out the dangers of accidental ingestion of 'adult' aspirin, 'childrens' aspirin, and therapeutic overdosage."

Mr. Chairman, therapeutic overdosage has been a very important matter in these studies. It is strangely listed as accidental—that is the way the tables show it—but therapeutic overdosage is by the doctor or the mother. The conference report continued:

“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.”

Mr. Chairman, in reference to the published tables we are prone to say “aspirin” when actually the tables deal with “aspirin and other salicylates,” and of course, as you well know, there are many salicylates and some of them are much more potentially dangerous than aspirin. Methyl salicylate has already been mentioned here.

The Council on Family Health was incorporated in Delaware on April 6, 1966, as a nonstock 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, p. 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 to my statement as appendix V. I think it was from that that Dr. Tainter read a while ago.

Senator Magnuson again referred to the Proprietary Association and to what he called government-industry cooperation in this time of aroused consumerism. That is in the Congressional Record, May 27, 1969, page S5679.

I would like to say at this point and in appreciation, Senator Magnuson came to the association's convention last May. His entry in the Congressional Record of that time included copies of the speeches of the president of the association, Mr. High, and of the Food and Drug Commissioner, Dr. Ley, both of whom addressed that convention.

I want to say in appreciation to Senator Magnuson and to you, Mr. Chairman, that something has happened in this field. An industry which 30 to 40 years ago was derisively referred to as the patent medicine business has become a needed and respected industry to supply home medication and to play its part in the ever-enlarging health program of a growing nation.

I would like to underscore that, and I hope you will receive it with all of the earnestness and sincerity I have about it. This is a big industry in this country today and a very necessary one, as we have to spread health care over a growing population.

In my statement, I have listed a number of undertaking related to prevention of accidental ingestion and the safety in the use of home medicines, to which this association has made grants and in which the staff has aided in organizing programs, conducting seminars, and otherwise participating.

Mr. Chairman, I have put that in the statement, not as a boast but

as an indication of my client's interest and as an outline of the scope of the activity which has been going on in this field.

So, trusting that what I have put in the record may be looked at sometime in this connection, I will move to page 14 of my prepared statement and make this comment, which is written there:

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

Mr. Chairman, it is in these circumstances that we have felt constrained to say, as to drug products, it is not time for turning the matter of safety packaging over to legislative disposition.

The timeliness, or the untimeliness of the bill as to drugs is underscored by uncertainty as to what the bill actually requires. It has been described as an enabling act. I have some questions. They are rhetorical, you understand. I don't presume to ask you questions, Mr. Chairman. Does the bill 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 I think for his protection, because the Secretary ought to have boundaries thrown around him to safeguard him against attacks of various sorts.

The bill is also lacking in limitations upon his powers. The gentlemen who have testified here have been trying to say to us that they can't at this time write such criteria or such specifications. They would gladly do it; they want to do it, but they don't know how to do it at the present time. As I understand, much of the investigation that they are carrying on is with a view to evolving criteria or specifications, whichever word we should use, that could be written into a bill to guide the Secretary in what he should do.

My second question would be: 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. I listened to Dr. Done and others today on the difficulty you would have in including strip packaging unless the bill did apply to packaging. So I appreciate the motivation for carrying the bill into the packaging field. But there should be some limitation, especially against going into the field of labeling. And labeling, of course, is a part of packaging unless specifically excluded.

I'm speaking only for drugs, but when you see the appendixes to my statement and see the extent of control over labeling of drugs, I really don't believe, Mr. Chairman, you want this bill to get into labeling in those areas; in any area other than as related to the safety of the package. So, I ask: Would the bill enable the Secretary to prescribe the labeling for the multitude of products under his jurisdiction?

With drugs there are two elements of control: (1) The composition

of the drug and (2) the labeling of it. The user must be told how to use a drug and how not to use it. A drug used one way is dangerous; used another way is curative. So labeling is vital, just about as vital as the composition. And, drugs are now specifically regulated as to both. I do respectfully urge upon you, if this bill is to move, that some limitations ought to be written into the bill with respect to drug labeling. Otherwise there could be a chaotic situation, and I refer again to the appendixes to my statement to illustrate how extensive the regulation is, and what the opportunities for confusion would be.

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. But 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. Mr. Verhulst touched on that yesterday. I think the gentleman from "Palm and Turn" touched on it, and said he didn't contemplate that everyone should be compelled to get the same closure.

Whatever container or closure ultimately is required must assure the integrity of the product and not permit deterioration of the contents. Surely we would all agree on that. 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.

There are substantial economic considerations which should be safeguarded by the bill. When I use the term "economic," Mr. Chairman, I'm not complaining at all of the expense to the industry to comply with whatever you order here. I don't suggest that we are free spenders, but expense is really not of consequence on this subject. It is not in our case. If you order a closure, or if the right closure is found, we will put it on regardless of the expense.

The only place where expense comes in, and Mr. Luther touched on that a moment ago, would be in the case of standards on a trial-and-error basis. That is to say if one set of standards is promulgated and the industry, at the expense of millions of dollars, tools up for it, and then in a short while thereafter the Secretary modifies the standards or imposes new ones, I think we might complain without reproach.

On the matter of whether it costs a penny or two or more to put the package up, that is not a part of our case, and I don't want it even considered in this context. But if we do have to retool then machinery and equipment must be capable of meeting the Secretary's regulations as to the form of packaging required. Manufacturers of drug products and containers would have to make necessary investments, and there should be safeguards against reckless administration.

I respectfully say that it is appropriate to emphasize the danger inherent in legislation of this sort. I am approaching the ground Dr. Tainter was on a few moments ago in the dialog with you. Even if described as an "enabling act," the bill, if enacted, would put the Secretary under stress to promulgate regulations lest he be accused of failing to carry out a statutory duty. Quite properly the administrator is sensitive to that, and quite understandably he is sometimes made a little more sensitive by congressional action in inquiring as

to what he has or has not done in the administration of his office. At a time when there is no consensus on the acceptability of present safety closures, such stress could lead to premature requirement of unproven packaging. I rest that on human nature, simply.

I heard your questions to Dr. Tainter. I don't think some of the questions are capable of specific answers. I think what we are trying to say here is that it is the way of human nature, that when an authority like the Government moves in, we are inclined—without deliberation or pronouncement of any kind—to say, "Well, the Government has taken over." And "maybe we don't have to give the same attention to it." Also, the industry would be discouraged from seeking improved packaging, because changes would require further retooling and even greater expense.

So, for what my opinion may be worth, and I think I'm not only expressing a personal opinion but that of those with whom I've talked before coming here today, 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.

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 discussion has related to container closures. And to containers for dry products, at that. Apparently, the development of safety closures is in its infancy. I'm using the terms of gentlemen who have been working in the field. The development is in its experimental growth. Will it be to the ultimate good of all concerned to have present imperfect closures legally mandated?

Shall we settle for the 80-percent safety Dr. Done mentioned? He said he wasn't willing to do it. Will the industries, the professions, inventors, and containermakers 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.

Mr. Chairman, I did not want to conclude my statement without trying to offer some alternative, or to say something on the affirmative side of the matter. The best I was able to come up with is in the last paragraph of my statement. 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 recommendations.

Now, it has been perfectly apparent here that there are a great many agencies working on this. The National Safety Commission, which originated in this committee, is working on it. So have others of which you have heard. My statement listed quite a number. There is indeed a job of coordination needed here. I don't submit my suggestion to you with any pride of authorship, but I did want to come

before you with some affirmative thing to say, some further indication of our good will and desire to be helpful. So it just occurred to me that if you took that part of your bill and set it up with the job to coordinate, it might then come in with the criteria which Dr. Done and the others say they cannot at this time supply.

I thank you very much. I'm sorry that the hour is so late.

(The statement and appendix follows:)

STATEMENT OF JAMES F. HOGE

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 immeasurable. It would embrace every household commodity which is designed for "consumption or use by individuals for purposes of personal care or the performance or 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, cleaners, 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 product 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 and IV. 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 closure, 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 Proprietary 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 Clearinghouse 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 1½ 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 dependents 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 adopted 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 a 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 discussion 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 imperfect 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 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 recommendations.

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.

- 131.1 Purpose of issuance.
- 131.2 Definitions.
- 131.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503 (b) (1) (C).
- 131.4 Warnings suggested for drugs by formal or informal statements of policy.
- 131.5 Warnings required on insulin intended for over-the-counter sale.
- 131.6 Warnings required on certifiable antibiotics exempted from prescription-dispensing requirements.
- 131.7 Warnings required by official compendia.
- 131.8 Warning statements in relation to conditions for use.
- 131.9 General warnings re accidental ingestion by children.
- 131.10 Conspicuousness of warning statements.
- 131.11 Warnings on veterinary drugs intended for administration to diseased animals.

Subpart B—Drugs for human use

- 131.15 Drugs for human use; recommended warning and caution statements.
- 131.16 Drugs for human use; warning and caution statements required by regulations.
- 131.17 Drugs for human use; warning and caution statements specifically required by law.

Subpart C—Drugs for veterinary use

- 131.20 Drugs for veterinary use; recommended warning and caution statements.
- 131.21 Drugs for veterinary use; warning and caution statements required by regulations.

