Why Oversight of Tobacco and Tobacco Products is Both Necessary and Inevitable

We must recognize the roles business managers are required to play and simply set in counterposition a group with a fundamentally different role. Against businesses, whose first job is profit, we must set groups whose first job is safety. It is after all, common sense.

Philip Hilts, "Protecting America's Health – The FDA, Business, and One Hundred Years of Regulation"

- Voluntary programs do not work
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As tobacco companies line up to develop and market 'reduced risk' products, many in the public health community worry that we are headed down the same road that resulted in the development and marketing of low tar and low nicotine cigarettes: a market place filled with chaos and deceptions. As the IOM report, **Clearing the Smoke** noted, the reality is that the development and availability of these products in the market place is upon us now. How harm reduction products are dealt with in the future cannot be looked at in isolation, but must be considered as part of the broader regulatory framework for tobacco products and in the context of the spectrum of tobacco products on the market. The market and the products available to the public will continue to change as the industry is faced with having to comply with responsible regulatory standards coupled with competition to develop and market products that are *truly* lower in risk.

The question we are facing is how do we sort out what might be legitimate science based products and claims versus illegitimate products that, like their low yield cigarette predecessors, are fraught with Madison Avenue marketing gimmicks designed to sell products with little real concern about public health. In addition to transparency and corporate accountability, we will need to have effective but fair oversight and regulation of tobacco products by an agency like the Food and Drug Administration.

Any discussion, dialogue, or engagement with the industry should be based on a clear acceptance by tobacco manufacturers that oversight of the industry and its products is not only the right thing to do for public health but the right thing to do with respect to the manufacturing and marketing of an inherently dangerous consumer product. In fact the IOM concluded:

> *Regulation of all tobacco products, including conventional ones as recommended in IOM, 1994, as well as all other PREPs is a necessary precondition for assuring a scientific basis for judging the effects of using PREPs and for assuring that the health of the public is protected. Regulation is needed to assure that adequate research (on everything from smoke chemistry and toxicology to long term epidemiology) is conducted to ensure that the public has current, reliable information as to the risks and benefits of PREPs. Careful regulation of claims is needed to reduce misperception and misuse of the products. If a PREP is marketed with a claim that it reduces (or could reduce) the risk of a specific disease(s) compared to the risk of the product for which it substitutes, regulation is needed to assure that the claim is supported by scientifically sound evidence and that pertinent epidemiological data are collected to verify that claim.*
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> *(IOM,* **Clearing the Smoke***, Conclusion # 5, page 6. See also, the IOM's suggested 11 regulatroy principles for regulating PREPs, page 1o—11)*

In spite of 'reservations' made by some, it is also clear from statements suggested in the IOM report as well as some in the public health and scientific community that engagement with the industry and other stakeholders will be required and is inevitable.

The question, therefore, is not whether such engagement will take place, but rather when and how. As we noted in an earlier chapter, it is not just public health organizations and the tobacco manufacturers who will be involved in the discussion, but tobacco producers, scientists, researchers, biotech companies, agronomists, pharmaceutical companies, marketing experts, and consumers. We need the involvement of key experts to help shape policies and craft legislation that will serve the public interest both in the short and long-term.

The effort to secure FDA oversight of the tobacco industry and its products has been and remains a hard fought battle. The first Surgeon General's report was released in 1964, at a time not unlike today where the prospects for the development of lower risk cigarettes was on the 'horizon'. In the late 1980's, several petitions to the FDA (coupled with the introduction of legislation) renewed efforts to have it regulate tobacco either as drugs and devices under the agency's existing jurisdiction, or to establish a separate chapter under the Food Drug and Cosmetic Act (legislation). In 1996, the FDA issued proposed regulations and a massive and extensive record as to why it was regulating tobacco products under its existing drug and device authorities. These efforts brought a swift and massive counter attack from the tobacco industry which at the time was unified in its opposition. The battle was taken all the way to the Supreme Court, where in a 4-3 ruling, the court found that the agency did not have jurisdiction over tobacco products. This threw the issue back to the US Congress for further consideration., where it has since remained. Several efforts within Congress have come close to giving the agency jurisdiction but, for a variety of reasons the Congress has failed to act. As noted below, the players in the debate, their views and their support have changed the environment significantly to the extent, that many now believe that some form of oversight over the tobacco industry and its products is not only possible but inevitable.

An investment prospectus prepared by JP Morgan in 2005 on the development of reduced risk-products noted:

> *"One of the main obstacles facing PREP cigarettes is the industry's inability to clearly and credibly communicate reduced risk attributes to smokers".*

The prospectus further noted that:

> *We see two major benefits of FDA regulation for the industry:*
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> - *Reduced forward looking litigation risk, as FDA regulation of product content, marketing and distribution makes it more difficult for plaintiff – lawyers to attack the industry in the court room, and*
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> - *Opportunity to successfully market PREPS cigarettes as the FDA determines which products are reduced risk and authorizes health claims.*

The issue of FDA oversight over tobacco products will need to be discussed and dealt with even as we await action from the Congress, which may take several years. Even if Congress were to enact legislation in the near future, the promulgation of regulations would be several years in the making and, given past history, challenged at ever step by some manufacturers.

