

If FDA is 'Broken,' Why is Congress Focused on Adding Tobacco Regulation to the Agency Rather Than Ensuring the Safety of Food, Drug and Medical Devices in the United States?

WINSTON-SALEM, N.C. – March 26, 2008 – Congress has criticized the Food and Drug Administration (FDA) in the past year for not ensuring the safety of the nation's food, prescription drug and medical device supplies. Senior members of Congress have stated at various times, "The health and safety of the American people is at risk ... our food supply becomes more dangerous all the time ... there is a fundamental breakdown for evaluating the safety of drugs ... the FDA is badly broken." These sentiments are reflected in numerous national media stories describing a variety of FDA warnings on and recalls of food and drugs.

In addition to elected officials, a scientific advisory panel recently reported that "American lives are at risk" due to the inability of FDA to oversee the safety of the food, drug and medical device supplies in the United States.

Despite the recognition of the need to address these issues, Congress is focused on legislation to expand FDA's responsibilities to include tobacco products with a new regulatory bureaucracy funded by more than \$7 billion in new fees and taxes. The House Committee on Energy and Commerce is expected to consider the legislation within the next several weeks.

"This raises the question of congressional priorities: should they be working to ensure the safety of food, prescription drugs and medical devices, or considering additional regulations on tobacco products, paid for by billions in new taxes and fees?" said Tommy J. Payne, executive vice president of public affairs for Reynolds American Inc.

"The FDA commissioner raised serious concerns with this legislation in testimony submitted to Congress last fall. The commissioner expressed concern that the bill may require the agency to divert funds from other programs like the safety of drugs and food; that it could undermine the public-health role of FDA; that the public might believe that products 'approved' by FDA are safe and that this will actually encourage individuals to smoke more rather than less; and finally, that the bill requires the agency to perform functions that are outside of its expertise," Payne said.

Payne also questioned the wisdom of adding \$7.6 billion in new taxes and fees to support a huge new bureaucracy in Washington at this time. "A majority of people want Congress to address the core safety issues FDA is already

responsible for, as well as a range of other issues important to many Americans, like the economy.”

Payne noted, “The FDA currently spends about \$1.68 per year per consumer on food safety. This bill, if signed into law, would have them spending \$10 per year per consumer on regulating tobacco products.”

In television ads that began running this week, Reynolds American questions the ability of FDA to implement a vast new regulatory scheme, given its current responsibilities.

“It is possible to create reasonable tobacco regulation that reduces the harm caused by tobacco products, provides accurate information to adult tobacco consumers, encourages development of new generation tobacco products and allows for legitimate competition,” Payne said. “Unfortunately, the bill being considered in Congress does not accomplish these goals.”

Editor’s Note: To see the ads Reynolds American is currently running, please go to www.FDAConcerns.org.

ABOUT US

Reynolds American Inc. (NYSE: RAI) is the parent company of R.J. Reynolds Tobacco Company; Conwood Company, LLC; Santa Fe Natural Tobacco Company, Inc; and R.J. Reynolds Global Products, Inc.

- R.J. Reynolds Tobacco Company, the second-largest U.S. tobacco company, manufactures about one of every three cigarettes sold in the country. The company’s brands include five of the 10 best-selling U.S. brands: Camel, Kool, Pall Mall, Winston and Doral.
- Conwood Company, LLC is the nation’s second-largest manufacturer of smokeless tobacco products. Its leading brands are Kodiak, Grizzly and Levi Garrett. Conwood also sells and distributes a variety of tobacco products manufactured by Lane, Limited, including Winchester and Captain Black little cigars, and Bugler roll-your-own tobacco.
- Santa Fe Natural Tobacco Company, Inc. manufactures Natural American Spirit cigarettes and other additive-free tobacco products.
- R.J. Reynolds Global Products, Inc. manufactures, sells and/or distributes American-blend cigarettes, including Natural American Spirit, and other tobacco products to a variety of customers worldwide.

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