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June 14, 2004

The Honorable Bart Stupak
U.S. House of Representatives
Washington, DC 20515

The Honorable Chris Smith
U.S. House of Representatives
Washington, DC 20515

Dear Representative Stupak:

Dear Representative Smith:

On behalf of more than 3 million volunteers and 1400 staff members of the March of Dimes, I want to thank you for introducing the "Isotretinoin Safety and Risk Management Act" to require a single, stringently monitored and restricted risk management program for the clinical use of isotretinoin. This legislation would mandate a risk management program designed to ensure that no pregnant woman takes isotretinoin, and no women taking isotretinoin get pregnant.

As you know, the March of Dimes is a national voluntary health agency whose mission is to improve the health of mothers, infants and children. More specifically, the Foundation works to prevent prematurity, birth defects and infant mortality through research, community services, education and advocacy. Isotretinoin is an oral medication approved for the treatment of recalcitrant nodular acne, an important but not a life-threatening disorder. This drug is widely used in women of reproductive age and is a known potent teratogen (an agent with a high risk of causing birth defects).

Despite current voluntary safety measures taken by the manufacturers, the Food and Drug Administration's (FDA) data show many pregnant women and their developing fetuses are continuing to be unnecessarily exposed to isotretinoin resulting in miscarriages and major birth defects. For several years the March of Dimes has urged the FDA to mandate a single, stringently monitored and restricted program for isotretinoin, such as the highly effective system applied to the use of thalidomide. The FDA has yet to act on this request.

Tighter controls on this potent teratogen are urgently needed. We thank you for your leadership and are eager to work with you to quickly achieve approval of this legislation.

Sincerely,

Dr. Jennifer L. Howse
President