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May 19, 2003

The Honorable Mark McClellan, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857-0001

RE: Docket Number 95N-0304
Dietary Supplements Containing Ephedrine Alkaloids

Dear Dr. McClellan:

I am writing today in response to the Food and Drug Administration's (FDA) request for comment on Docket Number 95N-034: *Dietary Supplements Containing Ephedrine Alkaloids*.

I firmly believe that complementary medicine, including dietary supplements, have an important role to play in our health care system, and that Americans have the right to make their own informed health care choices. As Chairman of the House Committee on Government Reform from 1997 to 2002, and now as Chairman of the Subcommittee on Human Rights and Wellness, I have made health care oversight one of my highest priorities. In particular, the Committee has been active in monitoring the FDA's implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA), and to-date, I believe the American public has not been well served by the FDA.

While Chairman of the Committee on Government Reform, I initiated an investigation of the FDA's implementation DSHEA. From this investigation, it became apparent that the FDA's failure to fully and properly implement the provisions of DSHEA stems in large part from a bias within the agency against herbal dietary supplements. I am concerned that this institutional bias could unduly influence the FDA's investigation into safety concerns of dietary supplements containing ephedrine alkaloids.

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Congress enacted DSHEA to ensure that consumers were able to make informed choices about their own preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements. The Act grants FDA the authority to scientifically determine whether a dietary supplement presents a "significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling," and to take action to protect the American consumer if such a risk is identified. While a number of scientific clinical studies have been conducted on the effectiveness of ephedra-based dietary supplements for weight control, few if any clinical studies have been conducted strictly on the safety of ephedra-based dietary supplements. Yet, it seems from reading Docket Number 95N-0304 that the FDA is already pre-disposed to classifying ephedra as a significant and unreasonable risk in the absence of those clinical studies.

As in 1997, when regulations on ephedra-based supplements were first proposed, FDA is currently relying heavily on case studies of Adverse Event Reports (AER) as the primary justification for action, the principle study being the recently concluded review by the RAND Corporation. I applaud FDA and the Department of Health and Human Services for commissioning the RAND Corporation to undertake this review. But even this review concluded that more analyses of existing data is unlikely to settle the safety issue, that new data is needed and that "the strongest evidence for causality should come from clinical trials."

An aggregate of the limited clinical trials available on ephedra-based dietary supplements that examined the efficacy of the supplement for weight loss indicates an Adverse Event Rate of approximately 1 in 1,000. According to a recent study published in the *Journal of the American Medical Association* (JAMA), the incidence of autism in this country is now approximately 1 in 150 children. Yet the FDA does not have the same zeal to eliminate the known toxin mercury from vaccines and dental amalgams that is a biologically-plausible cause of autism as it does to eliminate from consumers the choice to use the dietary supplement ephedra.

Even if we leave off the need for clinical trials and simply focus on a review of the case studies, the evidence isn't conclusive. In 1999, FDA estimated that 12 million Americans used ephedra or ephedrine-based products. The RAND study screened nearly 18,000 case reports, and identified 284 serious or major adverse events as well as 2 deaths. In comparison, according to data published by the American Association of Poison Control Centers ("AAPCC") in 2000, they received 16,649 reports on Aspirin, of which 297 were major adverse events and 52 were deaths. For Acetaminophen they received 56,731 reports, of which 856 were major events and 99 were deaths. Ibuprofen logged 57,876 reports of which 225 were major events and 5 were deaths.

Mr. Commissioner, the United States is undergoing a crisis of obesity threatening the long-term health of millions of Americans. Obesity has been clearly and scientifically linked to the Nation's number one killer – heart disease – as well as diabetes and other chronic conditions. A recent study released by the DHHS in the last week shows that the cost of treating health problems associated with overweight people is costing $93 Billion a year, with about half that cost being paid through Medicare and Medicaid. The clinical studies that are available on ephedra-based dietary supplements, and the RAND study supports these conclusions, find that ephedra-based dietary supplements can promote modest short-term weight loss of about two pounds more per month than placebo. Even such a small weight loss can have a beneficial health effect. On July 25, 2002, the House Committee on Government Reform conducted a hearing on "Diet, Physical Activity, Dietary Supplements, Lifestyle and Health." During that hearing, the Committee heard from a number of experts on weight loss and obesity. One internationally recognized expert, George A. Bray, MD, emphasized that small weight loss, even over a short period of time, can be highly beneficial to health. He testified:

> "Small weight losses can be highly beneficial in reducing the risk for the diseases I described earlier. In a study of which we are a part that is funded by the National Institutes of Health, called "The Diabetes Prevention Program," weight losses of 3 to 7 percent reduced by 58 percent and 31 percent the risk of people who are at high risk for diabetes from actually becoming diabetic. If you translate that into a 3-year delay in the complications of this disease, it saves billions of dollars by reducing the risk for human dialysis, for renal failure, for amputations, for blindness and other complications associated with diabetes. So modest weight losses can be highly beneficial. The dietary supplements that are available, particularly the ephedra-caffeine combinations, have clear evidence from clinical trials of up to 6 months suggesting that the weight loss in the treating group is substantially larger than placebo and in the range that would be associated with these reductions in risk that were demonstrated in diabetes prevention programs."

In short, ephedra, when appropriately used, can be a valuable tool in the battle against obesity and the added health problems associated with diabetes.

The key of course is to make sure that these supplements are used appropriately. That is why I support a strong warning label, such as the one outlined in Docket Number 95N-0304. I also urge the FDA and DHHS to consider a ban on sales of ephedra-based supplements to minors and a ban on marketing of the supplements for athletic enhancement, a claim not supported by the science. In addition, I believe that FDA and HHS should actively engage in a well-designed public information campaign to educate

consumers on the importance of reading and following label instructions and warnings, not just for ephedra-containing products or dietary supplements, but for all over-the-counter products and prescription drugs as well. Finally, I urge the FDA to support clinical trials that will examine scientifically the safety of ephedra when properly used. In the absence of such information, the FDA should be cautious about implementing any regulation that purports a definitive causal relationship between consumption of ephedra and adverse events.

Adoption of healthy lifestyle choices, including moderate physical activity, a sensible diet and the *appropriate* use of dietary supplements, can improve one's health. The American people deserve to have as wide a range of choices as possible, including the choice of using dietary supplements for their health care needs.

Sincerely,

Dan Burton
Chairman
Subcommittee on Human Rights and Wellness

cc: Sec Thompson