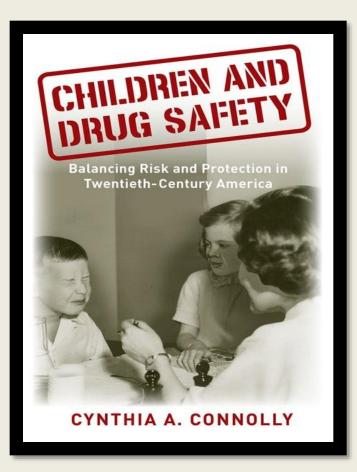
"A Case Study of Unintended Consequences: Children and "Candy" Aspirin in Twentieth Century America,"



Cindy Connolly, PhD RN Professor of Nursing, Rosemarie B. Greco Endowed Term Chair in Advocacy University of Pennsylvania School of Nursing



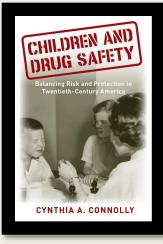
1953, Eli Lilly "Juvenile Board of Medication Taste Testers"



"Let the kids decide for themselves what flavor they like" by "giving them a taste of their own medicine."

Credit: American Institute for the History of Pharmacy, Madison, Wisconsin Courtesy: Eli Lilly & Co.

Thank You



- John Swann PhD, FDA History Office
- <u>https://www.fda.gov/about-fda/fda-history/fda-history-office</u>

<u>Funding Acknowledgements</u>: Robert Wood Johnson Foundation;

National Endowment for the Humanities; American Institute for the History of

Pharmacy;

University of Pennsylvania Research Foundation;

American Association for the History of Nursing; Trustees Council of Penn Women

Parent's Magazine, 1949



Mother ... IERE'S THE ASPIRIN TABLET THAT Fits OUR CHILD'S NEEDS

-

ST. JOSEPH

ASPIRIN FOR CHILDREN

T'S ST. JOSEPH ASPIRIN FOR CHILDREN! Approved by mothers everywhere because it solves child dosage problems and eliminates all guesswork as to the correct dose. Easy To. Give because it's not necessary to cut or break tablets. Assures Accurate Dosage because each tablet is 1/4 the regular adult aspirin tablet. Easy To Take because they are orange flavored and sweetened. It's the new "Mother-and-

Be sure to always ask for the there is no other product just





TT'S ST. JOSEPH ASPIRIN FOR CHILDREN! Approved and eliminates all guesswork about correct dosage. Easy To Give because it's not necessary to cut or break tablets. Assures Ac-ST. JOSEPH ASPIRIN curate Dosage because each tablet contains $1\frac{1}{4}$ grains of aspirin - $\frac{1}{4}$ the regular 5-grain adult tablet. *Easy To Take* because it's FOR CHILDREN orange flavored and sweetened to a child's taste. Bottle of 50

He sure to always ask for the original and genuine St. Joseph Aspirin For Children because there is no other product just





Mother ... HERE'S THE ASPIRIN TABLET THAT FILA YOUR CHILD'S NEEDS

POR CHILDREN' Approved to the current door. Long To

The Trousers Don't

Fit, Sonny ...



The Negligee Doesn't Fit, Honey ...

MRS. DEAN GOCHENOUR, Fort Wayne, Indiana, says

"My doctor prefers St. Joseph Aspirin For Children and I prefer its accurate dosage and safe, gentle action "

St. Joseph Aspirin For Children assures the best, safest, fastest pain-relieving, fever-reducing help money can buy. With this specialized tablet you give dosage "just as the doctor orders"—no over-size tablets to cut or break, no messy liquids to measure. Millions of mothers prefer St. Joseph Aspirin For Children because it acts so gently without stomach agent. Children like its pure orange flavor. No wonder it's America's mother-and-child favorite!



St. Joseph Aspirin For Children is approved by more doctors than any other brand



suger in

MRS. J.R. ANDERSON, Doneer, Colorado: "Bt. Joneph Aspiria For Children is the only brand Tener buy because II is easier on my children and use. With II I have I'm giving scientific desays."



MBR. HARLAND RAGER, JR. AMarta, Go., "My doctor always presenthes BL Juseph Aspiris For Children, My children welcome its strings flaver, and I'm same of going dange has a the doctor arthur."

"For my family's adult aspirin needs, I always buy regular St. Joseph Aspirin"



"What's The Best Aspirin I Can Give My Child?"



Thousands of doctors answer by specifying "St.Joseph Aspirin For Children"

> Doctors know this specialized tablet is right in every way for your child. So easy to give-each tablet is 1¼ grains (¼ regular adult dose), the preferred standard of accurate dosage measure. Children like its pure orange flavor and take it willingly. That's why it usually acts faster to bring relief.