Subpart D—Devices

- 131.25 Devices; recommended warning and caution statements.

Authority: §§ 131.1 to 131.25 issued under secs. 503, 506, 507, 701, 52 Stat. 1052, as amended; 55 Stat. 851; 59 Stat. 463, as amended; 52 Stat. 1055, as amended; 21 U.S.C. 353, 356, 357, 371. Interprets or applies sec. 502, 52 Stat. 1050, as amended; 53 Stat. 854; 21 U.S.C. 352.

Cross references: For interrelated regulations issued under the Federal Food, Drug, and Cosmetic Act, see Parts 1 (Drugs), 3, 130, 146, 146c, 146d, 146e, 164, 165.

Subpart A—Definitions and interpretations

§ 131.1 *Purpose of issuance.*

The warning and caution statements suggested in Subparts B, C, and D of this part, for inclusion in the label or labeling of drugs and devices subject to section 502 (d) and (f) (2) and other relevant provisions of the Federal Food, Drug, and Cosmetic Act are issued for the purpose of assisting industry in preparing proper labeling for these articles for over-the-counter sale and in meeting the legal requirements of the act that the label or labeling of drugs and devices bear adequate warnings, in such manner and form as are necessary for the protection of users. Only section 502 (d) of the act requires use of the specific language included in these suggested warning and caution statements. These suggested warning or caution statements are illustrative of those that may be necessary or desirable. It is the responsibility of the manufacturer, packer, shipper, or distributor in interstate commerce to see that such statements are adequate for compliance with the provisions of the law. Omission of any article from this suggested list does not relieve drugs and devices subject to provisions of the act from bearing adequate warning or caution statements where such statements are necessary or desirable for the protection of the user.

§ 131.2 *Definitions.*

(a) As used in this part, the term "act" means the Federal Food, Drug, and Cosmetic Act.

(b) The terms "drugs" and "devices" are defined in section 201 (g) and (k) of the act.

(c) Official compendia are defined in section 201(j) of the act.

§ 131.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503(b) (1) (C).

Drugs exempted from prescription-dispensing requirements under section 503 (b) (1) (C) of the act are subject to the labeling requirements prescribed in § 130.102(a) of this chapter. Although, for convenience, warning and caution statements for a number of the drugs named in § 130.102 of this chapter (cross-referenced in the text of this part) are included in Subpart B of this part, the inclusion of such drugs in §§ 131.15, 131.16, 131.17 in no way affects the requirements for compliance with § 130.102(a) of this chapter, or the provisions of an effective application pursuant to section 505(b) of the act.

§ 131.4 Warnings suggested for drugs by formal or informal statements of policy.

The warning and caution statements included in Subpart B in no way affect any warning statement suggested for such drugs or devices by any statement of policy or interpretation in Part 3 of this chapter.

§ 131.5 Warnings required on insulin intended for over-the-counter sale.

Warning and caution statements for insulin products sold over the counter must comply with the specific labeling provisions of the act and § 164.6 of this chapter.

§ 131.6 Warnings required on certifiable antibiotics exempted from prescription-dispensing requirements.

Certain certifiable antibiotic drugs are exempted from prescription-dispensing requirements under section 507 of the act, but are subject to the specific labeling requirements, including warning or caution statements, of the applicable section of the antibiotic regulations.

§ 131.7 Warnings required by official compendia.

Any drug included in the official compendia defined by the act shall bear such warning or caution statement as may be required by such compendia, and no statement in Subpart B or Subpart C of this part is intended to alter, modify, or permit the omission of any such statement required by such compendia.

§ 131.8 Warning statements in relation to conditions for use.

The mention in any warning or caution statement included in Subparts A, B, and C of this part, of a disease condition does not imply a finding on the part of the Food and Drug Administration that any drug or device is efficacious in such condition; nor is any drug or device bearing labeling referring to such disease condition precluded from regulatory action under the applicable provisions of the act if such claim is considered to be misbranding.

§ 131.9 General warnings re accidental ingestion by children.

Section 131.15 includes under certain items, but not all medicines, the statement: "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." 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 or a deceased 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 ANTISEPTICS FOR EXTERNAL USE PREPARATIONS

(See § 3.37 of this chapter)

Warning—This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician.

ANESTHETICS FOR EXTERNAL USE (LOCAL ANESTHETICS)

(See also § 130.102(a) (19) and (23) of this chapter)

Caution—Do not use in the eyes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIBIOTICS FOR EXTERNAL USE FOR PREVENTION OF INFECTION

(See also §§ 130.102(a) (5), 146c.202, 146e.402, 146e.407, 146e.409, 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.

Caution—In case of deep or puncture wounds or serious burns, consult physician. If redness, irritation, swelling, or pain persists or increases or if infection occurs discontinue use and consult physician.

The reference to wounds and burns is not required on preparations intended solely for diaper rash.

ARSENIC PREPARATIONS

Warning—Frequent or prolonged use may cause serious injury. Do not exceed recommended dosage. Keep out of the reach of children.

BELLADONNA PREPARATIONS AND PREPARATIONS OF ITS ALKALOIDS (ATROPINE HYOSCYAMINE, AND SCOPOLAMINE (HYOSCINE)); HYOSCYAMUS, STRAMONIUM, AND RELATED DRUG PREPARATIONS

Warning—Not to be used by elderly persons or by children under 6 years of age unless directed by physician.

Caution—Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs, decrease dosage. Discontinue use if rapid pulse, dizziness, or blurring of vision occurs.

See also Rectal Preparations for additional warnings.

Scopolamine or scopolamine aminoxide preparations for insomnia should include the following warning or its equivalent:

Warning—Not to be used by persons having glaucoma or excessive pressure within the eye, by elderly persons (where undiagnosed glaucoma or excessive pressure within the eye may be present), or by children under 12 years of age, unless directed by a physician.

In addition to this statement, the following or its equivalent should be included:

Caution—Do not exceed recommended dosage. Not for frequent or prolonged use. If dryness of the mouth occurs decrease dosage. Discontinue use if rapid pulse, dizziness, or blurring of vision occurs.

Scopolamine or scopolamine aminoxide preparations for motion sickness should include the following:

Warning—Not to be used by children under 6 years of age unless directed by physician.

Caution—Do not exceed recommended dosage. Discontinue use if rapid pulse, dizziness, or blurring of vision occurs.

BORIC ACID (POWDERED, CRYSTALLINE OR GRANULAR)

Warning—Do not use as a dusting powder, especially on infants, or take internally. Use only as a solution. Do not apply to badly broken or raw skin, or to large areas of the body.

BROMIDES

Caution—Use only as directed. Do not give to children or use in the presence of kidney disease. If skin rash appears or if nervous symptoms persist, recur frequently, or are unusual, discontinue use and consult physician.

CARBOLIC ACID (PHENOL) PREPARATIONS (MORE THAN 0.5 PERCENT)
FOR EXTERNAL USE

Warning—Use according to directions. Do not apply to large areas of the body. If applied to fingers or toes, do not bandage.

CATHARTICS AND LAXATIVES—IRRITANTS AND OTHER PERISTALTIC STIMULANTS

Warning—Do not use when abdominal pain, nausea, or vomiting are present. Frequent or prolonged use of this preparation may result in dependence on laxatives.

Mercury preparations should have added to the "frequent use" statement, the words "and serious mercury poisoning."

Phenolphthalein preparations should bear, in addition to the general warning, the following statement:

Caution—If skin rash appears, do not use this or any other preparation containing phenolphthalein.

See also Mineral Oil Laxatives.

CHLORATES: MOUTH WASH OR GARGLE

Avoid swallowing.

COBALT PREPARATIONS

(See also § 3.48 of this chapter)

Warning—Do not exceed the recommended dosage. Do not administer to children under 12 years of age unless directed by physician. Do not use for more than 2 months unless directed by physician.

This warning is not required on articles containing not more than 0.5 milligram of cobalt as a cobalt salt per dosage unit and which recommended 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 Propellant * * * 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 (METHYLOSANILINE 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 Belladonna Preparations * * * for additional warnings.

RESINS, OLEORESINS, AND VOLATILE OILS

Caution—If nausea, vomiting, abdominal discomfort, diarrhea, or skin rash occurs, discontinue use and consult physician.

RESORCINOL (NOT THE MONOACETATE) HAIR PREPARATIONS

Caution—Excessive use of this preparation may temporarily discolor blond, white, or red hair.

SALICYLATES, INCLUDING ASPIRIN AND SALICYLAMIDE (EXCEPT METHYL SALICYLATE, EFFERVESCENT SALICYLATE PREPARATIONS, AND PREPARATIONS OF 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.

§ 311.16 *Drugs for human use; warning and caution statements required by regulations*

ACETAMINOPHEN (N-ACETYL-P-AMINOPHENOL)

(See § 130.102(a) (1) of this chapter)

Warning—Do not give to children under 3 years of age or use for more than 10 days unless directed by a physician.

If offered for use in arthritis, or rheumatism, in juxtaposition therewith, the statement:

Caution—If pain persists for more than 10 days, or redness is present, or in conditions affecting children under 12 years of age consult a physician immediately.

