



National Headquarters

National Reyé's Syndrome Foundation, Inc. April 16, 2001
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*a disease that affects the liver and brain

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Docket No. 98N-0337
 Food and Drug Administration
 5630 Fishers Lane Room 1061
 Rockville, Maryland 20852

To Whom It May Concern:

I am writing to you on behalf of the National Reyé's Syndrome Foundation's Board of Directors. In 1999 when the Food and Drug Administration established standardized content and format requirements for the labeling of OTC human drug products, we commended your efforts. It is with grave concern that I write today regarding a labeling tactic that we feel is contrary to the health of the general public.

At our Annual Meeting in 1999, we had the privilege of having Debra Bowen, M.D., Deputy Director, Office of Drug Evaluation 5 of the Food and Drug Administration, as our guest speaker. Dr. Bowen discussed the labeling requirements and the need to aid the consumer in making an informed decision about the purchase and use of medications. Our understanding of the new label was that the warnings on products would take preference over the dosage directions so the purchaser would know the risk in taking a particular medication prior to its use.

In June 2000, it was brought to our attention that although the Bayer Corporation and other aspirin manufacturers did as required and placed the warning indicator for their products at the top of the back label on their over-the-counter medications, they placed the dosage directions on the FRONT of the label! The box containing the bottle of aspirin still lists the products warning after the indicators and dosage. Once again, giving priority to the use of their products over the health and well being of the consumers.

Prior to the warning label on salicylate containing products, many lives were lost to Reyé's Syndrome. Over the years the number of cases has diminished, but the disease has not been eradicated. We know that most laypersons and medical professionals do know not to

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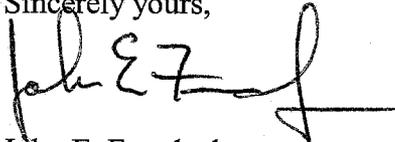
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give aspirin to children, but many do not remember why. There are fewer individuals who know that Reye's Syndrome also kills adults. Most of our adult cases result in death because it is assumed that they are beyond the age of Reye's. We are working diligently to educate the general public with our limited resources, but are daunted by the greater effect the drug industry has through their powerful use of advertisements.

While the aspirin manufacturers are promoting newfound uses for their product, we feel they have not acted prudently in alerting the general public to the possible dangers of their product as well. In the article, "FDA To Overhaul Drug Warnings," published by the Associated Press in December 2000, was a statement that acknowledged that, "too few doctors today even read vital drug warnings." If our doctors do not take the time to be informed, they will not forewarn their patients. The FDA most assuredly has the responsibility to act in the best interest of the consumer. The consumer must have this important information presented in the way it was intended in the original guidelines established by the FDA in 1999. The warnings for all dangers and side effects must be prioritized over and above the dosage so the consumer can make a wise and informed choice.

We ask that you reevaluate the labeling by the aspirin companies and all producers of over-the-counter medication to determine if the health and welfare of the general public is indeed being met. We do not want to witness an increase of Reye's Syndrome because of the narrow focus of pharmaceutical companies.

Sincerely yours,



John E. Freudenberger
President

Enclosure

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