The positions of the spectrum of stakeholders have been articulated in a number of places, including testimony before Congress, websites, public statements to the press, etc. Some have specifically refered to the need for the FDA to have authority including public health organizations, growers, some in industry, and consumers. A set of core principles issued by growers and health groups in 1998 and the presidential commission report, **Tobacco at a Crossroad** (May 2001) included recommendations for the regulation of tobacco by the FDA. More than one hundred grower organizations, health groups and others signed on to the recommendations contained in those documents. Philip Morris (Altria) has been most public with its endorsement of the FDA approach to oversight of the tobacco industry although other companies such as Star Scientific endorsed FDA as far back as 2000.

Philip Morris' website notes:

> *PM USA strongly supports the passage of this legislation (DeWine/ Kennedy) and remains committed in our support for comprehensive, meaningful, and effective FDA regulation of tobacco products. We believe FDA regulation would play a significant role in reducing the harm caused by tobacco. This is a goal that we share with the public health community and society and believe is good for our company, our employees and the industry as a whole.*
> For more information on the position and views of PM

USA on FDA, see http://www.philipmorrisusa.com.

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Two of the larger smokeless tobacco companies (UST and Swedish Match) have indicated a willingness to accept FDA under certain conditions. The UST 2005 annual report released in March 2006, for example, included the following statement:

> *Proposals for comprehensive regulation of tobacco products* will continue to be considered. To date, the Company has opposed such proposals because they fail to completely recognize the distinct differences between smokeless tobacco and cigarettes. However, the company would consider supporting such regulation if the proposed regulatory scheme included the following components:*
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> 1. *a meaningful regulatory process whereby the agency could certify, based upon submissions by a manufacturer, that the use of smokeless tobacco involves significantly less adverse health effects than cigarette smoking.*
> 2. *a meaningful regulatory process whereby the agency could approve, based upon the submission of a manufacturer, comparative risk communications to current adult users of tobacco products (e.g. cigarette smokers who do not quit and do not use medicinal nicotine products should switch completely to smokeless products; and*
> 3. *a meaningful regulatory process whereby the severity of any provisions regarding regulation of ingredients, constituents, advertising, promotion and availability could be reduced for products that were classified on a continuum as involving less risk (e.g. less restrictive regulations for products classified as significantly reduced risk, such as smokeless tobacco.*
>
> **including FDA*

Others remain opposed (including Reynolds American, and Lorillard) to regulation, preferring to preserve the status quo and using many of the same arguments used by the industry for years. We can also expect some of the smaller companies who are in it for quick profits to also work against FDA regulation of tobacco products.

The mainstream public health groups have long supported FDA regulation of tobacco products going as far back as the late 1980's, many of the them endorsed the DeWine/ Kennedy legislation in the 108th Congress. Some in the public health community remain opposed to 'FDA' because they say that the bills or approaches in Congress don't go far enough. Others remain opposed to FDA, arguing that the states should be fighting the battles with the industry. Given this current state of affairs, I am prompted to ask the fundamental question: Is preserving the status quo because of our failures to move perfect legislation forward a viable alternative when that means control by the tobacco industry? Common sense and history should tell us it is not. We have not employed an all or nothing approach to other tobacco control strategies, including excise taxes, clean indoor air legislation, or marketing and advertising restrictions and we should not do it here.

If we compare where we were on the issue for the need to have the industry regulated 5-10 years ago, we can only conclude that there has been a major shift in support of that goal by a widening spectrum of interests. While motivations may differ, there is some common ground that needs to be explored. The common ground has not only come from the more mainstream public health organizations, but from companies, growers, and consumers as well, who see that their interests may be best served in the long term by accepting such oversight and working within a system and process rather than against it.

Voluntary Programs Do Not Work

The lack of meaningful and enforceable standards and rules has led and will continue to lead to abuses from the industry. Even if some companies change their ways, there will always a few (or more) bad apples who will want to make quick profits at the expense of public health by doing things that could be ethically and corporately irresponsible. Such unchecked activities are a green light for other companies who might otherwise be willing to accept and play by a set of rules to continue their own abuses in order to protect market share. What is needed is a set of rules that prevents abuses, encourages science -based innovation, and makes reduction of disease and death from tobacco something that the industry fully accepts as a goal.