ALCOHOL RUBBING COMPOUND

(See 26 CFR 182.855(a) (5) ; The National Formulary, Tenth Edition 1955, pp. 27-28; and section 502(g) of the act)

Warning—For external use only. If taken internally serious gastric disturbances will result.

ANTIBIOTIC-CONTAINING DRUGS FOR EXTERNAL USE FOR PREVENTION OF INFECTION

(See § 130.102(a) (5) of this chapter)

Caution—If redness, irritation, swelling, or pain persists or increases or if infection occurs, discontinue use and consult physician. Do not use in the eyes.

ANTIHISTAMINICS, ORAL (PHENYLTOLOXAMINE DIHYDROGEN CITRATE, MECLIZINE HYDROCHLORIDE, DOXYLAMINE SUCCINATE, CHLOROTHEN CITRATE, CYCLIZINE HYDROCHLORIDE, AND CHLORCYCLIZINE HYDROCHLORIDE PREPARATIONS)

(See §§ 3.29 and 130.102(a) (4), (6), (13), (24) and (25) of this chapter)

Caution—This preparation may cause drowsiness. Do not drive or operate machinery while taking this medication. Do not give to children under 6 years of age or exceed the recommended dosage unless directed by physician.

If offered for symptoms of colds, the statement:

Caution—If relief does not occur within 3 days, discontinue use and consult physician.

* For chlorcyclizine-, cyclizine-, or meclizine-containing preparations, the statement:

Warning—Not for use by women who are pregnant or who may possibly become pregnant, unless directed by a physician, since this drug may have the potentiality of injuring the unborn child.

BACITRACIN-CONTAINING OINTMENTS

(See §§ 146e.402, 146e.407, 146e.411 of this chapter)

For use only in the prevention of infection in minor cuts and abrasions.

Use of the drug should be discontinued and a physician consulted if signs of infection or irritation appear.

BACITRACIN (ZINC BACITRACIN)-POLYMYXIN OINTMENT; BACITRACIN-POLYMYXIN-NEOMYCIN OINTMENT

(See §§ 146e.409 and 146e.422 of this chapter)

For use only in the prevention of infection in minor cuts and abrasions. Use of the drug should be discontinued and a physician consulted if signs of infection or irritation appear.

If it is in liquid form, also the statement "Not for injection."

CARBETAPENTANE CITRATE PREPARATIONS

(See Cough-Due-to-Cold Preparations)

"COUGH-DUE-TO-COLD" PREPARATIONS (DEXTROMETHORPHAN HYDROBROMIDE AND CARBETAPENTANE CITRATE)

(See § 130.102(a) (14) and (20) of this chapter)

Warning—Keep out of the reach of children. Do not administer to children under 2 years of age unless directed by physician. Persistent cough may indicate the presence of a serious condition. Persons with a high fever or persistent cough should not use this preparation unless directed by physician.

DEXTROMETHORPHAN HYDROMIDE 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."

IPPECAC 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 alkalis (lye) and strong acids, or petroleum distillates such as kerosine, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested.

ISOAMYLDIHYDROXYCUPREINE 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 VASO-CONSTRICTOR, IN NASAL PREPARATIONS (SPRAY OR DROP)

(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

(§ 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 MONOFLOROPHOSPHATE DETIFRICE 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))

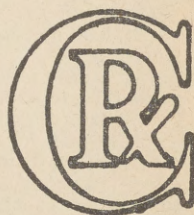
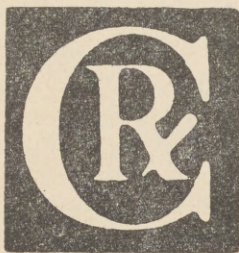
(h) If a drug has been found by the Secretary to be liable to deterioration, it must be packaged in such form and manner, and its label bear such precautions as the Secretary shall by regulation require as necessary for the protection of the public health. (Sec. 502(h))

(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 manufacturer, processor, packer or distributor."

(k) All depressant and stimulant drugs subject to the "Drug Abuse Control Amendments of 1965" (Sec. 511) must bear prominently on the principal panel of the label the following symbol or modifications:



The symbol in outline form is for use as a large, open-letter overprint.

(1) 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 repackaging"; "For investigational use"; "Diagnostic reagent—For professional use only." (21 CFR 1.106 (j), (k), (l))

3. Packaging and labeling are subject to review and approval under the provisions of Sec. 505 as to "new drugs." The Act provides for the submission of labeling material and the regulations make detailed requirements (21 CFR 130, et seq.).

4. Sec. 507 requires certification of antibiotics and extensive regulations prescribe numerous labeling and packaging requirements (21 CFR 141, et seq.).

5. Sec. 510 requires registration for the manufacture, processing or repackaging of drugs and requires factory inspection at least once every two years.

6. Sec. 704 provides for inspection of factories, including the materials therein and the labeling pertaining to them.

7. Sec. 801 forbids importation of any drug article which is misbranded. It permits exportation when labeled on the outside of the shipping package to show that it is intended for export.

APPENDIX III

CONFERENCE ON PREVENTION OF ACCIDENTAL INGESTION OF SALICYLATE PRODUCTS BY CHILDREN

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. $1\frac{1}{4}$ 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. $1\frac{1}{4}$ 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) I 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 averting 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 similar 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.

APPENDIX IV

TITLE 21—FOOD AND DRUGS

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Subchapter A—General

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Subchapter C—Drugs

PART 131—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

ASPIRIN

During hearings in 1966 on H.R. 13886, the Committee on Interstate and Foreign Commerce of the 89th Congress expressed the view that certain 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 attended 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 aspirin 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 labeling 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 Commissioner (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, manufactures 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 overdose, 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:

§ 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.]

APPENDIX V

[From the Congressional Record, Washington, Thursday, July 11, 1968]

SENATE

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 Serv-

ice, 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.

Senator Moss. I thank you, Mr. Hoge, and the gentlemen who accompanied you here today. You have a very excellent statement and have presented it to the committee in a way that will be very persuasive. I appreciate your suggestion of how you think the bill might be broken into a study section, examination section, before authorizing the Secretary to set standards and that you think we have, perhaps given him an impossible mandate to fill adequately at this time because the studies are still going on in the field.

I know you listened to my colloquy with Dr. Tainter before and your recommendation is somewhat similar to his, saying that it was premature to get into this field. So I don't need to go over that with you again. You seem to have much the same approach that he does on that.

Mr. HOGE. Yes, I do.

Senator Moss. I might ask you about this question of having a different kind of a closure available to people who have crippling diseases of some kind that should be available to them rather than the more difficult opening one. Would this tend to drive one out of the market as against the other?

Mr. HOGE. I don't know that it would, Mr. Chairman. I should say probably I am not a very good marketing man; I am a lawyer. I thought you were going to come to it in another way. I have had some difficulty with it. I think there has to be some arrangement for these crippled people. I tried to work out something to bring with me, but I haven't got anything I feel like submitting.

The question will be how to administer or police a choice. To leave it entirely to the individual probably won't accomplish all that you desire in the matter. But there ought to be a proviso that both types would be available. The arthritic or rheumatoid who must get aspirin in quantities, probably by the several hundred tablets.

I think we have also got to think of people other than the arthritics. We have been talking about salicylates and aspirin. But think of the heart patients who have to have digitalis, and they have to have it quick. When the attack comes, those people have to be taken care of too. I wish I could tell you how to do it. I have thought about it. My associates and I have tried to write something. But we have not

written anything which we feel like submitting to you formally at this time. It is going to be a difficult thing to police, and yet one way or the other, I think the bill would have to permit people who have to have aspirin—I use aspirin as an example, but say digitalis or anything else—some way we have to have it available for these people.

Senator Moss. Don't you feel that having the advisory committee study this further really just sets back the time when we really move toward this child-resistant packaging and closures?

Mr. HOGE. It would require more time, yes, because the committee would have to hold meetings and conduct investigations. But I think it is an expenditure of time that is justified. Otherwise, Mr. Chairman, you are going to have what I called trial and error a moment ago. That is the best phrase I can use for it. The Secretary who is charged with the administration of the law is going to try to get the standards or criteria. And let me say this too, and I hope nobody will think I am being critical of the Food and Drug Administration, but it is pretty well bogged down right now because of needed manpower and time to handle the number of matters that have been put upon it. I listened to the witness yesterday say that it could get along with one more doctor and six other people and an added appropriation of \$375,000. I shouldn't controvert him, but I wouldn't bet that it could be done.

Senator Moss. Well, you being a lawyer, would you prefer, assuming we were going to go ahead with the bill, that the power of the Secretary be put in the negative of being able to prohibit and bar certain kinds of packaging rather than set the positive standards and require positive compliance?

Mr. HOGE. Mr. Chairman, that question got me out of bed at 5:30 this morning.

Senator Moss. I am sorry about that, too.

Mr. HOGE. I couldn't sleep, because I thought you might ask me that question and I wondered what I was going to say. The answer is "Yes." I would prefer it, but in trying to be fair with you and with the subject matter, I then tried to work out how would I word the provision. Because we have to implement these things, I just can't say yes to the question. Again, I come to you without having worked it out. I hoped I could get a yellow tablet and write out something and when you asked that question, I could say "Yes," here is the way to do it; here is the way in which to frame the requirement.

