Public Citizen

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GOVERNMENT UNDERCUTS EFFORTS TO WARN PARENTS ABOUT REYE'S SYNDROME WHILE HOLDING "NATIONAL REYE'S SYNDROME WEEK"

Monday, November 7, 1983, the first day of National Reye's Syndrome Week, marks the second anniversary of unnecessary deaths and injuries in children because of the government's failure to warn parents about the increased risk of Reye's Syndrome in children with chicken pox or flu who are treated with aspirin. Reye's Syndrome is a childhood illness which occurs after chicken pox or flu, and is characterized by severe vomiting, which can rapidly progress to convulsions, coma and death.

Two years ago, a government advisory group reviewed several studies and concluded that there was a "strong association" between the use of aspirin-containing products in children with chicken pox and flu and the development of Reye's Syndrome. They recommended that all aspirin-containing products be avoided in children with chicken pox and flu.[1]

But the government has refused to require manufacturers to place warning labels on all aspirin-containing products to give parents adequate information to protect their children. Thus, while the existence of National Reye's Syndrome Week suggests that the government is interested in increasing public awareness about the illness, the government has refused to use the most effective means of reaching the public.

Meanwhile, in the 20 month period following the advisory group's recommendation, an additional 328 cases including 99 deaths, have been reported to the government,[2] and many more

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1. Report of CDC Reye's Syndrome Working Group, October 13-14, 1981, enclosed in a letter from E. Russell Alexander, M.D., Chairman, Reye's Syndrome Working Group, to Walter Dowdle, Ph.D., Centers for Disease Control, November 12, 1981.

2. Personal communication with CDC official, October 12, 1983. These cases occurred in the period from December 1, 1981 until July 30, 1983. Of the 328 cases, there is a known outcome in 300 -- resulting in a mortality rate of 33%.

cases go unreported.[3] Many of these cases and deaths could have been prevented if parents had been warned to avoid giving aspirin to their children.

Public Citizen's Health Research Group continues to challenge this government inaction through a lawsuit in federal court, but a final decision has not been reached.

Over a year ago, the Department of Health and Human Services decided that warning labels were necessary to protect the health of our nation's children,[4] but it reversed its decision under intense pressure from the aspirin industry, and instead is relying on information brochures and public service announcements to educate parents. However, not only will these minor efforts fail to reach millions of parents who do not receive brochures or hear the public service announcements, but the educational materials fail to warn parents directly of the risk of aspirin and simply tell parents to "check with your doctor". With this move, the Reagan administration creates a double standard of care, since the advice will not help poor or rural families who do not have access to a family doctor each time their child becomes sick.

Yet even this meager effort by the government has aroused the ire of the aspirin manufacturers. Calling the information "very misleading and potentially harmful", the aspirin manufacturers have threatened to sue those who disseminate the educational materials.[5] Clearly, the aspirin manufacturers are more concerned about the "potentially harmful" effect of the message on profits than they are about the health of small children.

While most of the Reyes' Syndrome organizations (including the American Reye's Syndrome Association, a group partially funded by Glenbrook Labs, the makers of Bayer Aspirin for Children[6]) emphasize diagnosis and treatment of Reye's Syndrome, we believe that parents would prefer to <u>prevent</u> Reye's Syndrome so that their children are spared unnecessary pain, brain damage, and death.

Public Citizen Health Research Group therefore urges all parents to avoid using aspirin-containing products to treat children with chicken pox and flu. Most fevers (under 102) need no drug treatment. Alternative methods for reducing a fever include warm baths, wearing light clothing and drinking hot and cold liquids.

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3. Federal Register 47, 57886. DHHS: FDA. Labeling for Salicylate-Containing Products. Advance Notice of Proposed Rulemaking. December 28, 1982.

4. HHS News. June 4, 1982.

5. AP story. October 10, 1983.

6. RS: Because you love children, learn about Reye's Syndrome. American Reye's Syndrome Association brochure, 1982. [Pamphlet financed by Glenbrook Laboratories, makers of Bayer Aspirin for Children.]

WHY IS IT IMPORTANT THAT I KNOW ABOUT REYE'S SYNDROME?

Reye's Syndrome (RS) is usually fatal if not discovered and treated in the early stages of the disease. As a parent you are the first to see changes in your child which require medical attention. Since, on the surface, RS looks like many other diseases, your mention of Reye's to your doctor could help lead to an early diagnosis if it is present.

WHAT IS REYE'S?

RS is an acute disease which affects all organs of the body, especially the liver and the brain. It usually follows a viral infection such as the flu, chicken pox, or even a mild cold. It mainly strikes children under the age of 18, although it can strike at any age. RS is not a contagious disease but can appear in cluster groups and may occur more than once in the same child. Some children recover completely while others may suffer from mild to severe brain damage.

The cause of Reye's is unknown. A combination of factors may be involved. These may include the effects of viruses, genetic factors, environmental toxins such as pesticides, chemical wastes, aflatoxins, etc., and medications used to control vomiting and fever such as antiemetics, aspirin and acetaminophen. How and to what extent any of these factors may be involved is not yet fully understood. However, a warning has been issued not to give drugs to stop vomiting to children with viral illnesses and testing is being conducted to see if there is any connection between the use of fever reducers during viral illness and RS. Until the time when definitive test results are obtained, **all medications should be used with caution in children.** To fully understand RS and its etiology, more research is desperately needed.

WHAT ARE THE SYMPTOMS?