In years past, whenever there were discussions about the prospects of regulating the tobacco industry and its products, the tobacco industry would always initiate voluntary programs

which, for the most part, were merely words soon forgotten once the prospect for congressional action was beaten back.

We are beyond voluntary programs; interim efforts must be with the full understanding and acceptance that governmental oversight of tobacco and tobacco products is both necessary and inevitable. Not only do voluntary approaches not serve public health interests but they also destabilize the tobacco production and manufacturing sector.

What Should FDA Oversight Entail?

Separate Chapter:

Legislative proposals in Congress over the last several years have shifted from regulating tobacco products under 'drug and device' provisions of the FD&C Act to establishing a separate chapter specifically designed to deal with the regulation of tobacco and tobacco like products. Public health organizations, growers, and some in industry have all agreed that tobacco should be regulated under such a scheme. In spite of this agreement and consensus, there are some companies who continue to deliberately cause confusion by suggesting that regulating tobacco under FDA will ultimately result in all tobacco being regulated as drugs and banned. I am unaware of any of the major stakeholders who supports FDA oversight advocating such a position.

Key elements of FDA oversight:

The key elements of what areas FDA should have over tobacco products have been well spelled out. Some of those elements include giving FDA the authority:

- To restrict the sale, distribution, marketing, and promotion of tobacco products to children and adolescents
- To require warnings labels and other information on all tobacco products, in tobacco advertisements, or other means that allows adult users of tobacco products to fully understand the risks and relative risks of the products they are using
- To restrict and prohibit advertising and marketing that is misleading and deceptive (consistent with the First Amendment). This includes advertising targeted at children and adolescents as well as advertising and marketing that makes unsubstantiated false and misleading health claims (e.g. low tar and low nicotine).
- To require that all tobacco products (generically and individually) disclose toxins, ingredients, additives, country of origin and other information to which adult users of tobacco are entitled
- To establish Good Manufacturing Practices (GMP's) for the industry

The FDA should also:

- Encourage the development of technologies and tobacco based products that have a reasonable expectation of reducing risks associated with tobacco use
- Work with other federal agencies CDC, NIH, USDA, EPA, FTC, DHHS, ATF etc) in establishing a cohesive and workable national tobacco program
- Work with entities in the private sector including scientists, researchers, public health authorities, industry, growers, and others

In his book, Protecting America's Health- The FDA, Business and One Hundred Years of Regulation, Phil Hilts, who has followed and written about the tobacco issue extensively, made the following observation:

> *We must recognize the roles of business managers are required to play, and simply set in counter-position to them a group with a fundamentally different role. Against businesses, whose first job is profit, we must set groups who first job is safety. It is, after all, common sense. Warren Kiefer, a public relations executive for Pfizer International, several decades ago spoke before Congress and then wrote, in a letter to the Saturday Review, "It was my experience in the drug industry that most executives were honest most of the time. But they were businessmen, who in the old American tradition, placed company interest first. Public interest was the FDA's lookout", he said. "It is the regulatory officials who are responsible to the people"*

In contrast to the FDA's poor resources but dedication and openness, American corporations overall have failed to evolve much as organizations. They have remained rigid hierarchies, with little input from the public or stakeholders when key decisions are made. Some management experts have begun to press for more open corporations, ones that include members of the board some workers, or members of the communities where the companies reside, or suppliers. Essentially, though, the logic of "profit alone" that dominated the companies in the nineteenth century dominates them today. This is one reason the FDA's job is difficult and necessary.(p 342)

Why Other Agencies Are Not Qualified to Take the Lead in Tobacco Product Regulation

For many years there have been arguments made (mostly by the tobacco industry and its allies) that regulation and oversight of tobacco products might be better dealt with by the Federal Trade Commission or the Centers for Disease Control and Prevention. While each of those agencies has a role to play in the tobacco arena, neither is suited to regulate the complexities of the tobacco product. FTC authorities should, as they do in the area of pharmaceutical products, compliment the FDA's primary authority, letting the FDA, as a science-based agency, set the primary directions of oversight and regulation as a public health matter. The CDC should, as it does in many other areas (obesity, nutrition, physical activity, etc.), continue to focus on tobacco control education, prevention, and surveillance. Suggesting that CDC regulate tobacco products would be similar to suggesting that CDC assume regulatory responsibility over the pharmaceutical, food, device, and dietary supplement industries. Some argue that, given FDA's current challenges and limited resources in other areas adding tobacco to its responsibilities will further erode the agency's ability to do its job. While there is some truth to such a suggestion, we cannot and should not forget that we are dealing with products that cause the deaths of over 400,000 Americans each year. We cannot forget that tobacco use accounts for annual medical and lost productivity expenditures totaling billions of dollars each year. Nor can we forget that the FDA is the most logical place to put tobacco given tobacco's complexities and public health ramifications. Creating a Center on Tobacco within the FDA, funded and staffed separately can and should be done. This would neither detract the agency from its other responsibilities nor siphon away funding from its other important regulatory responsibilities. From all perspectives, the FDA is the best suited and most logical place for tobacco products to be placed.

