

HHS NEWS

P85-40: ASPIRIN RELABELED

P85-39: BIOSYNTHETIC HORMONE APPROVED

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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(Food and Drug Administration)
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The Food and Drug Administration said today that aspirin relabeled with Reye syndrome-related warnings is reaching store shelves in quantity, in advance of the flu season. "The voluntary relabeling and educational effort which Secretary Margaret Heckler initiated earlier this year is working well," declared FDA Commissioner Frank E. Young, M.D.

"Some 58 percent of children's aspirin on store shelves in the first week of October had the new labeling, and we expect that figure to increase rapidly in the next few weeks," Dr. Young said.

"As for our educational effort -- our own and the manufacturers' -- a recent poll indicates that all but 12 percent of parents today would be unlikely to use aspirin for a child with flu or chicken pox unless advised by a doctor.

"But," Dr. Young said, "teen-agers, who may self-medicate without supervision, need to know they are susceptible to Reye syndrome, too."

Because a methodological study on 30 cases suggested aspirin's possible correlation with the subsequent development of Reye syndrome, the newly labeled aspirin advises caution in the products' use in children and teen-agers with flu or chicken pox. The agency will supplement this information with a "strong" public information campaign on Reye syndrome, with a special emphasis on reaching teen-agers. Dr. Young added that manufacturers of aspirin are also sponsoring what appears to be an extremely informational effort on Reye syndrome.

He said the FDA's campaign -- using television and radio announcements, notices in newspapers and magazines, and posters in doctors' offices -- will remind parents and teenagers of the new labeling and a methodological study suggesting a potential link between aspirin's use for childhood flu and/or chicken pox and Reye syndrome, a rare condition but one that can cause mental retardation or death. The poster and TV announcements will both emphasize the potential risk to teen-agers.

The relabeling is a result of a voluntary effort by manufacturers worked out with FDA at the urging of Health and Human Services Secretary Margaret M. Heckler in January.

The FDA said 100 percent of the aspirin produced by manufacturers who are members of the Aspirin Foundation of America carried the new labels as of Aug. 31, and these relabeled products are now reaching store shelves as older stocks are depleted.

FDA said its survey of retail stores in the first week of October showed a sharply increased percentage of labeled aspirin products on store shelves. Children's aspirin with the labeling, for example, jumped from 9 percent in July to over 58 percent in October.

The advisory wording generally used is: "Consult a physician before giving this medicine to children, including teen-agers, with chicken pox or flu."

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TESTIMONY OF SIDNEY M. WOLFE, M.D.

DIRECTOR, PUBLIC CITIZEN HEALTH RESEARCH GROUP

BEFORE

HOUSE HEALTH SUBCOMMITTEE

HEARINGS ON H.R. 1381

REQUIRING WARNING LABELS, ADVERTISEMENTS AND STORE SIGNS

CONCERNING ASPIRIN AND REYE'S SYNDROME

MARCH 15, 1985

Chairman Waxman and Members of the Subcommittee, thank you for the invitation to present our strong support for this urgently needed legislation.

Nothing can more clearly highlight the need for this legislation than the statements by parents whose children died or became brain-damaged as a result of Reye's Syndrome. No parent would ever give or have given a child aspirin for treatment of chicken pox or flu had they known of the strong association between the use of aspirin in these circumstances and the greatly increased risk of contracting Reye's Syndrome. Especially tragic is the plight of over 610 children, 175 now dead who have gotten Reye's Syndrome since the beginning of 1982, several months after an October 14, 1981 CDC (Centers for Disease Control) Advisory Committee recommended that the use of aspirin "should be avoided" for treatment of chicken pox or flu. Almost all of these children had been given aspirin. Their deaths and injuries were thus preventable.

