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Tobacco Farmers
FOR

Food and Drug Administration Authority Over Manufactured Tobacco Products: What does it really mean to the tobacco farmer? Why is it so essential to public health?

"We accept an interest in people's health as a basic responsibility, *paramount to every other consideration in our business.*"

Tobacco Industry paid advertisement
that appeared in the *New York Times*
January 4, 1954

Food and Drug Administration Authority Over Manufactured Tobacco Products: What does it really mean to the tobacco farmer? Why it is essential to public health

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For more than six years the tobacco companies have actively worked to convince the tobacco farmer and the tobacco producing communities that Food and Drug Administration authority over tobacco products means FDA controls over tobacco farming activities. In March of 1998, after many open and honest discussions between the tobacco producing and health communities, a clearer understanding of what FDA regulation means both to public health and tobacco producers was reached and incorporated into a set of **Core Principles** now endorsed and supported by more than fifty agricultural and health organizations. The key provisions related to FDA included in the **Core Principles** state the following:

- That it is in the best interest of the public health community and the tobacco producer community that *FDA should have authority to establish fair and equitable regulatory controls over the manufacture, sale, distribution, labeling (including country of origin) and marketing of tobacco products, both domestic and imported, comparable to regulations established for other products regulated by the FDA.* Such regulations shall have as their goal the protection of public health and the assurance that users of tobacco are provided with full and complete information about the products they are using. In order to accomplish this goal industry information and research should be made available for public review.

- That there be greater cooperation between tobacco growing communities and the public health community to ensure that quality control and health and safety standards are maintained in the production of tobacco, both domestically and abroad, and that industry information and research should be made available for public review. *Agencies with public health responsibility, including FDA (whose authority over manufactured tobacco products should not extend to on-farm tobacco production) should work cooperatively through structures already in place in the Department of Agriculture, and the Environmental Protection Agency so as not to extend any additional control and bureaucracy over on-farm production of tobacco.*

BACKGROUND

The public health community believes that FDA authority over manufactured tobacco products remains a cornerstone for national tobacco control strategies. Even as we await a decision by the Supreme Court, it is very probable that tobacco control legislation introduced or considered in the 106th Congress will include comprehensive and full regulatory authorities for the Food and Drug Administration over tobacco products.

Given that we can expect to see the tobacco companies actively working to once again use the tobacco producers to oppose any efforts to enact meaningful FDA related legislation, it is appropriate to provide further information to tobacco growers on what it is that is meant by FDA authority over "the manufacture, sale, distribution, labeling, and marketing of tobacco products consistent with FDA's authorities over other products".

The public health's concerns about the devastating public health consequences of tobacco stem from the use of **manufactured** tobacco products that are sold to consumers across the country and the tobacco companies' callous disregard for the public health consequences associated with their products. For close to four decades, since the first of more than 20 Surgeon General's reports on tobacco and health were released, the tobacco companies have successfully fought off fair and meaningful controls over their products. At the same time the tobacco companies have knowingly withheld valuable and critical health and safety information about their products that could have saved the premature deaths of millions of Americans. And they have routinely failed to adhere to their own advertising and marketing codes, that had they been effectively enforced, could have prevented millions and children from taking up the habit and helped adult smokers who wanted to quit, quit.

If tobacco products were invented today, and with the medical and scientific knowledge that we now have about its addictiveness and adverse effects on health, they would never be allowed on the market. But tobacco's history, the dependency of tobacco states and tobacco producing communities on this product, make it impractical for tobacco to be banned. At the same time that this reality is accepted by the public health community (see **Core Principles**), the public health community is also concerned about the lack of fair and equitable controls that are in place over the manufactured product. What the public health community has concluded therefore, is that given that tobacco products will continue to be manufactured, sold and used in this country, it is essential that we do everything feasible as part of a national state and local effort to:

- keep tobacco out of the hands of children and adolescents
- prevent misleading and deceptive marketing and promotion practices by the companies, and
- provide legal users of tobacco products with full and complete truthful information that will allow them to make an informed choice.

