

HON. RON PAUL OF TEXAS BEFORE THE US HOUSE OF REPRESENTATIVES March 22, 2004

Don't Let the FDA Block Access to Needed Health Care Information

Mr. Speaker, I rise to introduce the Health Information Independence Act. This Act restores the right of consumers to purchase the dietary supplements of their choice and receive accurate information about the health benefits of foods and dietary supplements. The Act restricts the Food and Drug Administration's power to impede consumers access to truthful claims regarding the benefits of foods and dietary supplements to those cases where the FDA has evidence that a product poses a threat to safety and well-being, or that a product does not have a disclaimer informing consumers that the claims are not FDA-approved.

Claims that could threaten public safety, or that are marketed without a disclaimer, would have to be reviewed by an independent review board, comprised of independent scientific experts randomly chosen by the FDA. Anyone who is (or has been) on the FDA's payroll is disqualified from serving on the board. The FDA is forbidden from exercising any influence over the review board. If the board recommends approval of a health claim, then the FDA must approve the claim.

The board also must consider whether any claims can be rendered non-misleading by adopting a disclaimer before rejecting a claim out of hand. For example, if the board finds the scientific evidence does not conclusively support a claim, but the claim could be rendered non-misleading if accompanied with a disclaimer, then the board must approve the claim- provided it is always accompanied by an appropriate disclaimer. The disclaimer would be a simple statement to the effect that "scientific studies on these claims are inconclusive" and/or "these claims are not approved by the FDA." Thus, the bill tilts the balance of federal law in favor of allowing consumers access to information regarding the health benefits of foods and dietary supplements, which is proper in a free society.

The procedures established by the Health Information Independence Act are a fair and balanced way to ensure consumers have access to truthful information about dietary supplements. Over the past decade, the American people have made it clear they do not want the federal government to interfere with their access to dietary supplements, yet the FDA

continues to engage in heavy-handed attempts to restrict such access.

In 1994, Congress responded to the American people's desire for greater access to information about the benefits of dietary supplements by passing the Dietary Supplements and Health and Education Act of 1994 (DSHEA), liberalizing rules regarding the regulation of dietary supplements. Congressional offices received a record number of comments in favor of DSHEA.

Despite DSHEA, FDA officials continued to attempt to enforce regulations aimed at keeping the American public in the dark about the benefits of dietary supplements. Finally, in the case of *Pearson v. Shalala*, the United States Court of Appeals for the DC Circuit Court reaffirmed consumers' First Amendment right to learn about dietary supplements without unnecessary interference from the FDA. The *Pearson* decision anticipated my legislation by suggesting the FDA adopt disclaimers in order to render some health claims non-misleading.

In the years since the *Pearson* decision, members of Congress have had to continually intervene with the FDA to ensure it followed the court order. The FDA continues to deny consumers access to truthful health information. Clearly, the FDA is determined to continue to (as the *Pearson* court pointed out) act as though liberalizing regulations regarding health claims is the equivalent of "asking consumers to buy something while hypnotized and therefore they are bound to be misled."

The FDA's "grocery store censorship" not only violates consumers' First Amendment rights- by preventing consumers from learning about the benefits of foods and dietary supplements, the FDA's policies are preventing consumers from taking easy steps to improve their own health!

If Congress is serious about respecting First Amendment rights, and the people's right to improve their own health, we must remove the FDA's authority to censor non-misleading health claims, and claims that can be rendered non-misleading by the simple device of adopting a disclaimer.

In conclusion, I urge my colleagues to help establish an objective process that respects consumers' First Amendment rights to non-misleading information regarding the health benefits of foods and dietary supplements by cosponsoring the Health Information Independence Act.