> > Boy 39¢ size today. Your child may need it tonight. A PLOUGH PRODUCT



390

World's Largest Selling Aspirin For Children

St. Joseph

ASPIRI

mah In

200 tablets 79é

100 tablets 49¢

12 tablets 10¢

"Children like its pure orange flavor...." Parent's Magazine, 1952

For Your Family's Regular Aspirin Needs Demand





Tastes Like your Children's Favorite Candy

Reading Eagle June 15 1952

A Big Business Built for Little Customers

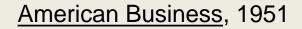
Plough, Inc., Memphis, Tennessee, employs almost every known automatic machine available for processing its products and handling a big volume of small orders profitably. Costs went down rapidly in newly opened plant and office

By Eugene Whitmore

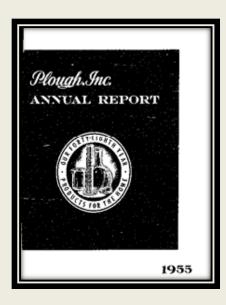
FOR the first 9 months of 1951, sales figures for Plough, Inc., showed an increase of from \$11,800,000 to \$12,326,000—a gain ing costs high, due to overcrowding, the necessity for small operating units, and a vast amount of handling and intercommunications about 900 sales calls daily. Chi stores and wholesalers buy 55 j cent of the company's volume a independent retail stores accor for the remaining 45 per or There are 65,000 active, three buying accounts on the books these, 35,000 are retail druggis the remainder is largely an general stores, variety stores a other retailers who handle one more, of the company's produc

There are 5,000 wholesale a chain-store customers. These 5,000 customers buy 55 per cent of total production of the comparand the other 45 per cent g to 65,000 direct small-custom accounts.

The 55 ner cent of seles to the







	TREND OF SALES 1946-1955
	SALES IN MILLIONS
	000000000000000
	1945
-	1947
-1	1948
-	1849
	1950
-	1951
	1952
-1	
	154
_1	153
	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
	SALES IN MILLIONS

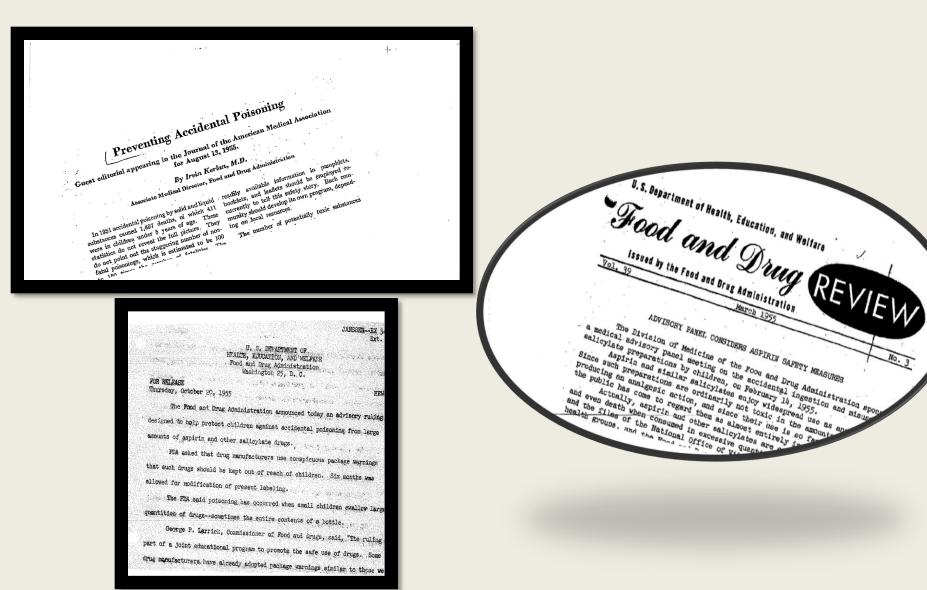
Plough Estimates 1956 Net At New High, 50% Above 1955

Wall Street Journal, Feb. 25, 1957



"We do not know of a single instance wherein serious results have accrued even though we have been made aware of several instances of children taking a whole bottle."

