**"If I always do what I have always done,
then I'll always get what I already got."
-Anonymous**

January 2011

Some Observations and Suggestions Concerning the e-cigarette 'Debate' and Beyond.

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Many of you have been following or are aware of the ongoing debates and discussions concerning e-cigarettes and how they should (or should not) be regulated. Some believe they should be banned outright. Others are taking the position that they should be regulated under the medical devices/drug provisions of the Food Drug and Cosmetic Act; others believe that they are tobacco products and should be regulated by the new FDA Center for Tobacco Products; and there are still others who think they should not be regulated at all. Mirroring what is occurring in many other areas of our society, these are positions of 'polarizing extremes' that are more often than not influenced by emotion, passion and an unwillingness to consider any *common sense* alternatives (i.e. As one highly respected international tobacco control expert once commented, for many, 'It's their way or no way'.) Because these views are extreme, and often dogmatic, they are the views that often, unfortunately, get the most attention (including by the media looking for a story).The result is that we are missing out on having any serious and meaningful discussions about issues and sub-issues that may hold workable short term and long term solutions and answers. There may in fact be more common ground than anyone wishes to admit. I encourage everyone to open their eyes, to step back and to see what is possible, rather than remaining in their protective silos refusing to even consider any serious possibilities for moving forward. I know many who will choose to remain in their silos and I know many who unfortunately don't seem to have the ability to check their egos at the door. But I also know many who are 'solution' oriented and I encourage them to step forward and to provide leadership and participate in a more *civilized* approach to problem solving.

The debate and discussions have been elevated to an even higher level as a result of a decision by the US Court of Appeals (December 7, 2010) that ruled that the FDA lacked the authority to regulate e-cigarette as drugs/devices (absent therapeutic claims) and that the products needed to be regulated as tobacco products by the Center for Tobacco Products. My own reading of the US Court of Appeals decision only reinforces my view that we are in urgent need of a more rational, comprehensive, pragmatic and workable regulatory policy for **all** tobacco, nicotine and alternative products that is based on the regulating these products based on risks, relative risks and intended uses.

We cannot ignore the fact (although I know many will continue to bury their heads in the sand) that this is not the 1990's and that we are in an environment that is also being driven increasingly by science, competition, and new product development between a growing spectrum of players for market share. Clearly the pharmaceutical companies view many of the new science-based products as threats to their business and are doing whatever they can to prevent products from entering the market place. As I noted in one of my earlier observation pieces, such an approach may not be in the consumer's or the public's best interest. I went so far to suggest that its the pharmaceutical companies who would most likely benefit in the short term from science based (regulated) competition especially in an environment that favorably puts their products up against all others.

The e-cigarette debate is just one example of where we need more rational thinking, dialogue and the involvement of experts that go beyond the normal cadre of players who have been on the scene for 20 plus years.

We cannot, nor should we assume, that all of the e-cigarettes in the market carry similar risks. E-cigarettes, like all other tobacco and nicotine products, should be labeled and marketed according to their risks and intended use and a **'risk profile'** established for not only the category but for each product. I don't think that anyone would disagree with that objective whether they are consumers, users, manufacturers, or public health advocates. Companies who refuse to play by a set of fair rules and want to cut corners deserve to be driven from the market place.

Last year at the Food Drug and Law Institute (FDLI) annual meeting Nancy L. Buc , a former Chief Counsel of the Food and Drug Administration and now a partner with the prestigious law firm of Buc and Beardsley, made a statement at one of the tobacco panel discussions that I think we should all consider and heed. Paraphrasing her, she said that *the remedy for dealing with a problem should be determined based on what will be needed to correct the problem.* In other words we should not be 'throwing the baby out with the bath water' in order to solve a problem, nor should we be using a regulatory sledge hammer to kill a fly when a fly swatter will do. In the e-cigarette debate there are obvious legitimate concerns being raised about how to deal with such things as safety, labeling, packaging, GMP's and marketing and they deserve attention. They can and should be dealt with within the tobacco Center. On the other hand the science on the e-cigarette indicates that these products are significantly lower in risk than the combustible cigarette. So rather than lobbing grenades and rhetoric at each other, let's talk about the issues and find solutions rather than prolonging a war of rhetoric that has no end.

Thirty years ago when the Coalition on Smoking OR Health (ACS,AHA,ALA) petitioned the FDA to regulate cigarettes as drugs and medical devices , it was done because there was no other avenue at the agency at the time. There was no tobacco Center. FDA's effort to regulate cigarettes as drugs and devices was eventually rejected by the US Supreme Court (Brown and Williamson) resulting in a renewed effort to enact legislation that at long last gave FDA regulatory authority over tobacco products within a new Center at the FDA.