The negative approach would fit into the overall pattern of the Food and Drug Act, which takes the form of defining a drug as misbranded if it does not bear adequate directions or warnings, if it is liable to deterioration and is not packaged as required, and so on. I tried to fit that pattern here, because it seemed to me that was the time honored pattern. The form for that would be a provision defining a drug as misbranded if it wasn't packaged adequately to resist children.

I would rather have the negative approach because I think, for one thing, it cuts down somewhat the scope of the bill. That is not a matter of escaping anything. I think we ought to cut the scope down if we can on the Secretary, so he doesn't have such a wide range of administration to undertake. It makes his work lighter. It makes the Federal budget lighter. And I think, from my standpoint, representing the industry, it would be better that way.

This is another illustration of how difficult it is to get our hands on some of the things we all want to do about the subject of child safety. We all do. This is one of the most unusual hearings I have ever been in, because I don't think there is any disagreement here in principle. I think everybody wants to get child resistant packaging. The things you have been hearing are necessarily said because of technological considerations, and everybody has been very sincere and very genuine about everything that has gone on here.

Believe me, if there is any way we can help you with this overall mission you have undertaken, we would like to do it. We don't like to be in opposition to a highly motivated bill of this sort. I said that at the outset. It is dangerous to come in and do what we have done, lest we be mistaken as opponents.

Senator Moss. I appreciate what you say and I am sure that all of us would like to reach the objective at the end that this is aimed at.

The question is the reasonable way to go and how to get there most rapidly and make sure that we haven't got something that is unworkable and doesn't accomplish our objective.

One final thing: What do you think about this idea of having some kind of a symbol less than the skull and crossbones, but some kind of a symbol?

Mr. HOGE. I think we would be in agreement on that. I am glad you took the skull and crossbones out for the simple reason that that it is an important symbol—the skull and crossbones—and if we make it too common, then we destroy the purpose of it.

I think we all realize that. In thinking about this, I have thought that, instead of anything severe, we might have something that would appeal to the child; it could be a little animal. I first said red star, but I thought that might go Russian on me. A little animal or something to intrigue the child would let mother say, "When you see that little doggie," or whatever it is, "don't go near that."

Senator Moss. Maybe it ought to be a snarling dog.

Mr. HOGE. Well, you had one witness here who suggested a picture of a baby in a coffin. That I am sure is the farthest anybody would go, and that would be self-defeating. But the idea of a symbol is good. We have got a comparable thing for the benefit of the druggists in the sale of depressant and stimulant drugs. A symbol consisting of a large letter "C" with the prescription symbol "Rx" in the middle is prescribed for those drugs. That enables the pharmacist readily to identify those drugs. So the idea is good.

Senator Moss. Well, thank you very much, your testimony has been very helpful.

As we consider this, we may want to work through some drafts of the bill, I would hope we could send you a copy and get your comments, perhaps in writing on sections we may want to rewrite. Or maybe we might want to shear the bill in two as you indicated, but we appreciate constructive criticism of what we are considering.

The reason for having the hearings is to get advice and not just have everybody agree with what has been written, if, indeed, they don't agree. What we get out of these hearings is, of course, the thinking of different people looking at it in different ways, and that involves, of course, some criticism of what is written there and suggestions as to how we might improve it.

Mr. HOGE. I would be glad to be of help, if I can. If we are closing, I would like to say something off the record.

Senator MOSS. You may.

(Discussion off the record.)

Senator MOSS. Well, thank you very much.

Thank you, gentlemen.

The hearings will now be adjourned.

(Whereupon, at 4:50 p.m., the subcommittee was adjourned.)

ADDITIONAL STATEMENTS AND LETTERS

STATEMENT OF JOHN T. THIELKE, VICE PRESIDENT, CORPORATE AND PUBLIC AFFAIRS,
ECONOMICS LABORATORY, INC., ST. PAUL, MINN., AND NEW YORK CITY

"CAUTIONARY LABELING PRACTICES WITH RESPECT TO CONSUMER PRODUCTS OF ECONOMICS LABORATORY, INC."

Economics Laboratory, Inc., manufactures a wide variety of detergents, sanitizers, and related products for the consumer and for industry (food service facilities, food processors, metal working and transportation companies). The Company is engaged in the general field of scientific cleaning and environmental sanitation. Two consumer products manufactured by Economics Laboratory, Inc., Finish and Electrasol, were mentioned in testimony at this Hearing.

I would first like to state that Economics Laboratory, Inc., as a corporation, has diligently sought to conform to all laws, regulations, and guidelines regarding the use of cautionary statements on packages of all of its products that are produced for consumer and institutional use. This has always been the policy of the Company, especially since the Hazardous Substance Labeling Act was passed in 1961.

Economics Laboratory, Inc., agrees with 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".

It is hopeful that our written testimony will provide additional information for the Committee that will be helpful in pursuing a course of action for promoting child safety. Based on our experience in placing cautionary statements on our consumer products package labels, it is obvious that caution statements alone have not resulted in the elimination of the hazard of accidental ingestion of consumer products on the part of children five years of age and younger. We like to believe, however, that they have reduced the incidence of such ingestions.

After the Hazardous Substance Act was passed in 1961, Economics Laboratory, Inc., independently consulted counsel for advice on the labeling of its consumer product packages. Commencing in 1961, the Company placed a "Caution" notice on the front and back of each package of "Electrasol" and "Finish" because it was the conclusion of our counsel that the law and regulations required such labeling. Our competitors did not follow suit.

In the mid 1960's (approximately 1965) for a brief period, Economics Laboratory, Inc., dropped the cautionary statement from the front panel while retaining it on the back panel of its packages of consumer dishwashing detergents. This was done for marketing reasons but only after counsel had raised the matter with the Food and Drug Administration.

Shortly thereafter, Economics Laboratory, Inc., was cited by the Food and Drug Administration for failure to properly carry a cautionary statement on its ELECTRASOL dishwashing detergent label. At this point Economics Laboratory, Inc., resumed use of the cautionary statement on the front, as well as the back, panels of both of its home dishwasher detergent products.

In the absence of specific guidelines relating expressly to dishwasher detergents, Economics Laboratory, with verbal guidance from the Food and Drug Administration, continued to work on the language of its cautionary statements and, only after such discussions with F.D.A., strengthened its warning by substituting the word "DANGER" for "caution" on both "Electrasol" and "Finish".

Economics Laboratory, Inc., felt the use of the word "DANGER" on the packages of its products could possibly have adverse effects on sales, but despite these possible consequences, the company decided that consumer safety required the stronger wording. It will be of considerable interest to this Committee that in Economics Laboratory's opinion, the use of the word "DANGER" rather than "Caution" did not adversely affect sales of the products.

Economics Laboratory, Inc., has no doubt that such labeling is a service to the consumer. At the same time, it is obvious that it is only through accidental

use or misuse of these dishwashing detergent products that a danger element can exist. The product is dangerous if it is ingested in concentrated form and not diluted with water, orange juice, or other liquid. Many products, including other household products such as furniture polish, aspirins and other pills and drugs, tobaccos, liquors, pins, pencils, toothpicks, etc., should also be kept out of the reach of children. Continuing education of the consumer is necessary. If cautionary statements or symbols designating danger on packages will contribute to a greater consumer awareness, and they do, Economics Laboratory, Inc., is 100 percent for it.

The testimony received so far indicates that a total program of warning labeling, consumer education and symbolism is required to reduce accidental ingestion. Through the existing manpower resources of health educators, public health officials, sanitarians, and social workers, housewives can be educated on the proper use of products that can be accidentally misused.

According to statistics put out by the Poison Control Center in the year 1967 there were 72,661 reported accidental ingestions by children under age 5 years. Medicines accounted for 52.8%, or 38,360 of these accidental ingestions. All soaps, detergents, and cleaners, accounted for 4.3% or 3,138. The category of solid detergents automatic dishwasher (granular) (within the 4.3%) totaled 204 and there were 16 brands involved—which represents less than $\frac{1}{4}$ of 1% of the total accidental ingestions in 1967.

During the course of the testimony repeated mention was made of dishwasher detergents, but as the above figures show this product category accounts for only a fraction of one percent of accidental ingestions. Nevertheless, Economics Laboratory, Inc., as a manufacturer of two brands of dishwasher detergent for the consumer market, would be pleased to be helpful to the Committee in finding a solution to the problem of accidental ingestions of this category of products and all other products, and would be glad to provide any information that may be helpful in coming to a conclusive decision.

We previously suggested to the staff working on this bill that consumer education is needed and that "caution" and "danger" statements alone may not be the final answer—that some form of alert, such as a symbol, might further help to call attention to the package directions and the caution statements. It is felt that a positive rather than a negative symbol should be used (such as "Smokey The Bear" for fire hazards) so that consumers would not be unduly alarmed about the product. It was brought out by Food and Drug Administration officials that the skull and cross bones approach dilutes itself over a period of time and becomes ineffective.

Further, in our opinion, symbolism by itself will not be effective without a related educational program supported by the mass media.