UNEXPECTED VOMITING
SLEEPINESS
PERSONALITY CHANGE
COMA

Vomiting, after the onset of a viral illness, is usually the first sign of RS except in **children under the age of two who may not vomit but may exhibit diarrhea and/or hyperventilation** (rapid, shallow breathing). Any time there is unexpected vomiting with a viral illness, a doctor should be notified. If it occurs with chicken pox, Reye's should be considered until proven otherwise. Typically the vomiting is recurrent and prolonged, however, in many cases, the vomiting has been limited to only a few times. Varying personality changes will be seen next, such as sleepiness, irritability, disorientation, hostility, etc. The child may have difficulty performing simple tasks. The temperature may be high, low, or normal and the pupils of the eyes may not dilate and contract properly. Typically, varying degrees of coma will follow--extreme sleepiness to inability to be wakened. Sometimes seizures may be seen. RS can progress quickly like a prairie fire in just a few hours, or it may take from 3 to 5 days from the onset of symptoms to coma and possible death.

WHAT SHOULD I DO IF I SUSPECT RS?

DO NOT PANIC
CALL A DOCTOR AT ONCE
TELL OF YOUR CONCERN ABOUT RS
ASK FOR A TEST FOR RS

Reye's strikes a small number of the millions of people who contract viral illnesses, so there is no need to panic. DO consider RS and call a doctor or go to an emergency room immediately if you see any of the symptoms. **Taking quick action is the most important thing you can do** to assure your child of the best chance of recovery, regardless of what may be wrong. Tell of your concern about Reye's Syndrome. Since many doctors are not familiar with RS, and the symptoms can be mistaken for meningitis, encephalitis, diabetes, poisoning, or, especially in older children and adults, drug overdose, it is important to remind them about Reye's. Ask for a blood test for RS. **It is impossible to rule out or confirm RS without proper blood tests (liver function).** If you are told the tests are not immediately available, it is your right to demand them or to request that your child be quickly transferred to a facility where the tests can be run. A children's hospital, large military hospital or a university hospital is usually best equipped to deal with RS patients. UNDER NO CIRCUMSTANCES SHOULD DRUGS TO STOP VOMITING BE GIVEN UNTIL RS HAS BEEN RULED OUT.

If you should run into any problems or have any questions, call our 24 hour number for assistance. (303) 777-2592.

HOW IS THE DIAGNOSIS CONFIRMED?

Suspicious symptoms along with an examination by a doctor and an abnormal liver function test without jaundice, makes the probable diagnosis of Reye's and treatment should be begun at once. Tests to rule out other conditions must also be run. These may include a spinal tap (the results will be normal if RS is present), blood sugar tests, sometimes a needle biopsy of the liver, and various other tests depending on the individual patient.

WHAT IS THE TREATMENT FOR RS?

Supportive treatment in an intensive care unit is vital for recovery since there is no known cure for RS. This consists of monitoring body fluids, administering drugs, relieving pressure on the brain tissue, aiding respiration when needed, and minimizing convulsions. The outcome of each case is related to the degree of brain swelling which occurs. That is why it is important to THINK REYE'S and to act quickly when suspicious symptoms are seen. **Time is the critical factor.**

WHAT CAN I DO TO PROTECT MY CHILD?

Learn the symptoms of RS and know the course of any illness your child gets. If there is a change from the normal pattern of the illness, a doctor should be notified. Do not hesitate to call a doctor if you see any Reye's like symptoms and be sure to mention your concern about RS.

Learn how to use medications correctly and only when indicated. Your child's doctor is usually the best judge. When dealing with a feverish child, most medical authorities advise that large quantities of liquids should be given and usually, unless a fever is over 102° and cannot be controlled by sponge bathing with tepid water, no medication is needed. If it is required to reduce fever, medication should only be used as needed to keep the fever in control.

ABOUT THE AMERICAN REYE'S SYNDROME ASSOCIATION

The ARSA is a non-profit, tax exempt organization made up of parents and interested medical and lay people whose goal is to find the cause, cure and preventive measures necessary to conquer Reye's Syndrome. The organization and education of the medical and lay communities are imperative to reach this goal. Education has lowered the mortality rate from around 60% four years ago, to around 30% today. With total awareness in the lay and medical communities, it is estimated that the mortality rate would decrease to 3%.

The ARSA depends solely on donations for funding. Your donation of time or money will help us to continue to alert the public to this devastating disease and fund research efforts. Please help. **The life of a child depends on it.**

TYPICAL PROGRESSION OF REYE'S SYNDROME

PREVIOUS ILLNESS

The majority of RS cases follow a viral disorder such as the flu, chicken pox, or even a cold. In some rare instances, RS seems to have started abruptly without a preceding disease.

RECOVERY PERIOD

There may be a brief period of recovery from the viral illnes when the child is not as sick as he was initially, but not completely well, either.

VOMITING

This may be the first sign of RS, except in children under the age of two, who may not vomit but may exhibit diarrhea and/or hyperventilation. Any time there is vomiting after the onset of a viral illness, a doctor should be notified.

BEHAVIOR CHANGE

The child may be extremely sleepy, easily annoyed if spoken to or touched, want to be left alone, and may be glassy eyed and/or sit staring into space. The pupils of the eyes may not contract and dilate properly. The child may become irritable, negative, disoriented, or hostile. He may develop twitching and jerking movements, use abusive language, moan, scream, kick, bite and demonstrate unusual strength. He may appear to be lost in time and space and be unable to carry out simple requests or answer simple questions.

COMA

In the earliest stages of coma, various behavior changes may be seen as those mentioned above. As coma progresses, the child may sleep all the time and show unusual postering (arms and legs extended, back arched). The ability to be aroused becomes increasingly difficult as coma deepens to the point where the child cannot be awakened and does not respond to pain. If the coma continues to progress without medical assistance, breathing will stop

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RS

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REYE'S SYNDROME

RS AMERICAN REYE'S SYNDROME ASSOCIATION