NATIONAL HEALTH FREEDOM ACTION

OPPOSE S1082/H1561 Subtitle B: The Reagan-Udall Foundation

Unless Amended to Protect Dietary Supplements

National Health Freedom Action is sending you this alert to encourage you to help preserve the foundation of the Dietary Supplement Health and Education Act of 1994 (DSHEA) and write to your Congressman from our website and let them know that you oppose S1082/H.R.1561 unless it is amended. Click here to write to your Congressman directly: http://www.democracyinaction.org/dia/organizationsORG/NHFA/campaign.jsp?campaign_KEY=11757&t=NewNHFAtemplate.dwt

S1082/H.R. 1561 sets up a non-profit corporation called the Reagan-Udall Foundation that would give the FDA a new and expanded role to be part of a Foundation with the purpose of implementing goals of the FDA in the area of new drug development. This means that the same organization that will be developing drug evaluation technology is also enmeshed in the agency that regulates the drug approval process, thus creating a situation that could potentially reduce the safety of the drugs and products made available to the public.

In addition to being focused on drug assessment technology development, the Senate added language to the bill which included food safety. The addition of amendments that include food safety, and the language of the original bill that included food and dietary supplements in the purpose of the Reagan Udall non-profit, are completely unacceptable to freedom advocates because it could mean down the road that foods, dietary ingredients and dietary supplements would be at risk for being treated like drugs when evaluated by the FDA with their new drug tools.

Foods and dietary supplements in the U.S. are not currently regulated as drugs, but are regulated as foods under DSHEA. Notably because of this, they are evaluated differently. Foods and dietary supplements are considered food nutrients generally regarded as safe and the evaluation of their safety is based on whether they cause a significant risk of harm as opposed to being evaluated under the toxic drug risk/benefit assessment. Risk/benefit analysis is reserved for toxic substances and the FDA approves drugs for market if the benefit justifies the risk. These foundational differences of drug and food safety assessments have recently been challenged in the Ephedra cases and because the Supreme Court has denied hearing the Ephedra case May 2007, there is a real possibility that drug assessments might be applied to foods in the future.

With a drug, a consumer has to choose whether they want to be harmed by the substance, in trade for getting a measured benefit. And the drug companies have to disclose side effects. But that is not the nature of food. Food is not generally toxic. Benefit of food should always be the consumer's opinion and the government should only block food from the market if they have shown harm. Because of the assumption that food is safe we have a wide variety of foods and supplements in the marketplace. If foods and dietary supplements were ever to be evaluated as drugs with technology developed for drugs and a risk/benefit analysis, it would no longer be up to the consumer to decide whether a food or dietary supplement were risky or beneficial to them. The FDA would be deciding that before they would be allowing them on the market. We then run the risk of natural products being incorrectly assessed as harmful because of a drug analysis

being applied to them and losing access to many wonderful foods and nutrients that we currently use.

Foods and dietary supplements should continue to be treated as food (DSHEA) and evaluated under food standards and technology instead of with toxic drug risk/benefit assessment tools. To accomplish this, an amendment must be added to the current bill S1082/H.R.1561. The following amendments are being recommended and drafted by the law firm of Emord and Associates in Washington DC:

> ***Proposed amendment to S 1082 and HR 1561:***
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> ***"The bills are hereby amended to prohibit the Foundation or Institute from evaluating the health benefit or efficacy of foods, dietary ingredients, and dietary supplements and to limit review of foods, dietary ingredients and dietary supplements to a determination of whether they are safe. In assessing whether dietary ingredients and dietary supplements are safe, the Foundation or Institute shall not compare product risks with health benefits or efficacy. Instead, the Foundation or Institute shall determine whether the product presents a significant risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are recommended or suggested in labeling, under ordinary conditions of use."***

This bill passed the Senate May 2007 and is now in the House. We need as many people as possible to email, write or call your legislators to demand that the above amendment be added.

Click here to write to your Congressman directly:
http://www.democracyinaction.org/dia/organizationsORG/NHFA/campaign.jsp?campaign_KEY=11757&t=NewNHFAtemplate.dwt

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