With regard to safety closures, we feel they may help but will not eliminate the problem because industry sources are of the view that consumers may bypass these closures. If the law does pass in its present form, it is hoped it will be uniformly applied and administered so that it does not become an economic burden on either the consumer or the manufacturer.

We hope this Committee will produce a sound workable bill that will accomplish the desired purpose.

CONTINENTAL RESEARCH & DEVELOPMENT LTD.,
Toronto, Canada, September 29, 1969.

Re Senate Bill S-2162; Poison Prevention Packaging Act of 1969.
SENATE COMMERCE COMMITTEE,
New Senate Office Building,
Washington, D.C.

(Attention Mr. John M. Cary,) Staff Counsel

GENTLEMEN: This written presentation is submitted for the October 1-2 Public Hearing record on the above-referenced Senate bill S-2162 concerning the proprietary child-resistant safety closure developed through our firm for marketing in the United States, Canada and throughout the world. Your files already contain technical and general information on our development while production samples have been submitted by our firm to your Committee. This presentation supplements our prior submittals with further data that have subsequently come to our attention.

In the past, both the drug and household chemical industries have opposed child-proof, safety-type, closures on their packaging for many reasons: their cost was substantially higher than that of existing closures (higher percentage-wise—but in fractions of pennies); few safety closures inherently combined ease of operation by adults while foiling opening attempts by children; and 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 manufactured in volume by simple production tooling and of single piece or unit construction requiring no assembly or other handling).
4. The closure must be liquid-tight (therefore, operating through a flexible or moving cap rim or related means, while the closure top remains firm, solid and non-movable).
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 multi-unit construction requiring costly handling and assembly—or the closures have been technically very difficult to produce at low cost by conventional production tools and machinery. They have otherwise been impossible to operate in darkness or by persons with poor eyesight (by requiring the alignment of slots or numerical combinations, utilizing trick hinges, etc.).

Probably the most important operating criteria not generally met 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 containers among household cupboards and opening them for use, as 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 Safety Closure*. This development is also patented in Canada, 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 goods 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 the "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 already provided your Committee prove that they meet the basic, essential economics and operating criteria listed above in this letter. Additional samples are available for distribution to all interested Government Departments and offices, 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 use. 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 Senate membership may require.

Yours very truly,

S. DONALD MOORE, *President*.

ACADEMY OF MEDICINE OF CLEVELAND,
POISON INFORMATION CENTER,
Cleveland, Ohio, September 25, 1969.

Hon. FRANK MOSS,
Chairman, Senate Commerce Committee,
Senate Office Building, Washington, D.C.

DEAR SENATOR MOSS: As one who is and has been very concerned with prevention of accidental poisonings I commend you and your associates for your interest in this problem.

S. 2162's concern with protecting children from the hazards in their environment may assist in achieving this goal by child-resistant packaging. This subject has been extensively studied by the Safety Closure Committee headed by Edward Press, M.D., director of the Oregon State Board of Health, 1400 S.W. 5th Avenue, Portland, Oregon. This committee was appointed by Harry Shirkey, M.D., the chairman of a Conference on Prevention of Accidental Ingestion of Salicylate Products by Children held in Washington, D.C., on November 21, 1966, at the invitation of the Food and Drug Administration.

The committee has studied the problem of safety closures, and its preliminary findings should be of interest to you and your associates. Their studies indicate there is, as yet, no certain closure that will protect all children and still be useful to that significant portion of our population who have infirmities that do not allow them to open a safety closure easily. The proposed legislation does not make provision for handicapped people, and properly should. A possible solution may be to permit purchase of products they require in containers presently in common use as well as in child-resistant packages.

May I also suggest that you consider including in the technical advisory committee representatives of the professional groups actively engaged in the everyday problems of poison control. The Secretary should take advantage of their experience and background.

Whether these points should be included in the Act is for you and your associates to determine. I trust you find these remarks helpful and respectfully request they be made a part of the hearing record.

Sincerely yours,

IRVING SUNSHINE, Ph. D.,
Technical Director.

STATEMENT OF THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, INC.,
RE S. 2162

The Chemical Specialties Manufacturers Association, Inc. is a non-profit trade association representing some 540 manufacturers and distributors of chemical specialty products for household use. The Association testified before the Senate Commerce Committee in support of the Federal Hazardous Substances Act when it was before the Committee in 1960. The Association gave this bill its full support and encouraged its enactment. In 1966, the Association supported the amendments to this Act known as the Child Protection Act of 1966, Public Law 89-756. More recently, the Association recommended to the Food and Drug Administration the inclusion of a category of combustible substances for purposes of labeling, in addition to the "flammable" category defined in the Act. The definition of combustible will be added to the Federal Hazardous Substances Act by the Child Protection Act of 1969, previously approved by the Senate and recently approved by the House.

The purpose of this bit of history is to establish for the Committee the record of this Association's support for sound legislation directed toward improving the safe and efficient use of its products in the household.

In the nine years of enforcement of the Federal Hazardous Substances Act, representatives of this Association have on many occasions met with representatives of the Food and Drug Administration to explore common problems and seek solutions. Representatives of the Food and Drug Administration regularly attend the semi-annual meetings of the Association, participate actively in its programs, and have made significant contributions to the work of the Association.

The Association did not present a witness during the hearings on this bill principally because there seemed little need for testimony in addition to that presented by the witnesses invited by the Committee. After careful consideration of the testimony offered at the hearings, the Association has concluded that it cannot support enactment of S. 2162. It is keenly mindful that this delegation of ex-

ceedingly broad authority may create very serious problems for the industry, with only speculative and doubtful benefits for the public. Additionally, Government-industry cooperative efforts should first be explored and there is considerable doubt that new packaging or closures will produce a significant change.

The testimony before the Committee and the records of the National Clearing House for Poison Control Centers point to few, if any, containers or types of containers which contribute significantly to ingestion of household products by children aged five and under.¹ This value can never be determined with precision. The hearings did establish that we must continue to strive toward a keener parental awareness of the hazard of leaving chemical products within the easy reach of children. To the extent that improved packaging would offer protection even in conditions of negligent or careless handling or storage of these products, this Association would extend its complete cooperation. No safety closure will prevent the ingestion of a product by a child when a busy housewife places the open container within reach to answer a persistently ringing telephone.

The tendency to store the unused portion of a product in a smaller container exposes children to many unmarked containers. Thus, we should take no comfort or security in this or any other legislation, but should continue a relentless education program through all means available to impress the consumer with the need to read and heed the label.

As pointed out by Dr. Roger J. Meyer, the human factors which occur in the household play a significant role in childhood accidents, including the ingestion of chemical products. Dr. Meyer's testimony was particularly important. The pica syndrome is rarely discussed and little known outside of specialty circles in medicine. The opportunity to educate expectant mothers to look for this condition is unlimited. Obstetricians, pediatricians, public health nurses, pre-natal health clinics, schools, the Red Cross and other agencies could be marshaled to bring the message directly to the family. Posters and ads are helpful but hardly as effective as direct contact. Packaging and closures will unlikely deter the pica child. We are not aware that the full resources of Government have ever been marshaled to reach this problem. This Association's public relations efforts on a "read and heed the label" program have hopefully had some impact, but the magnitude of the need is substantial. There are many agencies that reach the householder directly. It is at this level that there is the most promise of educating parents to the need for protecting their children from their own folly. This program does not need legislation, and it may not need supplemental appropriations. A directive to this effect in a report of this Subcommittee might provide the needed impetus to launch this campaign.

Proper labeling is also an important factor. The regulations issued by the Food and Drug Administration for the labeling of hazardous substances require (1) front panel labeling; (2) minimum type sizes; (3) suitable contrast by layout, color, or typography; and (4) an appropriate statement of the hazard, the hazardous ingredients and the proper precautionary measures. All hazardous substances and pesticides sold for household use contain the label statement, "Keep out of the reach of children." Since experience shows that these products are not kept out of the reach of children notwithstanding these label warnings, there is little merit in establishing a new governmental control for the packaging of these products. As suggested above, reported data does not usually indicate the circumstances which lead to an ingestion incident. Experience has taught us that many ingestion with children under five result from their exposure to open containers and to unmarked storage containers. Solvents, kerosene, turpentine and others are often stored in soft drink bottles.

There was very little testimony before the Committee describing packages which are considered to be of a type which contributes significantly to the risk of misuse by children. It seems apparent that there would be only a very few packages or types of packages regulated by this bill, if approved. It is appropriate, therefore, to approach the problem with a rifle, not a shotgun. Attention should be concentrated on those packages which are reported to make a significant contribution to the risk of misuse by children.

Many witnesses, including Dr. Wegner, Mr. Meade, Dr. Roane, and Dr. Meyer, stressed the need to encourage industry competition and innovation. This is a very important value because, as Dr. Roane expressed his concern, there is a tendency for a regulatory minimum to become a maximum. Industry can con-

¹ The unfortunate situation described by Mr. Snodgrass may not have been prevented by a different closure, but it would have been avoided by more careful storage of the product and the consequences might have been minimized by more effective medical treatment.

fidently meet a specific regulatory requirement but might be hesitant to risk development of containers or closures which might not be within the scope of a confining regulation or standard. There is no body of expertise, either in the Federal Government or in industry, with a monopoly on all of the answers. Industry would be expected to have more background and knowledge on the types of containers that are commercially feasible than any other single group. Industry and Government in a joint voluntary effort should be able to resolve the few problems that may exist.