Need for Coordination with Other Federal Agencies

Missing in the discussion of FDA oversight is the need for greater coordination and interface between the FDA and other agencies. This is particularly important in dealing with issues related to harm reduction and the development of reduced risk products.

I have been and remain a big advocate for establishing a comprehensive and cohesive national tobacco policy for this nation. There is a tendency on the part of some to look at FDA as the savior, as the only agency that has the capability for dealing with tobacco and which should have the authority to deal with the health ramifications of tobacco. In fact, while FDA is central to overseeing the industry and its products, other governmental agencies will also need to be involved. Agencies that need to be involved might include USDA, EPA, NIH, NIDA, CDC, FTC, ATF and even DHS.

Of particular importance to harm reduction is the role that the USDA must play.

USDA's role in Harm Reduction Efforts

FDA's working with the USDA will be particularly important for harm reduction efforts. As the JP Morgan prospectus noted:

There are two main ways in which cigarette manufacturers can produce a safer cigarette:

- *The tobacco leaf or ingredients can be altered*
- *Cigarette construction can be modified*

In a special program on obesity in America, the late Peter Jennings began by standing in a field of agricultural

crops saying "It all starts here". And so it is with tobacco. It would be naïve to think that somehow the production, curing, and processing of tobacco has nothing to do with issues related to harm reduction. The fact is that technologies and changing methods of production will have an increasingly more important role to play in harm reduction.

In the 108th Congress, as part of the tobacco buyout deal and at the behest of political interests and the special interest of one major tobacco company in particular, the Congress terminated the 1938 tobacco program. In effect, this dismantled programs that not only protected growers but also benefited public health. Instead of visionary thinking about tobacco and dealing with it effectively, Congress chose to in effect move the issue backwards. Once again, the fox has been left guarding the chicken coop. The interests of some in the tobacco industry have won out over public health and growers.

In order to effectively implement harm reduction efforts through product development and modification, changes must be made and important provisions and authorities restored to USDA that will not only help farmers but protect public health. These should include:

- Monitoring, tracking and testing tobacco that is produced in the US and overseas.
- Developing and implementing production standards that ensure the quality, health, and safety of the tobacco leaf.
- Providing incentives to tobacco producers, biotech companies, agronomists, and manufacturers to invest in and develop 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 (at the production level).

Regulatory oversight and the development of regulation will not occur overnight

It would be foolish to believe that even if FDA legislation and complimentary USDA legislation were passed by Congress tomorrow, the issues surrounding the production, manufacture, sale, labeling, promotion, and marketing of tobacco products would change overnight. The development of rules and regulation might take several years at a minimum. This does not mean that, as we pursue FDA and USDA oversight, there aren't important steps to be taken that could not only speed up the process of change under the current environment, but also have a significant influence and impact on helping the FDA and USDA when such authorities are finally provided. Recommendations on how that process might be accomplished and implemented are dealt with in the last chapter, "Where do We Go From Here?".

The need for effective oversight of tobacco and tobacco products is not just a US concern - but a global one as well

The challenges we face in ensuring effective but workable oversight of the tobacco industry and its products in the US are the same ones that need to be addressed and confronted globally. The World Health Organization's (WHO) Framework Convention on Tobacco Control (articles 9,10,11) established the groundwork for the regulation of the contents, disclosures, packaging, labeling, and marketing of tobacco products. The WHO Study Group on Tobacco Product Regulation has laid out a series of recommendations including establishing some **Guiding Principles for the Development of Tobacco Product Research and Testing Capacity and Proposed Protocols for the Initiation of tobacco Product Testing**. This research and testing capacity will be essential for the effective oversight and regulation of existing and new tobacco and tobacco like products. More information can be accessed through the WHO FCTC website at www.WHO.org).

Summary and Conclusion

The development of harm reduction products cannot be done in a vacuum. There must be a level playing field and a set of rules and standards developed that will ensure that all tobacco and tobacco products are what they claim to be (both products currently on the market as well as new ones). We cannot and should not depend on tobacco industry voluntary efforts. With new products on the hori-

zon with significant technology changes and more to come, we must bring order to what is currently chaos. Without effective oversight by both the public and private sector, we are doomed to a repetition of the mistakes that have been made in the past. The Food and Drug Administration is clearly the best suited and most logical governmental agency for overseeing the tobacco industry and its manufactured products, although it is critical that the FDA also work closely with other governmental agencies such as the EPA, FTC, CDC, NIH, Homeland Security etc. Of particular importance in the ensuring proper and effective oversight of tobacco and tobacco products will be the critical role that the USDA must also play.