

FOR IMMEDIATE RELEASE
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For Further Information
Contact:
Sidney M. Wolfe, M.D.
Cary LaCheen
(202) 872-0320

REAGAN ADMINISTRATION BANS EDUCATIONAL MATERIALS WARNING PARENTS ABOUT ASPIRIN & REYE SYNDROME

We have learned that following an early October meeting between officials in Secretary of HHS Margaret Heckler's Office and representatives of the aspirin industry, the Reagan Administration ordered FDA to ban the distribution of one-half million copies of a consumer pamphlet warning parents about the association between aspirin and Reye Syndrome, an often fatal disease. These pamphlets were to have been distributed in mid-October in 4200 supermarkets all over the United States. In addition, the distribution of a 30-second radio spot warning against aspirin use for treating chicken pox and flu to have been distributed to 5,000 radio stations, was also cancelled.

This is the latest in a series of largely successful efforts by the aspirin industry to stop FDA from warning parents against the use of aspirin for treating chicken pox or flu.

Over two years ago, (Nov. 12, 1981) an HHS advisory committee (convened by the Centers for Disease Control (C.D.C.)) recommended that "the use of salicylates (as in aspirin) should be avoided, where possible, for children with chicken pox and during presumed influenza outbreaks". In the 23 months between December 1, 1981 and October 31, 1983, 361 additional cases of Reye's Syndrome were reported to C.D.C. including 113 children who died from the disease.

By banning the distribution of these educational materials, as with the earlier cancelling of planned warning labels for all aspirin-containing products, the Reagan Administration is willing to condemn American children to death or brain damage from Reye Syndrome in order to please the aspirin industry.

CONTENTS OF BANNED EDUCATIONAL MATERIALS

1. PAMPHLET In the Question and Answer format of the consumer pamphlet (See Attachment) in response to a question, "But does it mean that aspirin should not be given to children during an influenza epidemic..?", the answer is "The Surgeon General of the Public Health Service, Dr. C. Everett Koop, and the American Academy of Pediatrics advise caution when giving aspirin or other salicylate products for such illnesses..." The one-half million copies of this pamphlet which were to have been sent from the printer (printing cost \$18,000) to 4200 supermarkets are now stored in an FDA warehouse.

2. RADIO SPOT ANNOUNCEMENT A radio Public Service Announcement, to have been distributed to 5,000 radio stations was also cancelled on October 14, 1983. It read, in its entirety, "The U.S. Surgeon General has issued an advisory to parents: Don't give aspirin to children who have chicken pox, influenza, or other flu-like illnesses. Recent medical research points to a possible association between aspirin and the chance of children developing an illness called Reye Syndrome. Although rare, it can be fatal and calls for immediate emergency medical attention. Symptoms include vomiting, violent headaches and bizarre behavior. Doctor C. Everett Koop, the U.S. Surgeon General, recommends that parents call their physicians for advice. The American Academy of Pediatrics agrees. Most childhood illnesses, he says, are minor and go away quickly without medications. Therefore, says Dr. Koop, it is not only unwise to give your child aspirin during a viral illness, but probably unnecessary."

STATEMENTS OF HHS OFFICIALS AND ADVISORY GROUPS BEFORE
THE ASPIRIN INDUSTRY WON ITS BATTLE TO CANCEL WARNING LABELS
AND MOST OF THE PUBLIC EDUCATION CAMPAIGN

- Secretary, Department of Health and Human Services (Richard Schweiker):

"the use of salicylates such as aspirin in children with influenza and chicken pox and certain other viral infections has been sufficiently associated with Reye Syndrome to warrant warning physicians and parents." (June 4, 1982)

- The Surgeon General of the United States:

"Because the use of salicylates such as aspirin for children with influenza and chicken pox has been associated with Reye Syndrome, the Surgeon General advises against use of salicylates and salicylate-containing medication for children with these diseases. The association of salicylates with Reye Syndrome is based upon evidence from epidemiologic studies that are sufficiently strong to justify this warning to parents and health care personnel." Surgeon General's Advisory (June 11, 1982)

- Assistant Secretary for Health, Public Health Service:

"Collectively, the results of the studies on their face establish a strong association between salicylate ingestion and [Reye's Syndrome.] Until the basis for the association can be definitely established, we believe that the interest of the public health require physicians and the public be advised of the association and warned against the administration of salicylate-containing medication to children with flu or chicken pox." Statement by Edward N. Brandt, Jr., M.D., before the House Subcommittee on Natural Resources, Agriculture Research and Environment (September 29, 1982)

- Food and Drug Administration:

"FDA concluded . . . that there was a significant association of salicylate use with Reye Syndrome that could not be eliminated by debated analysis. The agency recommended to HHS that consumers be alerted to the findings by new labeling." FDA Talk Paper (November 16, 1982)

- Centers for Disease Control:

"CDC advises physicians and parents of the possible increased risk of Reye Syndrome associated with the use of salicylates for children with chicken pox or influenza-like illness." CDC Morbidity and Mortality Weekly Report (February 12, 1982)

In addition, both groups of independent scientific experts appointed by the government to study the matter have also concluded that the scientific evidence demonstrates that aspirin poses an increased risk of Reye's Syndrome for children with flu or chicken pox, and that the public should be warned about that risk.

