CHAPTER IV

THE NEED FOR AN INTEGRATED REGULATORY FRAMEWORK

The options for rationalizing nicotine regulation include making all nicotine product regulation the responsibility of an existing agency such as a food or drug regulation agency, or by coordination and rationalization of the activities of different agencies that regulate nicotine products. We conclude however, that meeting the challenges of implementing effective tobacco control and nicotine harm reduction policies both nationally and internationally, needs the creation of dedicated, autonomous, and fully resourced national (and where appropriate international) nicotine and tobacco regulatory authorities.

–J. Britton, R. Edwards, ***Tobacco smoking, harm reduction and nicotine product regulation****, The Lancet, October2007*

One of the challenges that must ultimately be resolved is a determination about what is the proper and most effective and workable regulatory framework that will ensure that tobacco leaf and tobacco products (and nicotine products) are adequately tested, labeled and marketed – and more importantly how do noncombustible products fit within that framework. We noted earlier that there seems to be a well accepted consensus that noncombustible products are significantly lower in risk than combusted cigarettes but there is a great struggle with respect to how to deal with this reality.

The agency most suited for such regulation on the manufactured side, is, as I argued in my longer white paper on harm reduction, the Food and Drug Administration (FDA). The agency most suited for dealing with the leaf side is the USDA. The number of public health organizations, manufacturers and growers who recognize the critical importance of these twin regulatory and intertwined functions has been steadily growing. While there are some people who oppose FDA oversight, they are becoming more and more marginalized. Discussions are turning more towards "how" FDA should regulate tobacco and nicotine products. Some argue that the role of FDA is only to oversee products that are "safe and effective" and to set standards for such products (Statement of FDA Commissioner Von Essenbach, March 2007).

There are few products currently under FDA's regulatory authority that are 100% safe. Pharmaceutical products all have extensive warning labels on them about side effects and other dangers, and in some cases warnings about the risks of death. Food products are labeled for fats, cholesterol and sodium, all which have significant health ramifications for heart disease, diabetes and cancer. No one is suggesting that the fat, cholesterol and sodium in food products be "banned". The reality is that most products in the market place carry risks and relative risks. The political and historical uniqueness of tobacco should not serve as an excuse for the FDA not to have the authority to set regulations for such products as a public health goal. To fail to do so would be irresponsible. Just as pharmaceuticals, medical devices, foods, dietary supplements and cosmetics are all regulated under separate categories, so must we also deal with tobacco. Cosmetics have no public health "benefit", yet they are under the agency's purview.

What we will do in this section is explore more of what that regulatory framework should be, focusing to some extent on issues relating to smokefree products.

As we have noted throughout this paper, there is an increasing demand that tobacco products be tested for toxins, pesticides and other chemicals in term of risks and relative risks. Just as with our pharmaceutical products and our food supply, consumers expect that the products they choose to use or not use are thoroughly labeled and marketed with truthful and accurate information. Achieving such a goal with tobacco will require some major policy changes.

FDA, USDA – Coordinated Regulatory Authorities

1. FDA – Oversight of manufactured tobacco and nicotine products

There has been a "stand off" of sorts when it comes to deciding how and under what circumstances a noncombustible tobacco product should be labeled, marketed and sold. What can a manufacturer say about the risks and relative risks of the product? When does such information become a health claim? Should we be talking in terms of "relative risk claims" instead of health claims? What level of scientific evidence will be needed to evaluate the basis for accuracy and truthfulness of the claim? How do we determine if consumers are being misled by information or a claim? What kind of information should be provided to the consumer to allow decision making about the use of products to be a truly informed one? What are the First Amendment issues that need to be considered in restricting commercial speech? These are all questions that often get raised but have rarely to my knowledge ever seriously been discussed with respect tobacco.