There should be a great reluctance on the part of this Committee to delegate broad authority to a Government agency to establish standards for packaging of consumer products. The economic strength of this country stems not from overwhelming regulations but the energy and drive generated by free competition. Packaging is a highly complex field, and requires consideration of a number of factors, including practicality, objectivity and commercial feasibility, along with the ever present risk of a restrictive standard which would create a monopoly or near-monopoly in one or a few suppliers.

If, as the testimony indicated, some products should be sold only in containers with a certain rigidity, the straight-forward solution is for the Food and Drug Administration to suggest that the sale of these products in non-rigid or flexible containers be discontinued. There is no indication that this has been done. The record poses only the problem, and reflects no effort toward solution.

It is deceptively simple to suggest that standards can be drafted in terms of performance characteristics, and thus leave industry free to innovate to meet or exceed the performance requirements.

The National Traffic and Motor Vehicle Safety Act of 1966 contains precisely this directive. Yet, there has already been considerable litigation concerning the interpretation of "performance" and "aspect of performance" in the safety standards. Whether the standards define permissible equipment, thus limiting manufacturers to the confines of the standard, or whether they in fact establish minimum performance requirements with manufacturers free to innovate to meet or exceed these requirements, is the central issue. In *Chrysler Corp. v. Rhodes*, C.A. No. 7283 (1st Cir. decided June 26, 1969), rehearing denied, — F. 2d —, the First Circuit Court of Appeals held that the lighting standard of the Department of Transportation (Safety Standard No. 108) in effect is not a true performance standard, and the use of a light which exceeded the performance minimums was not permitted by the standard because the light was not specifically mentioned therein. The exact opposite conclusion was reached by two District Courts in Vermont and New York (*Chrysler Corp. v. Malloy*, 294 F. Supp. 524 (D.Vt. 1968); *Chrysler Corp. v. Tofany*, C.A. No. 68-CV-359 (N.D.N.Y. decided March 13, 1969)), and these cases are now pending in the United States Court of Appeals for the Second Judicial Circuit, having been argued before the court on September 16, 1969.

Government-industry committees sponsored by the Food and Drug Administration hold considerable promise for achieving solutions through conferences and full exchange of relevant information. The use of statutory coercion is unnecessary until such voluntary efforts fail. This will not be a monumental task since the number, or containers or closures that fall within the category needing attention is relatively small, and the testimony before the Committee is not to the contrary.

Significantly, the Department of Health, Education, and Welfare brought to the Committee no examples of better or safer packaging which the industry has failed to adopt. A fair assumption is that no such examples exist. Why then is there a need for legislative authority to compel industry to adopt standards which were not explained to the Committee and have not been discussed with industry.

S. 2162 is premature. Until the responsible agency can state that improved packaging is available and that industry has failed to use it, there is no justification for this Bill. The Committee should not delegate broad authority to set standards which were not described to the Committee. In fact, it is likely that no such standards exist. We assure the Committee of our desire to meet with the Committee staff and representatives of appropriate federal agencies at any time to discuss and consider this Bill more fully if that seems desirable.

THE MENNEN CO.,
Morristown, N.J., October 17, 1969.

Hon. FRANK MOSS,
U.S. Senate,
Washington, D.C.

DEAR SENATOR MOSS: Although I was asked to testify before your committee on the subject of safety closures, I declined, first, because I am so closely identified with The Mennen Company that I did not want anyone to get the impression that I was speaking in behalf of the company, and, secondly, because I am a stockholder in Safety Packaging Corporation and therefore could not speak as a completely disinterested consumer.

From what I read it would appear, as is many times the case, that the vocal minority got the headlines and created the strongest impressions. I think that some of the manufacturers and people present were making a lot of statements about the undesirability of this type of legislation more as a smokescreen and a delaying action than anything else. I don't believe, and I'm sure you don't believe, that legislation requiring this type of closure is in any way going to suppress or slow down research for an ideal closure. I don't think that delaying legislation a couple of years while the subject is dragged through committees and studies and reports, and all that sort of thing, is going to help tremendously. It will undoubtedly result in the loss of many lives that could have been saved. It is true that some bottle manufacturers may be well behind in the development of a good closure, and naturally it would be in their interest to delay any action until they can frantically come up with something. But necessity is the mother of invention, and when something has to be done manufacturers usually find a way and it doesn't take a long time.

One of the closures submitted at the hearing was the Pop-Lok closure made by Safety Packaging Corporation. If you take a good look at this closure you will see that it is not expensive nor is it complicated, nor is it going to require expensive changes in tooling and packaging machinery. In many ways it is like the safety pin—it is extremely simple, it's cheap, and it does the job. Many bottles that now have a screw cap need only to have the neck ring modified, which is not a big job, and the capping machinery which now puts on the screw cap can be easily modified to merely press on the Pop-Lok cap. No torque problems are involved as in a screw cap, and production can be speeded up. The Pop-Lok is actually cheaper than some types of screw cap, plus the fact that it is a safety cap.

Some firms have already been experimenting with the use of safety closures. The Walgreen Company in Chicago, who own and operate the chain of Walgreen Drug Stores throughout the United States, tested the use of one safety closure but discontinued it because they found out that adults had difficulty opening it. Their interest in the consumer prompted them to make a real effort to provide a safer container. It's interesting to note that some of the research done by Foster D. Snell showed that consumers did not like the type of closure used by Walgreen, and now the road is paved for something better.

Now another manufacturer, who was not part of the vocal minority at the hearing, in his interest to provide extra protection for the consumer, is testing his product with the new Pop-Lok closure. I am enclosing a bottle herewith so that you can take a look at it for yourself. I think you can see very easily that very little modification has had to be done on the bottle, and that the closure is very simple and yet very effective without being expensive. When you have exhausted the contents of the bottle I suggest that you fill it with some M&M candies and then show a young child, age 5 or under, how to open the bottle and see how successful he is with it. Our tests have shown that very few children can get this bottle open, and yet once an adult is shown it is quite simple for the adult to open it. It may be slightly confusing to some people at first—but I'm sure that the first time anyone comes across a safety pin he or she will be somewhat baffled by it, but once shown how to use it, it is simple. There's an old saying, "It's easy when you know how." With television and print media it won't be much of a problem to show people how to open this type of container. From there on, it's easy. On the other hand, the average very small child, even when shown, will have a very difficult job getting the container open.

I show you this, Senator, because I want you to see that it can be done; it's no great big complicated task that requires all kinds of committees and other

delaying tactics. Where there is a will there is a way, and those who are interested in seeing the consumer protected can have it done without undue and unreasonable expense.

Very truly yours,

W. G. MENNEN.

AMERICAN PHARMACEUTICAL ASSOCIATION,
October 17, 1969.

HONORABLE FRANK E. MOSS,
Chairman, Subcommittee for Consumers,
Committee on Commerce,
U.S. Senate, Washington, D.C.

DEAR SENATOR MOSS: The American Pharmaceutical Association, the national professional society of pharmacists, wishes to present its views on S. 2162 (Poison Prevention Packaging Act of 1969), a proposal now before your Subcommittee. We understand that the hearing record on this legislation has been kept open for receipt of comments from interested parties.

The American Pharmaceutical Association is completely representative of the pharmacists of this country, both vocationally and geographically. Through its House of Delegates, in which all state pharmaceutical associations are represented, the Association speaks for the pharmacists of the United States.

For 115 years, we have devoted our energy to maintenance and achievement of higher standards of professional practice as well as assuring the highest standards in public health and patient safety. It is important to emphasize that the American Pharmaceutical Association is a public health oriented society of professional individuals; it has no financial or business interest in any pharmaceutical product, manufacturer, packager or distributor.

We concur fully with the objective of S. 2162, to provide additional protection to children against adverse effects resulting from handling, use or ingestion of toxic household substances. Pharmacists have had a long-standing concern with problems associated with accidental poisoning. At its first regular meeting in 1853, the Association adopted a special committee report urging distinctive and conspicuous labeling of all containers of poisonous substances. Through pharmacists' efforts, the Congress designated a specific period each year as National Poison Prevention Week. The Association was instrumental in establishing, and is an active member of, the National Planning Council for Poison Prevention Week. For years, pharmacy organizations have sponsored and supported programs of public education dealing with accidental poisoning. This subject was recently the theme of the January, 1969 issue of the *Journal of the American Pharmaceutical Association* (NS9, 13, 16, 18, 19, 1968), which featured articles on safety closures, Poison Prevention Week, first aid treatment for poisoning and the pharmacist's role in poison centers. A copy of this issue is appended for the information of your Subcommittee.

Pharmacists would be directly responsible for complying with safety packaging standards adopted under S. 2162, in so far as the bill is applied to prescription medicines. Nearly all of these drug products are purchased in bulk by pharmacists and repackaged by them, in varying quantities, pursuant to prescription orders of licensed prescribers. Pharmacists perform this repackaging function more than one billion times a year. Hence, the profession of pharmacy would be remiss in fulfilling its responsibilities to patients which it serves if it did not call to the Subcommittee's attention, several areas of concern generated by S. 2162. Our concerns are threefold.