- The Centers for Disease Control Reye's Syndrome Working Group:

"In review of the case-control studies of Reye's syndrome that have been separately conducted in Arizona, Ohio, and Michigan, we believe that there is strong epidemiologic evidence for an association between the occurrence of Reye's Syndrome and the prior ingestion of salicylate-containing medication It was the consensus of the working group that until the nature of the association between salicylate and Reye's Syndrome is clarified, the use of salicylates should be avoided, where possible, for children with [chicken pox] and during presumed influenza outbreaks." Final Report (November 12, 1981)

- FDA Reye's Syndrome Working Group:

The Secretary of HHS reported that "it was the consensus of the [working group] . . . that the new analysis supported the earlier evidence of salicylates and Reyes' Syndrome association and was sufficiently strong to warrant warning health professionals and parents." (June 4, 1982)

Q. Getting back to Reye syndrome, is it a new disease?

A. No, it is not new. As early as 1925 it was considered a form of meningitis, an "inflammation of the brain area." It was named Reye in 1963 for the Australian pathologist who more accurately described it as edema (swelling) of the brain, combined with liver malfunction and blood chemistry disorders, usually resulting in death. Also, it is not a disease but a "syndrome," meaning a combination of signs and symptoms.

Q. Has the cause of Reye syndrome been identified?

A. No. Research is being done by the Public Health Service and other organizations throughout the country, but the cause is not yet known. It is a complication of common viral illnesses that affects only a small minority of patients, but does not affect the hundreds of thousands more who contract these illnesses. Why these few children are susceptible, no one knows.

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ATTACHMENT

A Word of Caution About Treating Flu or Chicken Pox



Reye syndrome (pronounced "rye") is an acute condition that may follow influenza and chicken pox infections in children from infancy to their late teens. It is characterized by vomiting, violent headaches and unusual behavior in children who appear to be recovering from an often mild viral illness. It requires immediate diagnosis and admission to a hospital where emergency care can be provided. Reye syndrome is rare, but when it does occur it is considered life-threatening.

Q. What are signs that a child with influenza may be developing Reye syndrome?

A. The symptoms usually appear as the child should be recovering from the flu. Often the first sign is persistent vomiting. The child may be sleepy and lethargic, but still responsive. Within half a day, the child can become disoriented, combative and delirious. If untreated, the child can go into a coma and die.

Q. Can a Reye syndrome patient be treated at home?

A. No. Reye syndrome is a medical emergency. An ill child who shows signs of developing Reye syndrome must be taken immediately to a hospital. There the necessary medications can be given, blood and body fluids can be monitored and corrected, a respirator used if breathing is failing and, in rare cases, surgery performed to relieve pressure on the swollen brain.

Q. How long is the treatment period for Reye syndrome?

A. The usual hospital stay is three to ten days. The patient must be closely watched and will likely be in an intensive care unit. The patient is considered out of danger when blood chemistry, respiration and other signs have been stable for 48 hours. This could happen at any point during the hospital stay.

Q. What is the problem with giving aspirin to children who have influenza and chicken pox?

A. There seems to be an association between children under age 16 taking aspirin and their developing Reye syndrome. State health officials in Arizona, Ohio and Michigan have done studies of Reye syndrome cases that tend to show this.

Q. Does this mean that aspirin can cause Reye syndrome?

A. It means only that studies have shown that children given aspirin for influenza or chicken pox developed Reye syndrome more often than those not given the drug. Many medical experts agree that this apparent relationship cannot be ignored. In June 1982 the American Academy of Pediatrics Committee on Infectious Diseases alerted pediatricians to the possible association of aspirin administration and Reye syndrome.

Q. But does it mean that aspirin should not be given to children during an influenza epidemic to help them with headache, fever and other symptoms?

A. The Surgeon General of the Public Health Service, Dr. C. Everett Koop, and the American Academy of Pediatrics advise caution when giving aspirin or other salicylate products for such illnesses. Dr. Koop pointed out that childhood illnesses are usually minor and self-limiting, meaning that they will go away without treatment. In most cases, it is unwise to give aspirin to a child with a viral illness, and it is also unnecessary. Your doctor is the best person to decide when medication is needed.

Q. What are salicylates?

A. Salicylates are compounds, such as aspirin, used in medicines to lessen pain, reduce fever or cut down on inflammation. Products containing salicylates are also used in external analgesics, such as body rubs.

Q. Then should aspirin and other salicylates be avoided altogether for children?

A. Get your doctor's advice. There are times when they should be used. For example, aspirin is often the recommended medication for rheumatic fever and rheumatoid arthritis. It is also recommended for simple pain. But for influenza and similar viral illnesses, and chicken pox, leave the aspirin on the shelf until you check with your doctor.