Preliminary Comments Concerning
Risk and Benefits of Long-term Use of Nicotine Replacement Products

The Need for a More Rational, Coherent and Comprehensive Tobacco, Nicotine and Alternative Products Regulatory System

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"Greater availability of medicinal nicotine, and perhaps even low-toxicity smokeless products, along with increasing restrictions on smoked tobacco, is likely to reduce tobacco-related mortality and morbidity. Given the known hazards of smoked tobacco, and given the numbers of people who smoke, innovative thinking is needed. We support harm reduction along side rigorously applied tobacco control policies".

Adding harm reduction to tobacco control
Editorial, The Lancet, (Vol. 1370, October 6, 2007)

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For many decades the public health community and the tobacco industry have waged a unrelenting war with each other. In the middle of that war were pharmaceutical companies who had developed, produced and marketed a number of nicotine products intended to assist smokers to 'quit' their use of cigarettes. Because FDA had no coherent regulatory policy over tobacco **and** nicotine (and in fact had no regulatory control over tobacco products) the approval or disapproval for the nicotine based products fell to the Center for Drug Evaluation and Research within the Food and Drug Administration.

CDER's announcement in the Federal Register (September 2, 2010 - Docket No. FDA-2010-N-0449) that it would organize and conduct a work shop on the Risk Benefits of Long-term Use of Nicotine Replacement Therapy Products is both welcomed and long overdo. At the same time however, this workshop is just the beginning of what must be an expanded dialogue to move towards the development of a more coherent and rational regulatory policy structure for **all** tobacco, nicotine, and alternative products--- one that is

based on science and common sense and one that regulates products based on the risks, relative risks, and the intended uses of such products.

With the FDA now having jurisdiction over tobacco, now housed in the recently established Center for Tobacco Products (CTP); with the tobacco, nicotine, and alternative products environment rapidly changing; with new technologies and new products appearing in the market place; and with the lines between what is a pharmaceutical company and a tobacco company becoming increasingly blurred, it is in deed time to put the tobacco wars behind us and to focus our attention in creating a regulatory structure that provides the needed flexibility to be able to set standards that are not based on rhetoric and emotion but on science and common sense. The spectrum of products is extensive and growing - from the highly toxic cigarette; to lower risk noncombustible smoke- free products that include traditional smokeless tobacco products, newer more novel non-combusted tobacco based products; to nicotine replacement therapies (from which the nicotine is derived from tobacco), and to other non-tobacco and non-nicotine products. We are in a 'new era' where it is now recognized and widely accepted that there is a significant difference in risks between the deadly combustible cigarette and non- burning products. Yet, it seems inconceivable that many in the public health and medical communities (let alone the general public) believe that nicotine causes cancer and other chronic conditions. It also seems inconceivable that the same is true when it comes to understanding the **significant differences** in risk posed between cigarettes and other noncombustible forms of tobacco and nicotine.

It is therefore, unscientific and disingenuous for anyone, especially in the public health community, to continue to make the statement that all tobacco products are equally harmful. Many of the products on the market today and many that will be developed in the future have and will have the potential for helping **reduce** the disease and death caused by cigarettes. And wasn't that the mission of the public health community ? The development of these products, whether nicotine based or tobacco based, whether sold as therapeutic cessation products or as products significantly lower in risk than cigarettes, should, as the IOM has noted, be **encouraged**, not discouraged. Thus looking into the risk and benefits of long- term nicotine use is not of value just to considering NRT products but all tobacco and nicotine based products which I now refer to as**, Smoking Replacement Products, or SRP's.**

While it was logical at the time to separate the regulation of tobacco, nicotine and alternative products into various Center's of the FDA such a separation no longer makes rational sense and is in fact counterproductive. The users of all of these products are the ones who need information that they can rely on and can trust --- information that is consistent and allows them to fully understand the risks and relative risks (and intended uses) of all the products in the market place.

Many of the pharmaceutical companies have long advocated the 'loosening up' of regulatory controls over NRT products including advocating for longer term use applications, something which I believe deserves serious consideration as a public health matter. The NRT products (the nicotine of which is derived from tobacco) are sold as

CDER notes, in both OTC forms and prescription forms, many of which are flavored in order to make the products consumer acceptable - which they need to be. At the same time, one of these companies has unfortunately called for the removal of competitive tobacco based products, which when compared with the deadly cigarette (not being advocated for removal by the pharmaceutical company) are potentially 90% plus lower in risk than the cigarette. This I believe is not a prudent public health position. These products should be evaluated, labeled and marketed based on their risks/benefits but they should not be removed from the market place, especially given the continued presence of the deadly cigarette. As the discussion about the long term use of nicotine continues, it would be wise to ensure that we include in the discussions, the broader topic of tobacco and nicotine regulation as well. All products on the market, whether cigarettes, smoke-free tobacco and nicotine products (Smoking Replacement Products, **SRP**'s) should be labeled, distributed and marketed based on the risks and relative risks of the products as well as their intended uses. This is the common sense approach we use for other products in society, many, if not all, which carry risks --- drugs (both prescription and OTC), foods (that have varying degrees of fats, cholesterol, sodium and other components that present adverse risks to health), automobiles where we have seat belt/ air bag laws, DUI laws, and other safety requirements, and many others etc.

