Congress of the United States

Washington, DC 20515

September 6, 2001

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Thompson:

We are writing to inquire into the facts underlying the article "Texas Delays Diet Supplement Rules" published in today's *Los Angeles Times*. The article reported extensive evidence that officials in your Department intervened to delay enforcement of a Texas public health regulation regarding the labeling of dietary supplements containing ephedra.[1]

Section 229.462(f) of the Texas Administrative Code states that the labeling of all dietary supplement products containing ephedrine from natural ephedra alkaloids "must include a toll-free number to permit consumers to report adverse effects. This toll-free number shall be 1-800-332-1088, which is the Food and Drug Administration's (FDA) MedWatch medical product reporting program."[2] The effective date of this regulation is September 1, 2001. Texas is the first state to impose such a labeling requirement, which was prompted by several deaths in the state.[3] According to J.C. Chambers, chairman of the Texas Board of Health, this regulation was adopted because Texas state regulators believe that adverse event reports and other evidence create a sufficient basis for concern for public safety and that this regulation would make it easier for Texas consumers to contact FDA.

Such public health concerns are by no means unique to Texas. Use of ephedra supplements has been the basis of intense nationwide media attention[4] as well as of FDA's own

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[1] *Texas Delays Diet Supplement Rules,* Los Angeles Times (Sept. 6, 2001).

[2] Texas Administrative Code, Title 25 §229.262, Product Labels for Dietary Supplements Containing Ephedrine (2001).

[3] *Texas Delays Diet Supplement Rules,* Los Angeles Times (Sept. 6, 2001).

[4] See, e.g., *Risks of Ephedra Usage in Spotlight*, Los Angeles Times (Aug. 27, 2001); *Supplements Lure Athletes, Skirt FDA: Lax Regulation Puts Users at Risk, Critics Say*, Chicago Tribune, (Aug. 20, 2001); *Supplement Use Widespread: Banned Stimulant Ephedrine Questioned in Players' Deaths*, Detroit News, (Aug. 15, 2001); *FTC Says Six Firms Used False Online Ads; Medical, Diet Claims Targeted by Crackdown*, Washington Post (June 15, 2001).

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proposed regulations.[5] In August 1999, the General Accounting Office (GAO) concluded that FDA was justified in determining that the number of events related to dietary supplements containing ephedrine alkaloids warranted FDA's attention and consideration of steps to address safety.[6] Yesterday, Public Citizen, a consumer safety group, along with Dr. Raymond Woosley, Vice President of Health Services at the University of Arizona, submitted a petition to FDA to ban ephedra-containing supplements citing, among other evidence, data from the American Association of Poison Control Centers that show an significant increase in adverse events associated with ephedra in dietary supplements reported to Poison Control Centers over the last two years.[7]

According to the *Los Angeles Times*, Texas health officials instructed staff to delay enforcement of the Texas public health labeling regulation for at least 60 days.[8] The article stated that the decision to delay enforcement of this regulation came after a member of your staff contacted Don Gilbert, the Commissioner of Health and Human Services of Texas.[9] The article also referenced e-mails which cited the Department's advice to delay the implementation date and enforcement of the rules for 60 days.

We ask that you confirm whether the Department has sought a delay in the enforcement of the Texas regulation, and if so, specify who did so, in what capacity, and when, as well as the scientific, medical, or legal basis for this unusual action. We would also like to know who in HHS spoke to representatives of the Texas Department of Health regarding the proposed labeling regulation as well as the date and substance of those contacts. We request copies of all documents, including e-mails, notes, and phone records regarding these actions.

Important public health and consumer protections should not be delayed. Nor should appropriate state activities to regulate public health be delayed or interfered with for inappropriate reasons.

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[5] 62 Fed. Reg. 107, *Dietary Supplements Containing Ephedrine Alkaloids* (proposed June 4, 1997).

[6] General Accounting Office, GAO/HEHS/GGD-99-90 (July 1999).

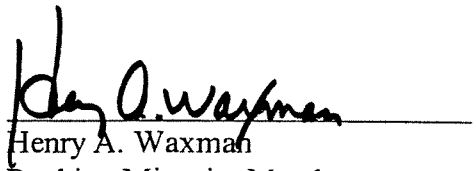
[7] *Petition Urges U.S. to Ban Supplements With Ephedra*, New York Times (Sept. 6, 2001).

[8] *Texas Delays Diet Supplement Rules,* Los Angeles Times (Sept. 6, 2001).

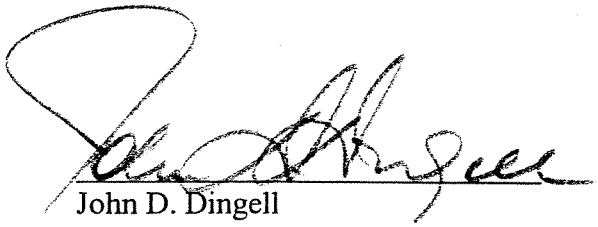
[9] *Texas Delays Diet Supplement Rules*, Los Angeles Times (Sept. 6, 2001).

We appreciate your attention to this matter and look forward to your response. Please respond to this letter by September 20, 2001, and contact Sarah Despres at (202) 225-5420 or Chris Knauer at (202) 226-3400 if you have any questions regarding this matter.

Sincerely,



Henry A. Waxman
Ranking Minority Member
Committee on Government Reform



John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce

cc: The Honorable Dan Burton, Chairman
Committee on Government Reform

The Honorable W.J. "Billy" Tauzin, Chairman
Committee on Energy and Commerce