For decades, and now widely accepted as a result of the massive numbers of internal industry documents, the tobacco companies have actively and irresponsibly worked to thwart all of these efforts.

The purpose of the Food and Drug Administration and the enforcing statute, the Food Drug and Cosmetic Act has been to ensure that products that are consumed, eaten, inhaled, implanted or applied to the skin are safe effective, properly manufactured and responsibly marketed and promoted. The agency's authorities cover a wide spectrum of such products including, foods, prescription and over the counter drugs, medical devices, cosmetics, and dietary supplements. As with many issues involving health and safety, a majority of Americans understand and accept that one of governments functions is to make sure that consumers are protected to the most reasonable extent possible and that manufacturers of products are adhering to reasonable health and safety standards in the manufacture sale and marketing of their products. This is particularly the case where there are serious risks associated with a product. Not only are such standards applied to those products governed by the Food Drug and Cosmetic Act, but we as a society demand that there be health and safety standards for the automobiles we drive, the planes that we fly in, the water we drink, the appliances we use is our households and the toys and products that fall into the hands of young children and infants. For the tobacco companies and their manufactured products there have been no standards, and in fact the tobacco industry has in spite of the well-known dangers of their products fought aggressively to prevent such standards being applied to them. It seems ironic that food products manufactured by Philip Morris and RJR are held to a higher health and safety standards by the Food and Drug Administration than are the deadly addictive tobacco products that take the lives of more than 400,000 Americans each year. It seems inconsistent that nicotine patches, gums and inhalers designed to help people quit their smoking habit are held to a higher regulatory standard than are the products that caused the addiction and disease in the first place.

The public health community believes that it is time that the there be a level playing field in the public health protection of the American people, both children and adolescents who should not use tobacco products and adults who make a choice to use tobacco products.

WHAT THE FDA'S ROLE IN TOBACCO PRODUCT REGULATION SHOULD BE:

The key elements for FDA policy initiatives over tobacco products should include:

- The labeling of all tobacco products including package inserts and other educational messages consistent with warnings and other information required for other legal products (drugs, medical devices, foods etc.)

- The establishment of sound scientific methodologies for the testing, labeling and information disclosure of constituents and ingredients in tobacco products and tobacco smoke.

- Restrictions on advertising and marketing of tobacco that are designed to prevent or discourage youth from purchasing and using tobacco products and which prevent the use of misleading and deceptive advertising practices in the sale and promotion of tobacco products.

- The implementation of the most effective measures for reducing access and use of tobacco by children and adolescents.

- The technical and commercial feasibility of reducing or eliminating nicotine and other harmful or toxic substances in tobacco products and the public health consequences of such actions.

- The establishment of regulatory review and regulatory controls over all ingredients used in the manufacture of tobacco products.

- The feasibility of establishing performance standards for tobacco products.

- The establishment of good manufacturing practices for manufacturers of tobacco products.

WHAT THE FDA'S ROLE SHOULD AND SHOULD NOT BE IN OVERSEEING THE PRODUCTION OF RAW AGRICUTURAL TOBACCO LEAF

The Food and Drug Administration is the nation's lead public health agency in ensuring that *manufactured* products that are consumed are used by the public are safe, properly manufactured, properly labeled, and properly marketed. Authorities for regulating the agrictural production of tobacco should remain primarily with the USDA and the EPA.

Should the Food and Drug Administration, in its responsibilities in regulating manufactured tobacco products, find that a public health and safety risk exists because of something that has occurred in the agricultural production of tobacco, the FDA should work with and through its sister agencies, the EPA and the USDA in taking the necessary steps to deal with potential health problem.

Nothing should however, prevent the FDA from removing a ***manufactured product*** from the market for public health and safety reasons even if the public health problem occurred at the agricultural level.