

ORAL STATEMENT OF: DOUGLAS C. ROSE

CONGRESS OF THE UNITED STATES -HOUSE OF  
REPRESENTATIVES

COMMITTEE ON GOVERNMENT REFORM

“10 Years after the Implementation of DSHEA: The Status  
of Dietary Supplements in the United States.”

March 24, 2004, at 10:00A.M.  
2154 Rayburn House Office Building

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## TESTIMONY OF DOUGLAS C. ROSE:

Mr. Chairman, Members of the Committee, thank you very much for the privilege and honor to address this committee today.

My name is Doug Rose. My wife, Michelle, joins me today. I am President of Irwin R. Rose & Co., Inc., an Indianapolis, Indiana based commercial real estate firm. We own and operate multi-family apartment communities, operating in five states. We have no financial interest in the dietary supplement industry. We do not receive any government grants or funding. We have an interest in supplements because they have been shown to prevent some of the most severe birth defects.

We are the proud parents of a daughter who was born with birth defects. Our youngest daughter, Emily, age 4, was diagnosed at birth with achondroplasia, a form of dwarfism, which is a birth defect caused by a genetic mutation. While medical science knows a great deal about her condition, it is not yet known how to prevent her condition. Fortunately, this is not the case, as it relates to two of the most common, and devastating birth defects... spina bifida, and anencephaly.

My family knows how the birth of a child with a permanent birth defect is a life altering experience that should not occur if it could be prevented. A family with a child, without birth defects, is a family helped. We are interested

in seeing our country declare war on birth defects, and conduct the research and implement prevention programs so that not a single baby anywhere develops any birth defects.

Since our daughter was born, we have learned that folic acid, a simple B vitamin that is in multivitamin supplement pills, has been proven in randomized controlled trials, to prevent two of the most common and severe birth defects—spina bifida and anencephaly. This has been known since 1991. In the mid 1970s, FDA regulations permitted multivitamins and servings of cold breakfast cereals to have 400 micrograms of folic acid in them. Americans who consumed these products had many fewer babies develop birth defects and they themselves have been reported to have less cancer and less cardiovascular disease.

The United States Public Health Service, including the Centers for Disease Control and Prevention and the Food and Drug Administration recommended in summer of 1992 that all women consume 400 micrograms of folic acid a day to reduce the risk of birth defects. In 1998, the Institute of Medicine clarified by recommending that all women capable of pregnancy consume 400 micrograms of synthetic folic acid a day. The FDA required, beginning on January 1, 1998, that synthetic folic acid be added to all “enriched” grain products at a rate that would add 100 micrograms to the average woman’s diet.

The folic acid fortification of enriched grains has been remarkably successful. It has raised blood folates and has

prevented about 1000 of the 4000 cases of spina bifida or anencephaly that develop each year in this country. Recently presented research from CDC suggests that the fortifications may have also prevented each year 50,000 fewer people from dying from heart attacks and strokes.

In spite of the progress, we still have more work to do. The current estimate is that if folic acid fortification were increased to the levels that CDC, the American Academy of Pediatrics, the March of Dimes recommended, then nearly two to three times as many birth defects could be prevented. The FDA has shown no indication that it will be requiring more folic acid to be put into enriched grain products. Thus, if we are to prevent all the folic acid birth defects that are preventable, we must find additional ways to get American women capable of becoming pregnant to consume at least the 400 micrograms of synthetic folic acid recommended by authoritative sources.

The FDA should raise the concentration of folic acid currently required in enriched grain products by 150%-- to the level that the CDC, the American Academy of Pediatrics, the March of Dimes, the Spina Bifida Association of America, the Teratology Society and other organizations have recommended. If we are to prevent all the folic acid-preventable birth defects that we can prevent, this change in the FDA regulation is a necessary complement to the proposed CDC program.

There are two current ways, and a third way in progress, that can increase the amount of folic acid women consume.

Vitamin supplement pills with 400 micrograms are widely available in the usual multivitamin and in the servings of a large number of breakfast cereals. Supplements with 400 micrograms of synthetic folic acid should be readily available to Americans as multivitamin or single vitamin supplements and in single servings of cold breakfast cereal. Access to these products in the last 40 years has prevented thousands of American families from having children with severe birth defects and is likely to have prevented tens of thousands of adults from dying of heart attacks, strokes and colon cancer.

Johnson and Johnson are working with FDA to bring oral contraceptive products to market that will include 400 micrograms of folic acid so that women will not need to take two pills. I hope that this product is on an expedited path as it could almost instantaneously result in 20 million American women consuming the recommended amount of folic acid. Perhaps the committee can help see that these products get to the market rapidly.

According to the March of Dimes supported Gallup poles, only 30% of American women of reproductive age consume enough folic acid. It is critical, of course, that vitamin supplements and breakfast cereals sold in this country continue to have 400 micrograms of folic acid in a pill or a serving. Given that it has been nearly 13 years since science proved that folic acid will prevent severe birth defects and given that only 30% of our young women are adequately protected from having a baby with these birth defects, there must be better programs implemented to

increase the proportion of young women consuming enough folic acid. The Centers for Disease Control and Prevention would be the agency to lead the campaign for the total prevention of folic acid-preventable birth defects. So far their appropriations have fallen far short of what is needed to get the job done. As I understand it, it would take about \$2.0 million a year, per state, to implement successful programs or a national program requiring \$100 million. Currently the CDC spends less than \$10.0 million on folic acid prevention programs. While I know this is not an appropriation hearing, I trust that you can encourage your colleagues on the appropriations committee to increase CDC's appropriations to this level, to build an effective program that will prevent all folic acid preventable birth defects. With the necessary resources, CDC, working with the supplement industry, can substantially increase the likelihood that that our babies will not develop preventable birth defects.

Mr. Chairman, thank you for the Committee's attention and interest. I would be happy to answer any questions.