Letter dated May 3, 1954 from H. B. Solmson Plough Executive Vice President to American Academy of Pediatrics Food and Drug Administration Archives, National Archives College Park, Maryland. RG 88, File Number 500.23 Box 1991



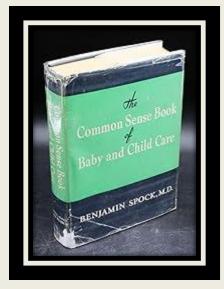
FDA History Office, Silver Spring, MD

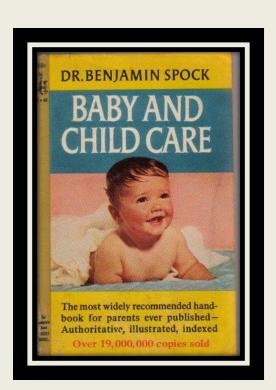
"....safety cap designed To prevent opening...."

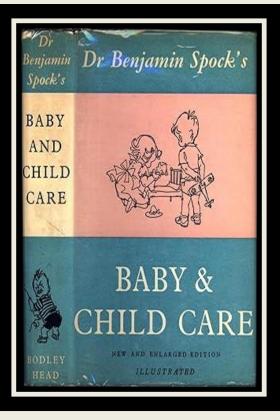
Parent's Magazine, December, 1958



Benjamin Spock







Sen. McGovern Urges Controls On Sale of Aspirin for Children

Washington Post, August 16, 1965 p A.3



CHILD SAFETY ACT AND PERSONNEL TRAINING

HEARINGS BEFORE THE SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES EIGHTY-NINTH CONGRESS

JIII I-NIMIR CONGRES

SECOND SESSION

ON

H.R. 13884, H.R. 14634

BILLS TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT FOR THE PURPOSE OF STRENGTHEN-ING AND FACILITATING MUTUAL COOPERATION AND ASSISTANCE. IN-CLUDING TRAINING OF PERSONNEL, IN THE ADMINISTRATION AND ENFORCEMENT OF THAT ACT AND OF STATE AND LOCAL LAWS RE-LATING TO FOOD, DRUGS, DEVICES, OR COSMETICS, AND FOR OTHER PURPOSES

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

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

JUNE 24; AUGUST 15, 29; SEPTEMBER 12, 19, 1966

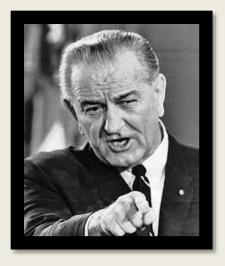
Serial No. 89-43

Printed for the use of the Committee on Interstate and Foreign Commerce

U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON , 1966

68-965



THE CHILD SAFETY ACT

Children must be our first concern. They are our hope and our future. Too many children now become seriously ill--too many die--because of accidents that could be avoided by adequate labeling and packaging of dangerous substances. This is senseless and needless tragedy....

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

Rendezvous with Destiny

By JAMES F. HOGE

The Following Article Was Presented at the Second General Session of the 85th Annual Meeting of the Proprietary Association in White Sulphur Springs, West Virginia, on May 18, 1966. Mr. Hoge Is General Counsel of the Proprietary Association and a Member of the New York Bar.

THE DRUG INDUSTRY THIS YEAR has come to what may be its rendezvous with destiny. Its future is being cast in circumstances of scientific, political and social change; and also—as pertaining particularly to it—in circumstances of unfortunate events and unsympathetic attitudes. New laws have been enacted and more are proposed—laws designed to change the industry's relationship to the public and to the government. Saying that he was "aware of pressures to bring the drug industry under tighter federal control," Commissioner Goddard—who may be the catalyst of our destiny—last month told the Pharmaceutical Manufacturers' Association (PMA):

There is a real danger that the pharmaceutical industry as you and I know it today may be altered significantly, altered beyond your present fears, and altered beyond recall.

The Commissioner related this danger to industrial irresponsibility. He gave that as his diagnosis of a disease which can undermine an industry, and he based his diagnosis on an enumeration of symptoms, including poorly prepared Investigational New Drugs (IND's) and New Drug Applications (NDA's), and improper labeling and advertising.

Taking that as a starting point, let me say that my long experience in this field does not support a charge of irresponsibility, or any comparable generalization. But it does impel me to say that the Commissioner is ever so right in associating these symptoms with the dangers of tighter federal control.

The Commissioner's remarks were directed specifically to the pharmaceutical part of the industry. But the proprietary part is not President's "consumer message" and related to it. One of them, H. H 13884, pertains to federal and state cooperation in the enforcement of federal, state and local laws. Another, H. R. 13885, would be calle the "Drug Safety Act of 1966." As to proprietary drugs, it woul amend existing law so substantially as to swallow up and replace nearly all other labeling requirements. The third, H. R. 13886, pe tains primarily to the protection of children, dealing specifically wit aspirin products and hazardous substances.