I will not go into further detail about why the FDA is the appropriate agency for overseeing the regulation of tobacco. More details on that can be found in the paper "Tobacco and Tobacco Products at a Crossroads in the 21st Century", Chapter VIII. This paper proposes that for the FDA to deal with an ever increasing number and variety of tobacco and nicotine products on the market, all tobacco and nicotine containing products should be brought under the same "regulatory umbrella" by establishing a Center at the FDA, entitled the "Center for Tobacco and Nicotine Products". The legislative proposals reintroduced at the beginning of the 110th Congress have many gray areas that will treat some products as tobacco and others as drugs under what would be two very distinct categories. While that approach may have made some sense at one time, the rapidly changing tobacco and nicotine market suggests that we should be rethinking what the proper regulatory structure should be. Many public health experts have called for a more coherent and comprehensive tobacco and nicotine policy. (See for example, *Toward a comprehensive long term nicotine policy*, "Tobacco Control" 2005:14:161-165, N Gray, JE Hennigfield et al.; See also the discussions on pages 124-137 of the Special Issue: The Conference on Tobacco Dependence: Innovative Regulatory Approaches to Reduce Disease and Death, "Food and Drug Law Journal", Volume 53 Supplement, 1998).

With all tobacco and nicotine products subject to a more cohesive integrated regulatory system, the FDA would be able to establish labeling and marketing restrictions and allowances based upon the risks and relatives risks of the products and their intended use. The model proposed below is based on the model used by the FDA for medical devices. As the Institute of Medicine noted in its report "Clearing the Smoke":

> *The medical device provisions of the FDCA provide a model for this policy in that high risk products are subject to pre-market approval, while products of lesser risk are subject only to pre-market notification.*
>
> (Clearing the Smoke, Institute of Medicine, National Academy Press 2001 page 214)

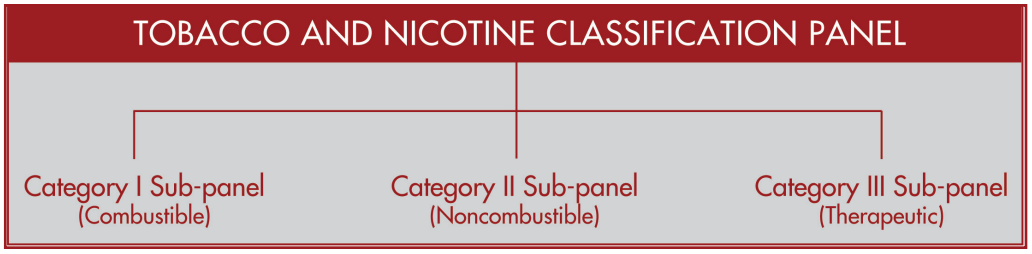
Within this new "Center" at the FDA, it would make sense to establish three distinct but inter-related categories – one for combustible products, one for noncombustible products and one for cessation/therapeutic products.

To oversee and set regulatory requirements for each of these categories the FDA should establish a Tobacco and Nicotine Classification Panel (TNCP), composed of three sub-panels. The TNCP (and the three sub-panels) would be charged with overseeing a range of regulatory issues (manufacturing, sales, distribution, labeling, marketing, GMPs, performance standards, etc.) for all tobacco and nicotine products. The panel would be composed of "persons who are qualified by training and experience" to evaluate issues and to make recommendations for meaningful workable regulatory controls. Such persons might include experts in:

- Public Health
- Pharmacology
- Toxicology
- Addiction
- Biotechnology
- Advertising, marketing and promotion
- Production and agronomy
- Labeling
- Good manufacturing practices

- Consumer affairs
- First Amendment
- Harm Reduction

The TNCP and the three sub-panels would be structured as follows:



Each of the three sub-panels would do the majority of work in looking at the science related to a particular category and the products in that category. Each panel would develop proposed labeling and marketing requirements and allowances for not only the category, but for individual products within each of those categories. The panels would have the authority to convene hearings and call witnesses to assist them in their duties.
Classification panels would make recommendations to the larger panel, which would then, on behalf of or through the Commissioner (Secretary), publish proposed rules and issue final regulations governing the labeling and marketing of products. New products that do not meet "substantially equivalent" requirements would require pre-market review and approval. Any interested party would be allowed to petition the panel for reclassification of a product or even removal of a product not meeting regulatory specifications. In addition, each panel might also include non-voting members representing the interests of consumers, tobacco manufacturers, biotech, pharmaceuticals, producers, etc.

2. United States Department of Agriculture

In October 2004, as part of the tobacco buyout legislation ("Fair and Equitable Tobacco Reform Act of 2004"), Congress effectively repealed all aspects of the U.S. government's involvement with tobacco production.

From the standpoint of ensuring the health, safety and quality of tobacco leaf produced in the U.S., but more importantly being imported into the U.S., this action represents a significant disservice to U.S. tobacco producers, the public health and responsible tobacco manufacturers.

