

March 20, 2001

## Congressman Paul's Statement on Dietary Supplement Regulation and Research

Joint Statement from Congressman Ron Paul and Peter DeFazio (D-OR) submitted to the House Committee on Government Reform: "Six Years After the Enactment of DSHEA: The Status of National and International Dietary Supplement Regulation and Research" Mr. Chairman, we appreciate the opportunity to submit comments regarding the need to protect consumers from intrusive regulations which interfere with the availability of dietary supplements. Today's hearing is just the latest example of the leadership you have shown on this important issue. Over the past decade the American people have made it clear that they do not want the federal government to interfere with their access to dietary supplements. In 1994, Congress responded to the American people's desire for greater access to the truth about the benefits of dietary supplements by passing the Dietary Supplements and Health and Education Act of 1994 (DSHEA), which liberalized the rules regarding the regulation of dietary supplements. Congressional offices received a record number of comments in favor of DSHEA. Despite DSHEA, officials of the Food and Drug Administration (FDA) continued to attempt to enforce regulations aimed at keeping the American public in the dark about the benefits of dietary supplements. However, in the case of *Pearson v. Shalala*, 154 F.3d 650 (DC Cir. 1999), reh'g denied en banc, 172 F.3d 72 (DC Cir. 1999), the United States Court of Appeals for the DC Circuit Court reaffirmed consumers' first amendment right to learn about how using dietary supplements can improve their health without unnecessary interference from the FDA. The FDA has been forced to revise its regulations in order to comply with *Pearson*. However, members of Congress have had to intervene with the FDA on several occasions to ensure that they followed the court's order. Clearly Congress must continue to monitor the FDA's action in this area. The freedom of consumers to use, or even obtain truthful information about, dietary supplements

could also be threatened by the United States participation in the Codex Alimentarius Commission (Codex). Codex is a part of the Food and Agriculture Organization of the United Nations and the World Health Organization Food Standard Program operating under the authority of the Sanitary Phytosanitary Agreement and the Technical Barriers to Trade Agreement. Codex is the vehicle through which the World Trade Organization (WTO) is working to "harmonize" (e.g. conform) food and safety regulations of WTO member countries. Codex is currently creating a guideline on the proper regulations for dietary supplements with the participation of the Food and Drug Administration (FDA). We are concerned that the end result of this process will force the United States to adopt the same strict regulations of dietary supplements common in European countries such as Germany, where consumers' cannot even examine a bottle of dietary supplements without a pharmacist's permission. By participating in this process, the FDA is ignoring the will of Congress as expressed in DSHEA and in the FDA Modernization Act of 1997, which expressly forbid the FDA from participating in the harmonization process, as well as the will of the American people. While Codex has no direct authority to force Americans to adopt stringent regulations of dietary supplements, we are concerned that the United States may be forced to adopt Codex standards as a result of the United States' status as a member of the WTO. According to an August 1999 report of the Congressional Research Service, "As a member of the WTO, the United States does commit to act in accordance with the rules of the multilateral body. It [the US] is legally obligated to ensure national laws do not conflict with WTO rules." Thus, Congress may have a legal obligation to again change American laws and regulations to conform with WTO rules! If Congress were to refuse to "harmonize" US laws according to strict Codex/WTO guidelines, a WTO "dispute resolution panel" could find that the United States is engaging in unfair trade because of our failure to "harmonize" our regulations with the rest of the world. In any such trade dispute, the scales are tipped in favor of countries using the Codex standards because of WTO rules presuming that a nation who has adopted Codex has not erected an unfair trade barrier. Therefore, in a dispute with a country that has adopted the Codex standards it is highly probable that America would lose and be subject to heavy sanctions unless Congress harmonized our laws with the other WTO countries. Harmonization may be beneficial for the large corporations and international bureaucrats that control the WTO but it would be a disaster for American consumers of dietary supplements! In conclusion, we once again thank Chairman Burton for holding this hearing and for all his efforts to protect the freedom of American dietary supplement customers and for the opportunity to express our concerns regarding the threat to American consumers posed by the WTO and the Codex Alimentarius process. We also express our hope that Congress will act to protect the freedom of American consumers from overregulation of dietary supplements whether imposed by the FDA or through the back door by an international organization such as the WTO.