The challenges and opportunities facing the Food and Drug Administration (and Congress) with respect to the e-cigarette (and other products) are not so unique as they may seem. Advancements in science, technology and new product development have been standard for other areas under the FDA's purview (foods, prescription drugs, OTC drugs, medical devices, dietary supplements) and has prompted the FDA and the Congress to modify laws to meet those challenges and opportunities. A couple of examples (and there are many others) will suffice. When medical devices, which had long been regulated under the 'drug' provisions of the Act became increasingly complex and even murky, Congress saw fit to create a new medical devices division. When food manufacturers began to demonstrate a new level of scientific knowledge that warranted the allowance of health claims (i.e. reference to a specific disease) in labeling and marketing but would have made such products 'drugs' under the FDCA, Congress clarified the issue as part of the NLEA (Nutrition Labeling and Education Act) to ensure that these claims would be regulated and set by the center for foods and not drugs. FDA has since developed a multi-tiered claims structure for foods that includes disease specific 'health claims' . These types of actions clearly support the idea that the time has come to restructure and re-evaluate how tobacco, nicotine, and other products could be more consistently regulated based the rapidly changing science and technology, and new product development.

As I have pointed out on numerous occasions, and as we are now seeing become very obvious, the FDA tobacco legislation (which was based on a legislative model of the 1990's, the result of a *deal* between PM and the CTFK, and the clear influence of the pharmaceutical industry) was out of date in many important areas even before President Obama's signature was dry. Many would justifiably argue that the legislation did more to protect the cigarette industry and Philip Morris in particular, than it did to provide incentives (as recommended by the Institute of Medicine) or encourage the development of science based lower risk products. Looking back, it remains almost inconceivable that such a prestigious report (**Clearing the Smoke**), totaling more than 500 pages, developed and produced at the request of the Food and Drug Administration, was never mentioned in the legislation nor were some its most important recommendations incorporated or even considered. The report's primary recommendations include calling for incentives (in a regulated environment) for the development of reduced risk products that have a reasonable expectation of significantly reducing disease and death. The existing statute raises the bar so high as to virtually keep all reduced risk products off the market, something clearly not in the public health interest.

Time for the Reconsideration of Outdated Policies on Tobacco, Nicotine and Alternative Products

It has been more than five (5) years since I first suggested that what was needed (in addition to FDA oversight of tobacco which I worked for most of my professional career) would be **a** more **comprehensive, rational, and consistent regulatory policy for all tobacco, nicotine, and alternative products** --- one that looked at the spectrum of products and regulated them based on their risks, relative risks and intended use. The current system in which some products find themselves being regulated by the drug and device Centers at the FDA while others fall under the tobacco Center, makes no sense in today's rapidly changing environment. Unless there is a serious and rational discussion about how best to implement such a comprehensive policy there will continue to be serious regulatory and legal challenges that in my opinion may serve the interests of some of the stakeholders (tobacco versus pharmaceutical versus public health advocates etc,) but certainly not necessarily the public or the consumers of these products. In fact if you think consumers are confused now about the risks and relative risks of various products, just wait. **All** of the various tobacco, nicotine and alternative products should be brought under **one umbrella** (Center for Tobacco Products....renamed as the **Center for Tobacco and Nicotine Products**). As FDA does with medical devices, FDA should consider establishing Classification and Regulatory Panels to deal with the expanding number of types of products, their risks and relative risk and their intended uses. I have suggested the formation of three such panels, one dealing with combustible products (i.e. highly toxic cigarettes), one dealing with noncombustible, smokefree, and ***smoking replacement products*** (SRP's), and one dealing with products making more traditional therapeutic health claims. We have to accept that it is not the 'tobacco' that causes the serious public health risks but rather how that tobacco is grown, processed, cured, manufactured and most importantly used (example: combusted versus non-combusted.). We have to accept that we need a more uniform workable tobacco and nicotine policy that deals with a spectrum of products from the highly toxic cigarette to a vast spectrum of smokeless products to nicotine replacement therapies and other alternatives.

I can think of a number of avenues that could be pursued (other than the public relations wars of rhetoric or tying things up in litigation) in moving us forward to developing a more rational and workable regulatory system and structure not only for the e-cigarette but for all tobacco, nicotine, and alternative products. Here are a few:

1. Initiating a dialogue in an independent forum similar to the one that was effectively used by the public health community and tobacco growers.
2. Convening a meeting at the FDA with players both separately and collectively to consider finding a path forward that deals with present concerns but at the same times maps out a longer-term term regulatory timetable. FDA has held such meetings on many topics.
3. Making the discussion a part of the agenda at the (Food Drug and Law Institute) FDLI annual meeting. This could be on e-cigarettes or on the broader subject of how best to ensure fair, comprehensive and workable regulation of **all** tobacco, nicotine, and alternative products.

4. Having open, balanced, transparent and informative discussions at other meetings including at tobacco control meetings, scientific meetings, trade associations etc.
5. Revisiting the statute in Congress through *meaningful, balanced and fair* oversight hearings with a focus on establishing a more workable and rational regulatory structure that regulates, tobacco, nicotine, and alternative products based *on risks, relative risks and intended uses*.

I can think of many sub-issues pertaining to the e-cigarette discussions where I believe common ground and understanding could be found.

As was done in the dialogues between the public health community and the tobacco growers, consideration should be given to developing a set of ***Core Principles*** that could be agreed upon by a broad spectrum of interests. From there policy decisions within the FDA and even in Congress could be developed that would better serve the public health goals of this nation and move us out of 20th century thinking and into the 21st century.