The "evil genius" of these bills is that they are embodied

Food, Drug, Cosmetic Law Journal, August 1966, p 432

James L. Goddard MD, FDA Commissioner, 1966-1968





CHILD SAFETY ACT AND PERSONNEL TRAINING

HEARINGS severe very SUBCOMMITTER ON PUBLIC HEALTH AND WETTER COMMITTER ON INTERSTATE AND FORFICE NOMMERCE HOUSE OF REPRESENTATIVES HOUTY MUTH CONCRESS

> H.R. 13884, H.R. 14634 TO FROTH'T THE FUELC BRAITH BY AMENDING THE FEDEL BOD, AND CONNETC AT FUEL THE FUELDED OF STREMATTS SUBJECT OF INTERAL COOPERATION AND AMERICAN CONNET OF THE ACT AND OF TATES AND EXCLUSION

Н.R. 13886, Н.R. 14557, Н.R. 14632 в ключе из ликонно чен режел годо, акр соцект ключе из ликонно чен режел годо, акр соцект социально социального почина и почека очатака со лисская и почина и почека очатака со лисская и почина и почека и почина со лисская социального почина и почека и почина и почина и почина и почина и почека и почина и почи

UNE 24; AUGUST 15, 29; SEPTEMBER 12, 19, 1966

Serial No. 89-43

U.S. GOVERNMENT PRINTING OFFICE

48 CHILD SAFETY ACT AND PERSONNEL TRAINING												
Products among "Top 10" substances which were reported 100 or more times, July 1959 to December 1961												
Product	Cases	Percent 1 hospital- ized	Product	Cases	Percent 1 hospital- ized							
1. Aspirin. 2. "Clorox". 3. Kerosene. 4. "Ex-Lax". 5. "Drano". 6. Ammonia. 7. "Pride" furniture polish. 8. "Lysol". 9. "Old English" polishes. 10. "Gator Roach Hives". 11. "Lestoll". 12. Lye. 13. "Purex". 14. "Pine-Sol" disinfectant. 15. "Black Flag". 16. "Real-Kill". 18. "Windex".	1,855 1,656 1,021 989 420 360 356 303 275 262 245 240 212 200 194	13.9 14.3 39.5 6.0 50.9 40.8 32.6 29.0 50.3 21.3 21.3 27.9 55.1 13.0 81.5 26.5 26.3 26.3 22.3,1	19. "Comet". 20. "Harris Famous" roach tablets. 21. "Gelz" insect repellent. 22. "Poly-Vi-Sol". 23. "Mr. Clean". 24. "Sani-Flush". 26. "Carter's Little Pills" 26. "Roman" cleanser bleach 27. "Jog". 28. "Chocks" vitamins 29. "Alax". 30. "Lilly's" ant oup. 31. "Easy-Off" oven cleaner Total "31". Total cases with trade name specified.	161 158 145 127	0.0 6.6 8.5 0.0 13.8 22.5 7.5 6.5 5.7 0.0 13.6 27.3 29.8 20.1 20.0							

CHILD SAFETY ACT AND PERSONNEL TRAINING 55												
Substances most frequently ingested by children under 5 years of age, reported by poison control centers, ¹ 1959–62												
	1962		1961		1960		1959					
Type of substance	Num- ber	Per- cent	Num- ber	Per- cent	Num- ber	Per- cent	Num- ber	Per- cent				
Aspirin Bleach Soaps, detergents, cleaners Insecticides (excluding mothballs)	<mark>8, 799</mark> 2, 155 1, 727 1, 678	21.6 5.3 4.2	6, 968 1, 417 1, 384 1, 687	21.8 4.4 4.3	<mark>5,930</mark> 1,055 1,417 1,413	<mark>20.5</mark> 3.6 4.9	<mark>2, 901</mark> 527 728 941	<mark>19.0</mark> 3.4 4.8 6.1				

Aspirin Industry Response 1966 Child Protection Act Hearings

- Deny the problem/data
- Blame parents (and children)
- Regulation harms children's interests and American business

A Model Public Private Partnership?

"The process of development of the use of these closures may be viewed as a model for other areas of accident prevention."

Lorne K. Garrettson, "The Child Resistant Container: A Success and a Model for Accident Prevention," *American Journal of Public Health* 67 (February 1977): 135–136.

Considerations for 2023

- Is there data available to suggest that "candylike" features accelerate a trend toward their use?
- Do adults perceive more palatable medications as safer?
- Is there evidence that candy/palatability marketing shapes consumer behavior?
- Was the "candy-like" formulation to blame for the increase in poisoning?