In 1968, the Association's House of Delegates adopted the report of our Committee on Public Health which recommended "continued research in the hope that an acceptable safety closure may be developed" and urged pharmacists when packaging medication upon a prescription order "to use safety closures once an effective closure has been found which is available at a reasonable cost."

Earlier this year, we published in the January, 1969 issue of the *Journal of the American Pharmaceutical Association* an article on safety closures by Georg S. Maisel, Chief of Education and Training Program, National Clearinghouse for Poison Control Centers, U.S. Public Health Service. Mr. Maisel's article, "Another Key To Children's Safety," also expressed the opinion that "none of the devices on the market today meet all of the criteria presented as prerequisites for a safety cap." The subject of safety closures for drug containers was subject to further review this year by both our Committee on Public Health and Committee

on Legislation. Based upon their reports adopted in May 1969, the Association's House of Delegates continues to find reason to question the adequacy of available safety closures. Following review of the safety closures which are now on the market and others which are in the stage of development, the Committee on Public Health reported that "although the cost of safety closures prescription vials available today is competitive with conventional closures, there is need for more data from controlled studies before objective appraisals of their relative effectiveness can be made." In evaluating these studies, the Committee had difficulty in objectively assessing the contribution of the safety closure container itself since pharmacists, in instructing patients on how to open these containers, also convey a respect for proper drug storage and use. The Committee on Legislation emphasized further that "the safety closures available are not airtight and, hence, would not protect liquid preparations against evaporation nor solid preparations from moisture."

Several Committees of the Association have recognized the value of an alternative method of packaging as a safety measure. There is an increasing trend toward availability of major drugs in strip packaging units for institutional use. We believe that this trend will accelerate in the near future to a point where drugs in strip packages may be available and routinely used for non-institutional use. Strip packaging may provide additional protection against accidental ingestion of drugs by children.

A second and equally important cause of concern to pharmacists is that this legislation would prohibit the distribution in commerce of products made the subject of the proposed regulatory controls, unless the packaging of such products meets required standards. Thus it appears that many household items, including pharmaceuticals, could be made available to the public only in "child-resistant" packaging, which aged or handicapped patients find difficult to open. Difficulties reported by pharmacists utilizing safety closures reveals that some elderly patients cannot operate the devices and may, once the container is open, leave the closure off. This increases the potential for accidental ingestion of drugs, especially by children. Special safety packaging for medication should also be analyzed from the point of view of adult patients who have no children, or no young children in the family. If they had difficulty in successfully manipulating such packaging, there would be the risk that their medication might be left uncapped or transferred to another unlabeled container. This would increase the danger of errors in drug administration, and of deterioration of the product. For the foregoing reasons, the Association cannot endorse routine use of safety closures for all prescribed medication at this time.

Another aspect of the bill which merits the Subcommittee's critical examination is the conflict which may be created between packaging standards adopted under this bill and packaging requirements established by the official compendia under the Federal Food, Drug and Cosmetic Act. National Formulary requirements for use of "well-closed" and other container specifications apply to all products dispensed by pharmacists unless an exemption appears in the particular drug monograph. We therefore believe it necessary to clarify Section 3 of the bill regarding the selection of "packaging consultants" to serve as members of the technical advisory committee. The Section's present language calling for selection of "widely recognized independent packaging consultants" may be too restrictive to permit the HEW Secretary to avail himself of the expertise of National Formulary representatives or members of other scientific bodies. The result could be possible conflict with packaging requirement of existing law as well as the likelihood of a less objective appraisal of packaging standards proposed for adoption under the terms of this bill.

Although the American Pharmaceutical Association cannot endorse S. 2162 at this time, you and other members of the Subcommittee are to be commended for your efforts and activities with respect to this most important matter. We pledge our full support and assistance in meeting the objectives of this legislation. We respectfully request that this letter be made a part of the record of the Subcommittee's proceedings on S. 2162.

Sincerely,
Enclosure.

WILLIAM A. APPLE.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., October 16, 1969.

Hon. FRANK E. MOSS,
*Chairman, Subcommittee on the Consumer, Committee on Commerce,
U.S. Senate,
Washington, D.C.*

DEAR SENATOR MOSS: Thank you for your kind letter informing us of the hearings scheduled by the Subcommittee on the Consumer on S. 2162, 91st Congress, the proposed Poison Prevention Packaging Act of 1969. We appreciate the opportunity to present a written statement on this bill for the Committee's consideration and for inclusion in the printed record.

The Pharmaceutical Manufacturers Association is a voluntary, nonprofit trade association composed of 125 companies engaged in the development and production of prescription drug products. Our member firms manufacture approximately 95 percent of the prescription drug products sold in the United States today.

S. 2162, as we understand it, would authorize the Secretary of Health, Education, and Welfare to establish, by regulation, standards for the child-resistant packaging of household substances (including prescription drugs) found by the Secretary to be hazardous to children. Hazardous substances in packages failing to comply with such standards would be barred from interstate commerce.

While we wholeheartedly support the objective of S. 2162—that is, to protect children from injury or death due to ingestion of hazardous substances—we have serious doubts that enactment of such legislation at the present time would be in the public interest.

We share the increasing public and Congressional concern about the number of young children (particularly those under the age of five) who accidentally ingest poisonous substances, and we fully agree appropriate action should be taken to reduce such accidental poisonings to a minimum. The drug industry has taken affirmative voluntary action in recent years—and is accelerating its efforts—to reduce the number of such poisonings from drugs. We believe it would be premature, however, to impose mandatory federal packaging requirements in this area at this time. The present state of the art of packaging is not sufficiently advanced to provide a practical child-resistant closure for drugs that will also meet the needs of many aged, disabled, rheumatic and arthritic patients. In addition, presently available safety closures have inherent difficulties from the standpoint of product stability and protectability. The majority of safety closures available today, for example, are plastic and would not provide adequate protection for drug products that are sensitive to moisture and air. Further, no satisfactory safety closure has been devised as yet for liquid preparations.

Since the drug industry is taking definitive steps on a voluntary basis to reduce child poisonings to the maximum degree possible—including extensive research aimed at development of improved safety closures, educational programs aimed at parents, teachers and children themselves, and extensive testing programs to insure the safety of new products even when taken in amounts greatly in excess of the recommended dosage—we believe the imposition of mandatory federal standards as proposed in S. 2162 not only would be premature, but could stifle such voluntary efforts and impede current and future safety packaging research.

We respectfully recommend, therefore, that the bill not be enacted in its present form at this time.

Sincerely yours,

C. JOSEPH STETLER.

KAUIKEOLANI CHILDREN'S HOSPITAL,
REHABILITATION CENTER OF HAWAII.
Honolulu, Hawaii, September 29, 1969.

Re Comments on S. 2162.

Hon. FRANK E. MOSS,
*Chairman, Subcommittee for Consumers,
U.S. Senate,
Washington, D.C.*

DEAR SENATOR MOSS: My name is Harry C. Shirkey. I am a licensed physician in Hawaii, Alabama, and Ohio and a licensed pharmacist in Ohio and Alabama. Professor of Pharmacology and Pediatrics (Chairman) University of Hawaii, School of Medicine, a member of the American Academy of Pediatrics, Consultant

and former Chairman of its Committee on Drugs, member of the American Pediatric Society, member and former President of the American Association for Poison Control Centers, member of the American Medical Association, and Vice Chairman of its Council on Drugs, member of the American Society of Pharmacology and Experimental Therapeutics and other groups concerned with drugs, children, and drugs or other substances which result in poisoning in children. As a member of the Revision Committee of U.S.P. and the National Formulary Board (N.F.), I have been engaged in defining standards for drugs, their preparations, their packaging and safety.

At the request of Dr. James Goddard, then Commissioner, The Food and Drug Administration, I was Chairman and he was host to the Conference on Salicylates which was responsible for a number of important changes or details as related to salicylates, e.g. the number of tablets per bottle, their sizes, their labeling, warnings, etc.

It was my understanding that the Commissioner was charged with the responsibility of calling together industry, the scientific community and government to attempt to bring about solutions to problems related to salicylates after failure to gain changes over a ten year period and after proposed legislation had failed to pass Congress.

The necessary changes were agreed to at this conference in less than six hours. In addition to that accomplishment, a special Subcommittee of the three responsible groups was appointed with Dr. Edward Press as its Chairman. This subcommittee was charged with obtaining solid data so that we could speak from facts which could offer added progress rather than to go forward with action based only on emotion, opinion, or otherwise unsupported.

I submit these comments as that Committee Chairman and as an individual and not as a representative of any group. (See Addendum A)

You and the Subcommittee are to be praised and commended for your activities and efforts not only for those children now living, but, as well for those as yet unborn.

All of us are dissatisfied with the speed of production of safety closures, but recognize that had some of the great variety of safety closures been adopted earlier for general use we would have found them disappointing. There are few who have attacked this problem in depth, but there are many, many opinions, all desirous of doing good but without guarantee for such.

There is great need to plan and support studies to produce results upon which we can depend. We do not now have sufficient studies or data to offer any, but fragmentary suggestions leading to a clear direction of activity.

