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The Honorable Mark B. McClellan, Commissioner
Food and Drug Administration
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 1996N-0417
Good Manufacturing Practices for Dietary Supplements

Dear Commissioner McClellan:

I wish to comment on proposed regulations establishing Good Manufacturing Practices (GMPs) for dietary supplements. These are very important to me because of the size of the dietary supplement industry in Utah. Any proposed regulations must take into account the realities of dietary supplement production, and in that connection, the expertise of Utah industry representatives is important.

The Utah Natural Products Alliance has submitted comments on the proposed regulation, and in general I wish to associate myself with those comments. They provide extensive information that the Agency can use in evaluating and modifying its proposals. In addition to those comments, I would like to address a couple of points as a Member of Congress.

The first is the legal basis for the regulations. While I was not a member of Congress in 1994, when the Dietary Supplement Health and Education Act was originally passed, I have since examined it carefully, particularly in light of my membership on the Government Reform and Oversight Committee, and as current Vice Chair of the Wellness and Human Rights Subcommittee on which I serve because of its importance to my congressional district. I am also aware of proposals for much stricter regulation of dietary supplements, and the view that the proposed regulations are a first step toward the eventual regulation of supplements as prescription drugs.

The Agency, of course, has jurisdiction over both food and drugs. It is important to keep that distinction in mind, and to avoid applying the stricter regulation entailed in drug marketing to products that are not drugs. The application of protocols appropriate to

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drugs is not appropriate for such products as dietary supplements. Despite the attention paid to the effects of a few supplements, the safety record of natural supplementary products is exemplary, and the Agency should avoid overreaction.

At some point Congress may change its instructions to the FDA with respect to food additives, and I am sure you are aware that legislation has been introduced to do that. Until that legislation is acted on, the Agency should avoid using expansive definitions of such words as "model" to bootstrap itself into new realms of administrative and regulatory authority.

The second point I would like to make is with the lack of economic analysis provided to the public along with the proposed regulations.

To put it mildly, the economic effect of the regulations suggested in the proposals is orders of magnitude out of line with reality. UNPA has provided the Agency with several case studies refuting the assumptions that are the basis of the Agency's analysis. I strongly urge you to accept the expertise of the industry in re-evaluating the economic assumptions.

More importantly, and in my capacity as an overseer of the regulatory process, I am concerned that the proposals were rushed into print and a comment period established without the publication of some of the core economic analysis that undergirds them.

How did this happen? How common is such a divorce of proposals from the economic analysis that informs them at the FDA? I would appreciate answers to these questions and at your earliest convenience. These questions are outside the regulatory comment process.

I understand that an additional 29 days have been allocated for comments on the economic data from the Agency, at such time as those become available, and I reserve the right to comment additionally on them during that period. It is possible that the economic analysis will give rise to additional comments on other areas of the proposals, and I strongly urge the Agency to accept whatever comments it receives during that extension period.

Finally, I would like to comment on the use of the regulatory process as an anti-competitive tool.

It is no secret that industries and companies regulated by the Food and Drug Administration have very different attitudes about the legitimacy of competition from other companies and sectors of the industry. In developing regulations, it is important that the Agency not allow rent seekers from one side or another to use the power of the Agency to raise barriers to entry or expansion against new products, companies, and processes. The danger to the Agency of assuming the desirability of the status quo is high. Companies now in dominance will urge its maintenance. The Agency should use special care to avoid limiting the introduction, marketing, use and expansion of new

products and services. Obviously, public safety is critical, but you and your fellow commissioners are dealing with a vibrant, dynamic industry, one that constantly challenges accepted ways of doing business and accepted ideas about obtaining and maintaining health. This has proven enormously beneficial to a generation of Americans who are healthier and fitter than any in the past.

The citizens of the United States owe an enormous debt to the medical and pharmaceutical professions. At the same time, those professions are subject to the same incentives as other actors in our economy, and the Agency has to insist that the marketplace be open to competing theories and practices. In the final analysis, the consumer is the supreme regulator, and the Agency must be careful not to restrict the consumer's access and choices for any reasons short of compelling issues of safety.

I look forward to your response to my questions, and to an opportunity to examine the economic data that will be forthcoming shortly.

Sincerely,

Chris Cannon
Member of Congress