As we move towards what will inevitably be oversight over the manufacture, sale, distribution, labeling and marketing of manufactured tobacco products by the FDA, it makes no sense to in effect deregulate the production system, leaving no accountability. FDA's working with the USDA will be particularly important. As a JP Morgan prospectus noted last year, one of the ways that a lower-risk tobacco product can be produced is through the "alteration of the tobacco leaf and ingredients."

In the 108th Congress, as part of the "buyout" deal and at the behest of special interests (in particular one of the major tobacco companies), Congress terminated the 1938 tobacco program. This in effect dismantled programs that not only protected and served the interests of U.S. growers but also benefited the public health. Instead of visionary thinking about tobacco and dealing with it effectively, Congress chose to move the issue backwards, once again leaving the fox to guard the hen house.

To effectively implement strategies for smokefree tobacco and nicotine products that encourage science-based modification of products, important authorities will need to be restored to the USDA that will not only help U.S. producers, but also protect public health. At a minimum, these should include:

- Monitoring, tracking and testing tobacco that is produced in the U.S. and overseas.
- Developing and implementing production standards that ensure the quality, health, safety and integrity of the tobacco leaf.
- Providing incentives to tobacco producers, tobacco manu facturers, biotech companies, agronomists, etc. to invest in and develop new technologies and new forms of leaf that are scientifically tested and evaluated to reduce harm associated with tobacco.
- Identifying research priorities that have a reasonable expectation of lowering risks associated with tobacco use. This is particularly important in the area of smoke free, noncombustible products.

Without the restoration and expansion of important functions, we will not be able to effectively track where the tobacco used in manufactured products comes from. We will not know the levels of toxins and pesticides in the leaf. We will not be able to ensure adequate quality controls over products which may claim to be lower in risk. The regulatory chain must include production, processing, manufacturing, sales, distribution, labeling and marketing of not just manufactured products but in the tobacco leaf itself.

As Congress considers the enactment of the FDA legislation it must also consider and implement parallel standards and requirements for tobacco leaf. It must give the U.S. tobacco farmer the tools and support they will need to produce the type of crop that public health and safety requirements will demand.

To that end, we should work toward the establishment of a system that would parallel that of the FDA, establishing a Center on tobacco at the USDA that would be charged with carrying out the objectives noted above. A Tobacco Production Advisory Committee or Panel could be established composed of experts in tobacco agricultural production, agronomy, toxicology, biotechnology, pharmacology, etc.

As with FDA, a small user fee could be assessed per pound of leaf to pay for a number of programs that would serve to benefit producers, manufacturers (broadly speaking) and the public health.

3. Other Agencies that Need to be Involved

In addition to the important dual, complementary functions that will need to be played by the Food and Drug Administration and the U.S. Department of Agriculture, there are other agencies that will have to be involved as part of a broader more comprehensive approach to ensuring proper oversight of tobacco and nicotine products. These include but are not limited to the Centers for Disease Control and Prevention, the Environmental Protection Agency, the Federal Trade Commission, the National Institutes of Health, the National Institute on Drug Abuse, the Bureau of Alcohol Tobacco and Firearms and even the Department of Homeland Security.

Conclusion

To effectively deal with the complex issues associated with the production, processing, manufacture, sale, distribution, labeling and marketing of tobacco and nicotine smokefree products (as well as all tobacco products), Congress must enact legislation that gives the FDA and the USDA the complementary authorities needed to effectively get the job done. At the FDA, such legislation must seek to bring tobacco and nicotine products under the same umbrella instead of treating them separately (as does the current legislation pending in Congress). FDA must also ensure that the manner in which this spectrum of products (from highly toxic cigarettes to significantly lower-risk tobacco and nicotine smokefree products) are regulated is based upon their risks and relative risks and that manufacturers of the lower-risk products are given necessary incentives to "develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco-related disease". Other agencies such as the CDC, FTC, EPA and NIH should also be integrated into the efforts of the FDA and USDA.

Note: For conclusions and recommendations suggesting restructuring and enhancing regulatory authorities over tobacco and nicotine products contained in the Royal College of Physicians Report, "Harm reduction in nicotine addiction; helping people who can't quit," See Appendix, Item 2.