The evidence that aspirin (salicylates) is strongly associated with Reye's Syndrome is now based on five studies, four of which were completed over three years ago. Three years ago, Public Citizen Health Research Group petitioned FDA to require warning labels on all aspirin-containing products and later, along with the American Public Health Association, filed a lawsuit against the FDA. In remanding the case back to the U.S. Federal District Court, the U.S. Court of Appeals said, of HHS's November 1982 reversal of its earlier plan to require warning labels,

"The record evidence indicating that industry pressure precipitated this reversal is particularly troubling in that the pace of agency decision-making may jeopardize the lives of children... The current record strongly suggests that the pace of agency decision-making is unreasonably dilatory. All scientific evidence in the record points to a link between salicylates and Reye's Syndrome..."

RESULTS OF MARCH 12-13, 1985 NATIONWIDE DRUG STORE

SURVEY ON VOLUNTARY PROGRAM

Over two months ago, (1/9/85), HHS Secretary Heckler asked the aspirin makers to voluntarily: 1) "immediately remove any

labels which recommend that aspirin products be used to treat flu or chicken pox in children or teenagers" and 2) "further label all aspirin products to indicate that there is a possible association between the use of aspirin and the onset of Reye's Syndrome in children and teenagers, and that aspirin products should not be used in those cases unless a physician is first consulted." That subset of aspirin-makers who belong to the Aspirin Foundation later "voluntarily" agreed to put warning signs in drug stores.

1)CHILD & ADULT ASPIRIN PRODUCTS WITH LABELS STILL
RECOMMENDING FLU AS AN INDICATION FOR ASPIRIN USE.

As of this week, the following nationally-distributed aspirin products were found in drug stores with labels recommending use for treatment of flu:

CHILDREN'S ASPIRIN: St. Joseph's, Bayer

ADULT (& THEREFORE TEENAGE) ASPIRIN:

MAXIMUM STRENGTH ANACIN; REGULAR, MAXIMUM

& ARTHRITIS STRENGTH BAYER; REGULAR and

EXTRA-STRENGTH BUFFERIN; EXCEDRIN.

Thus, Secretary Heckler's first request, for "immediate" removal of such labels is not being taken seriously since it is "voluntary".

2) RELABELLING ALL ASPIRIN PRODUCTS TO WARN AGAINST USE FOR CHICKEN POX OR FLU BECAUSE OF THE INCREASED RISK OF REYE'S

SYNDROME: Secretary Heckler's second request has been met with equal enthusiasm by the aspirin industry. A survey by phone of 53 drug stores in 31 states found that no store had aspirin products with labels. The voluntary promise by the Aspirin Foundation to label newly manufactured products has not yet showed up in stores nor, when it does, will the labels mention Reye's Syndrome.

3) THE ASPIRIN FOUNDATION PROMISE TO VOLUNTARILY PUT WARNING SIGNS IN STORES:

of the 53 stores surveyed this week, only 17 had posters, many of which had come from the American Pharmaceutical Association, the pharmacist organization which sent members a warning poster 1 1/2 months ago. In other words, over 2/3 of stores had no warning poster.

In summary, the voluntary program is a cruel disaster. During this heavy flu and chicken pox season, no aspirin purchased in this country has warning labels and some of the biggest selling products actually recommend use for treatment of flu.

H.R. 1381

Because HHS has failed to require mandatory warning labels, the introduction and passage of H.R. 1381 is very important. By taking into account interim warning labels, advertising, signs in

the stores, and the labels for future-manufactured products, it covers four crucial areas which have been left largely unim-plemented as a result of the voluntary approach. H.R. 1381 also recognizes that many people don't have a doctor to go to and that many who do, don't consult her/him for chicken pox or flu. Thus, the straight forward language that "this product should not be given..." rather than "consult a doctor" is quite appropriate.

In conclusion, there is little doubt that many of the hundreds of children and teenagers who have died or suffered brain damage from Reye's Syndrome would be alive and healthy today if the Reagan Administration had not yielded to pressure from the drug industry 2 1/2 years ago and canceled its plan for mandatory aspirin warning labels.

Thank you