Need for A More Coherent and Science Based Regulatory Policy for Lower Risk Tobacco, Nicotine, and Alternative Products

In the FDA's long 100 plus year history the statute has been amended dozens of times in order to deal with a changing environment and a need to adjust to new technological developments, new science, new products and new public health concerns **and** opportunities. This has been done in the areas of drugs, devices, foods, cosmetics, and dietary supplements. I would contend that with all its positive attributes and an urgent need to at long last regulate tobacco products, the statute enacted into law in 2009 was out of date in many areas even before the ink of the President's signature had dried. The legislation that was enacted was the product of an era of the 1980's and 90's and failed to take into account the dynamic changes taking place that were rapidly occurring with respect to science and technology. This is the case for the use of nicotine and why FDA needs to reconsider its current policies on NRT. But it goes much further as well. It must begin to set policy based on both science and common sense. Incredibly, the legislation even failed to acknowledge or recognize the land mark report of the IOM, **Clearing the Smoke** (which had been requested by the FDA), which should have been as a *blue print* for developing a more rational and coherent regulatory strategy for tobacco and nicotine regulation.

On numerous occasions I have suggested that **all** tobacco, nicotine, and alternative products be brought under a single regulatory umbrella and renamed the Center for Tobacco and Nicotine. The FDA needs to go back to Congress with recommendations that would accomplish that goal and **bring tobacco and nicotine policies into the 21st century.** Revisions to the statute are particularly urgently needed in the area of harm reduction. It is very clear that the language of the current law intentionally raised the bar

so high and was written by 'special interests' that the language actually could be a **disservice to public health**. It fails to follow the primary recommendations of the IOM report that calls for manufacturers (of all harm reduction products) to be given incentives and for which there is a reasonable expectation that the product will reduce the harms caused by tobacco.

I have suggested that in order to effectively oversee and regulate the spectrum of products, that the Center for Tobacco and Nicotine Products establish a Tobacco and Nicotine Product Classification Panel that would include three sub -panels (working independently but cooperatively) to deal with:

A) All combustible products
B) All noncombustible products
C) All therapeutic products (that make health claims) etc.

This type of model is based in part on the type of model used for medical devices. As the IOM noted in the **Clearing the Smoke** report,

> 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 to only pre-market notification". (**Clearing the Smoke**, page 214)

I can see a day not too far off in the future when a noncombustible Smoking Replacement Product (SRP) that is tobacco based will possibly be allowed to make health claims and be used specifically as a therapeutic.

Having worked on food and nutrition labeling reforms, I would also like to suggest that much of what has been learned in the food area also be considered in developing a new regulatory framework for tobacco and nicotine, particularly in the area of noncombustible products. The issue of 'health claims' on foods was for example an area where it made no sense to have regulatory authorities housed in two different centers in the FDA, and it made no sense to try and withhold truthful information about a product that was not considered to be 'health claim'. On another 'side note' related to food regulation, it was Dr. David Kessler's decision to take on the food industry (in his infamous 'Paper Tiger' speech), that prompted me to author the petition that went to the agency in the late 1980's seeking to regulate certain tobacco products under the FDCA. In that petition we argued that the tobacco companies were making implied and direct health claims that warranted the agency classifying those products as 'drugs'. We believed that if Dr. Kessler and the FDA could take on the foood industry for making misleading claims it could certainly do the same for tobacco.

I encourage CDER staff and others to read, "**Smokefree Tobacco and Nicotine Products - Reducing the Risks of Tobacco Related Disease-- A constructive and practical "Road Map" towards a civil dialogue to influence public and private sector policy decisions "** which can be found at www.tobaccoatacrossroads.com .

CDER should also take the initiative within the FDA and in cooperation with the Center for Tobacco Products to advocate that the FDA as a whole, support statutory modifications that would bring all tobacco, nicotine and alternative products under one umbrella. The logical place would obviously be the new Center for Tobacco Products, which should as I mentioned above, have its name changed to the Center for Tobacco and Nicotine Products. In the mean time it should work towards the establishment of a more workable, uniform, consistent and rational tobacco and nicotine policy that establishes labeling and marketing (and recommends even taxation) policies based on risks and intended uses.

It is my intention to submit additional materials into the docket before the closing date of December 27, 2010.

Respectfully Submitted,

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