There are numerous groups and people working, some with years of experience and some of only expertise are the U.S.P., N.F., the Committee of The American Academy of Pediatrics, The National Clearinghouse and the American Association of Poison Control Centers, the F.D.A., The Proprietary Association, The Pharmaceutical Manufacturers Association, and the appointed Committee mentioned above.

It is my understanding that Congress in the past suggested that solutions be reached by those concerned; as Chairman of the "Salicylate Committee", it was clear that this concept offered the greatest opportunity of definitive action, cooperatively gained, and which had the greatest opportunity of reaching solutions.

I am confident that all of those concerned, as I do, support the ideas of this bill; however, the F.D.A. which would probably be charged with the responsibilities of the bill is already overwhelmed with other activities, continue to have difficulty in recruitment, have waxing and waning strength as we have learned historically, and unfortunately are subject to political pressures which, I, as a child's doctor, should not like to see as determining force in deciding the needs of children.

We have seen the pediatric catastrophic ("Elixir" of Sulfanilamide) producing the drug amendments of 1938 (Safety) and the thalidomide disaster producing the drug amendments of 1962 (efficacy) result in an intolerable situation in which, since 1962, approximately two thirds of the drugs approved are forbidden for use in children (See "Therapeutic Orphans" attached Addendum B) ¹

There are at present only limited facilities for investigating children's drug needs and preparing those who could give meaningful data on which to base legislation. (Addendum C) ²

¹ The information is in the committee files.

² The information is in the committee files.

The elements mentioned in this bill are but a small part of the total drug related needs of children. I fear that passage of this bill as it now is written could not accomplish its purpose, but would give a false sense of security since it would "legally" "provide" for provisions not now possible of provision.

Instead, may I urge you and your good committee of statesmen to consider the larger problem of children's drugs, their safety packaging (about which we know little), insecticides and other household poisons and their safety packaging (about which we know less) and that having considered the greater need that a study in depth of the total needs be made quite soon, a study conducted by those who by their experience and background can delineate the needs and set about in an orderly way to attack the problem rather than piece meal legislation of a fragmentary nature. Financial support should be proportionate to and appropriate for a true concern of children, their protection and other drug related needs.

The results of the Salicylate Conference (5-6 hours) and the Drug Efficacy Study (National Academy of Sciences—National Research Council) attest to the productivity possible by calling on a responsible group of knowledgeable and responsible individuals. May I now offer what I believe is constructive praise or criticism of what I understand are portions of the bill:

(1) "to provide for child-resisting packaging to protect children from serious personal injury or serious illness from handling, using, or ingesting any hazardous substance etc." I cannot see how the bill can "provide" this. The Secretary of H.E.W. neither can "provide" this as the provisions for such safety are not known.

(2) "serious illness resulting from . . . ingesting . . ." The bill intends to prevent ingesting rather than illness resulting from ingesting.

(3) He "*may* after consultation" is not required to accept the advice which the technical advisory committee may recommend. (italic added)

(4) "Establish, by regulation, standards for the child-resistant packaging." This part would be excellent provided there were agreement on standards. This could provide for a stepwise production of needed standards once they were derived (by solid data) and agreed upon.

(5) "The Secretary shall appoint a technical advisory committee composed of." There are a number of organizations quite knowledgeable of the problems, methods needed for solving these, and other known strengths not mentioned in the bill. The organizations are delineated earlier in these comments. We have all experienced the phenomenon of being called by government agencies or committees when it is pretty well known ahead of time what we stand for. These calls or appointments do not allow for true representation. The organizations themselves could best choose a number of the knowledgeable members from their group. The Secretary of H.E.W. could then choose but from these names. Precedent exists for this in a number of government boards, committees, etc.

Our many cooperative efforts are associated with a decline of mortality from poisoning in children below 5 years of age including declining deaths from salicylates. There are many points to attack for improvement including education, research, better patient care, and legislation. They are not separate but additive.

May I thank the committee for an opportunity to express my views and again thank all of you for your efforts in behalf of our priceless possession—our children.

Respectfully submitted,

HARRY C. SHIRKEY, M.D.,
Medical and Executive Director.

PREVENTION OF ACCIDENTAL INGESTION OF SALICYLATE PRODUCTS BY CHILDREN

FOOD AND DRUG ADMINISTRATION—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

(November 21, 1966)

The meeting convened at 10 a.m. with Dr. Goddard host, presiding; Dr. Shirkey, chairman.

PARTICIPANTS

Harry Cameron Shirkey, M.D. Director, The Children's Hospital of Birmingham	Mr. L. F. Bonham, President
University of Alabama Medical College	Mr. Robert Becker
Allan B. Coleman, M.D.	Norwich Pharmacal Co.
Chairman, Subcommittee on Accidental Poisoning	Mr. John Culligan, President
American Academy of Pediatrics	Dr. John Shaul
Jay M. Arena, M.D.	Mr. Marston Blunt
Director, Poison Control Center	Whitehall Laboratories
Duke University Hospital	Mr. William M. Bristol, III, Group Vice President
Marjorie E. Conrad, M.D.	Mr. J. Richard Edmondson, Assistant Secretary
American Academy of General Practice	Dr. Peter D. Orahovats, Vice President
Alan Kimball Done, M.D.	Bristol-Myers Co.
Associate Professor of Pediatrics	Mr. George W. Cain, Chairman and President
Director, Poison Information and Ther- apy Center	Abbott Laboratories
University of Utah Medical Center	Mr. Don Hamilton
William Kitto, M.D.	Rexall Products
Associate Director	Mr. John L. Harvey
Department of Drugs	Drug & Allied Products Guild
American Medical Association	Mr. Fred B. Kienzle, President
Edward Press, M.D.	Dr. K. R. Ravel
Chairman, Subcommittee on Safety Closures	McKesson Laboratories
American Academy of Pediatrics	Dr. Laurence Marks
Illinois Department of Public Health	E. R. Squibb & Sons
Clarence E. Rozgay, M.D.	Dr. Robert S. Warner
Director, Poison Control Information Center	Wyeth Laboratories
Seattle Children's Orthopedic Hospital	Dr. George L. Wolcott, Medical Director
Medical Center	Consumer Products Division
Samuel C. Southard, M.D.	American Cyanamid Co.
Past Chairman, Committee on Accident Prevention	Mr. Richard Fisher
American Academy of Pediatrics	Director of Public Affairs
Irving Sunshine, Ph. D.	Glass Container Manufacturers Insti- tute
President, American Association of Poison Control Centers	Mr. Forest L. Neal
Mr. Harry B. Solmson, Vice President	The Garrett Corp.
Mr. Charles Sullivan	James L. Goddard, M.D.
Plough, Inc.	Commissioner of Food and Drugs
Dr. Maurice L. Tainter, Vice President	Basil G. Delta, M.D.
Mr. James Luther	Mr. Gifford D. Hampshire
Dr. Audrey J. Jongbloed	Judith Ditsborough
Sterling Drug, Inc.	Mr. Frederick J. Delmore
	Mr. Donald Early
	Food and Drug Administration
	Mr. Henry L. Verhulst
	Public Health Service

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:

(1) The smaller aspirin tablets, often referred to as "children's aspirin" tablets, shall continue as gr. 1¼ in size.

(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 similar 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.*

STATEMENT OF PACKAGING MACHINERY MANUFACTURERS INSTITUTE
OCTOBER 16, 1969

The Packaging Machinery Manufacturers Institute (PMMI) appreciates the opportunity to submit testimony on the United States Senate Bill S. 2162, "Poison Prevention Packaging Act of 1969."

PMMI shares the concern expressed in the bill: "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 . . ."

This objective should be pursued in the most possible and realistic manner by all concerned.

S. 2162 would authorize the Secretary of Health, Education, and Welfare to "establish, by regulation, standards for the child-resistant packaging of such substances." And it explains: "For the purpose of assisting in developing such standards the Secretary shall appoint a "Technical Advisory Committee" repre-

sentative 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."

PMMI believes this approach to reaching the desire objective would prove unworkable, because it is impossible to "set standards" in this or any other field until and unless the necessary technology described in such standards has been developed.

If a "Technical Advisory Committee," as outlined in the bill, were capable of developing standards which it were physically possible to adopt or apply, it is not likely that a regulation would be required to have them in fact broadly adopted by industry.

Producers of hazardous substances have spent large amounts of money over a period of many years to develop "safe" packaging and they are still working on this problem.

Some progress has been made in the area of closures—if not in general packaging and wrapping—but where a closure is truly "child-proof" it is generally also "adult-proof," not to mention difficult or impossible to handle by people afflicted with arthritis and other dexterity-impairing conditions.

The central flaw of the bill remains that unfortunately the technology on which standards could be based does not yet exist, and a "Technical Advisory Committee" is not likely to produce the needed technology.

Perhaps, rather than authorizing the Secretary of Health, Education, and Welfare to "set standards" in this area, it should authorize him to contract for the kind of research needed to develop the desired technology.

PMMI, and we are sure others, would be pleased to assist in any realistic effort to explore possible avenues of approach to solutions of the problem.

Respectfully submitted,

LEIF OXAAL,
Executive Director.

