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January 28, 2000

The Honorable Jane Henney, MD  
Commissioner, Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Henney:

As a pediatrician and former Chair of the National Academy of Sciences' Committee on Pesticides in the Diets of Infants and Children, I am writing to express my grave concern over the Food and Drug Administration's final regulation defining the types of statements that can be made concerning the effects of dietary supplements on the structure or function of the human body. I am particularly concerned by your decision in this regulation to classify various complications of pregnancy such as morning sickness and edema of pregnancy as "non-diseases," a decision that appears to have been made in order to exclude these conditions from the scope of regulation, but that runs counter to medical understanding and practice. This decision has the potential to put pregnant women and their offspring at serious risk of unwitting exposure to chemical teratogens in inadequately labeled health products and patent medicines.

A major finding of the NAS Committee on Pesticides in the Diets of Infants and Children that I chaired is that fetuses, infants, and children are fundamentally different from adults in their vulnerability to a wide range of xenobiotic compounds. We encapsulated this concept in the phrase "Children are not little adults." It was on the basis of our recognition of fetuses', infants', and children's unique patterns of exposure and unique susceptibility to chemical pesticides that we recommended that legislative and regulatory procedures for establishing standards, "tolerances," for pesticide residues in diet in the United States be fundamentally revamped so as to take cognizance of the special risks and vulnerabilities of children. This recommendation was accepted by the Congress and formed the basis for the Food Quality Protection Act of 1996.

The Presidential Executive Order of April 21, 1997, "Protecting Infants and Children from Environmental Health and Safety Hazards" extends further this recognition of the unique vulnerability of fetuses, infants, and children. It recognizes that children are at heightened vulnerability to a wide range of environmental hazards and chemical substances, and it requires all agencies of the federal government to take into account the unique vulnerabilities of infants and children in setting standards and issuing regulations.

The Food and Drug Administration's final rule on labeling directly contravenes the scientific findings of our NAS Committee, and it contravenes both the letter and the spirit

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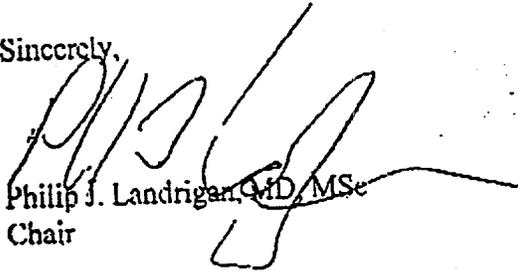
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of President Clinton's Executive Order. A fundamental shortcoming of this final regulation is that it fails to recognize the unique vulnerability of the fetus and infants to patent medications. Your final rule fails to recognize that if a pregnant woman ingests an inadequately labeled patent medicine that contains a fetotoxic chemical, then the result can be structural malformation or functional deficit in her developing child.

A phrase that I found especially unsettling in your final rule was the statement that medications intended for alleviation of "morning sickness associated with pregnancy" would require no warning on the label even if such a medication contained a potentially fetotoxic compound. To any pediatrician of my generation, this statement calls powerfully to mind the chilling story of the teratogen thalidomide that forty years ago was specifically recommended for the treatment of morning sickness. No warning was affixed to the label. The drug was prescribed widely in Europe. As a result, many thousands of babies were born with limb defects. Scientists at FDA, however, learned early of concerns expressed in Europe that thalidomide was teratogenic. Acting on fairly preliminary data, FDA banned the use of thalidomide in this country. As a result, thousands of babies were saved from deformity. FDA's decision to ban thalidomide was one of its finest hours.

I respectfully urge you to reconsider the content and the logic of your final rule.

Sincerely,



Philip J. Landrigan, MD, MSc  
Chair

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Public Citizen Health Research Group  
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