Encourage the FDA to Keep the Existing Warning Labels for Smokeless Tobacco

R.J. Reynolds Tobacco Company (RJR) is currently pushing the U.S. Food and Drug Administration (FDA) to change the warning labels for smokeless tobacco products. On July 28, 2011, RJR filed a Citizen Petition asking the FDA to issue a new regulation altering the text of the required smokeless tobacco product warning statement. For further information about Citizen Petitions, see our publication Citizen Petitions: An Underutilized Tool in Tobacco Regulation.

To date, few public health professionals or advocates have submitted comments informing or opposing the RJR Citizen Petition. Because revising the warning labels on smokeless tobacco would be harmful to public health, we urge the public health community to submit comments to the FDA on this important topic.

The current warning label for smokeless tobacco products reads: "WARNING: This product is not a safe alternative to cigarettes." RJR is petitioning FDA to change the warning to: "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes."

This change to the warning label would allow the tobacco companies to promote non-cigarette tobacco products as less harmful than cigarettes in an attempt to persuade cigarette smokers to use smokeless tobacco products rather than to quit using tobacco products completely. For many years the tobacco companies attempted to manipulate scientific data and mislead the public about the dangers of smoking. Now they are using the same tactics to obscure the dangers of using smokeless tobacco products. If the FDA were to grant RJR's request, the tobacco industry would be permitted to market smokeless tobacco products as being less dangerous to consumers. Currently, the Family Smoking Prevention and Tobacco Control Act provides a procedure for the approval of Modified Risk Tobacco Products (MRTPs). Granting this petition would allow RJR to circumvent that procedure and market smokeless tobacco products as MRTPs without proving that they actually reduce the risk of harm to users.

A large portion of RJR's petition focuses on the relative risk of cigarettes and smokeless tobacco products. In particular, the petition highlights epidemiological studies of the mortality rates and rates of various tobacco-caused diseases. However, it appears that much of the scientific data included in the petition was either commissioned by the tobacco companies, is taken out of context, or is explained in a way that is misleading. It is critical that the FDA have accurate and

complete information to review RJR's request. To ensure that that the FDA makes an informed decision to protect public health, we encourage public health advocates and professionals to submit a comment to the FDA on the RJR petition. Comments could include one or more of the following points or evidence:

1. RJR's proposed change to the warning label will harm public health and is not supported by existing scientific research.
2. The studies presented in the RJR petition are biased and/or misleading or presented in a deceptive manner.
3. Present data on the relative risks of cigarettes and smokeless tobacco products. This data does not need to be peer reviewed. The FDA can use preliminary data to inform its rulemaking process.
4. Present data on the harm caused by smokeless tobacco products.
5. Present data on dual-use and poly-use of tobacco products.
6. Present information on why the current warning label is not misleading and is effective to educate the public on the risks associated with smokeless tobacco.
7. Present information on the potential harms that could be caused by accepting the changes to the warning label as suggested by RJR.
8. RJR contends that there is a consensus in the public health community that smokeless tobacco products present a significantly reduced risk of disease than cigarettes –explain to the FDA that there is not a consensus and that doubt still exists about the claims made regarding harm reduction.
9. Explain to the FDA that such a drastic change to something as fundamental as a warning label needs to be well researched to ensure that the change protects the public health. The research presented by RJR does not satisfy that burden.