

“Toto, I have a feeling we’re not in Kansas anymore”

----Wizard of Oz ---

The Changing Regulatory Environment of Tobacco, Nicotine and Alternative Products – Time for a More Constructive Civil Dialogue and Engagement*

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Several months ago, I gave a presentation entitled, ‘ **Tobacco and Tobacco Products in a “New Era” of Regulatory Oversight**’. Originally I had planned to give the presentation with a focus on the FDA’s newly acquired mandate to regulate tobacco products. But after realizing that everyone else was doing the same thing, I decided that what might be even more useful would be to look at how the tobacco (and nicotine) environment had changed since the release of the landmark Surgeon General’s report in 1964, and in particular since the height of the “tobacco wars” in the 1980’s and 90’s. Several years ago Dr. K. Michael Cummings and his colleagues at the Roswell Park Cancer Institute had put together a DVD of clips of tobacco industry media statements and interviews from those years, that were in retrospect almost *comical*. Watching those clips brought back a lot of recollections, having participated and been deeply involved in the ‘tobacco wars’. But it also made me realize just how extensively things have changed and that we are indeed in a very different era than the 1980’s and 90’s. Am I suggesting that we trust the tobacco industry and take them at their word? Of course not. But in a regulated environment and one that is very different than past years we must consider taking new approaches – approaches that actually engage and challenge those who manufacture tobacco, nicotine and other alternative products.

Today not only has the environment changed but the positions of *a number of* the various stakeholders and interest groups have also shifted, some more extensively than others. One only had to watch and listen to the recent discussions by the FDA’s Tobacco Products Scientific Advisory Committee to know that the change is here. The irony is that it is the more mainstream and traditional tobacco control groups, and some the individuals who have been leaders in the movement since the 80’s and 90’s who seem to

be the ones most resistance to any change and new ideas--- still clinging instead to the good old days of the 'tobacco wars'. (i.e. if it worked then it will work today). I was recently reminded by a public health colleague that when in the late 1980's, I started to actively promote the idea that tobacco needed to be brought under the purview of the Food and Drug Administration that I was said to be "on a fools errand" and that we needed to rely on the more traditional tobacco strategies of the time. That view obviously changed! But today many of those same groups and many of those same individuals seem stuck in a similar mode --- not being able to fully recognize that things are not what they were and that it is science and the civil discussion of science, and technology that needs to be shaping policy rather than rhetoric and public relations campaigns.

In talking about 'change' I often use an adage in my presentations that goes like this: **"If I always do what I've always done then I'll always get what I already got:"** I use it to suggest that we need to always be thinking about new opportunities as well as removing barriers to change. We need to take calculated risks when there are opportunities that can positively impact on public health. There are many in tobacco control who would rather take the position: "I've always done it that way, and I am not going to change. The 'status quo' is what I want and where I want to be". This is reflected in the views of many who still see the 'tobacco wars' as they were in the 1980's and 90's. Folks, we're not in Kansas anymore. This change in environment has caused some to shift to being even more moralistic and prohibitionist in their views. There are some who now talk about eradicating all tobacco in any shape or form; others suggesting that nicotine in any form should also be banned. Many oppose any new products coming onto the market even if the science is clear that the products are significantly lower in risk and would be strictly regulated (i.e. FDA).

The Family Smoking Prevention and Tobacco Control Act with all its positive and long overdue provisions was in some areas outdated even before President Obama's signature was dry. The legislation signed last June was a product of the tobacco wars of 1990's. This was very evident as I watched the debate on the Senate floor last Spring, and as Senator after Senator seemed to have pulled old 'fire and brim stone' statements out of their file drawers, dusting them off and focusing in on the evils of 'Big Tobacco'. I felt as if I was in a time warp listening to rhetoric and statements that I had myself had used and in some cases crafted as long as 20 years ago. But the real irony to me, as I listened, was that the biggest of the tobacco companies had actually played an active and critical role in helping to craft the legislation and had worked for its passage behind the scenes. And no one wanted to talk about or acknowledge that.

Even President Obama is often used as the 'poster child' for the reasons for the passage of the legislation, himself being addicted to cigarettes. But at the same time he is also a good example of why we need a science-based more flexible regulatory structure in place that will provide users of tobacco (especially users of the most toxic cigarette) with more science-based options to consider as they seek to lower their risks, and to not merely take the 'quit or die approach' advocated by some.

Convergence of the Tobacco, Pharmaceutical and other Alternative Product Markets

Let's face it, part of what is transpiring in the tobacco, nicotine and alternative products market is about competition and profits. Competition is not something that the tobacco control community thinks much about or the critical public health role that it can play in altering the types of products (in a regulated environment) that are on the market. The often cutthroat competition between various interests has been around for many years, not just between the tobacco companies but others as well. Pharmaceutical companies have long been active in their efforts (including providing financial contributions) to gain the public health community's support for their products and they clearly had a role in the shaping of the legislation in Congress. Like the tobacco industry the pharmaceutical industry has always been known for its 'special interest' clout in Washington.

I have been told that some of the pharmaceutical companies have considered or may even already be developing tobacco based products. It is also very clear that some more traditional tobacco companies are clearly looking into developing nicotine and more pharmaceutical like products. And then there are numerous companies and interests that have been looking at developing products that may be tobacco or nicotine based products but that are very different from the products of the last 40 years—the e-cigarette being but one example. One thing I think I can say however, with some assurance, is that it seems that all of the nicotine used in these various products is derived from tobacco.

I have suggested for a number of years that **Regulation + Competition+ Incentives** can be one of the most of effective ways of changing corporate behavior. And changing corporate behavior can and should be considered as a significant way of advancing a public health agenda. This is true not just in the tobacco, nicotine, and alternative products markets but also in every market including the food, drug, energy, and automobile industries etc. The importance of competition and incentives for manufacturers was reflected in one of the major recommendations of the Institute of Medicine in its landmark report, **Clearing the Smoke**, a report requested by the FDA (See Below). But when one reads the Family Smoking Prevention and Tobacco Control Act, there is nothing to be found that would even suggest that incentives or competition have any role to play, nor is there any reference in the Findings of the legislation to the **Clearing the Smoke Report**, the very report that should have been used as the *blue print* for the drafting of an updated FDA bill. How can that be?

I sometimes wonder, what if in the last 15 years, in addition to the traditional tobacco control strategies, we had also been able to take a different added approach? What if we had gotten a regulatory structure in place such as the FDA (that was not perfect at the time) and we had given companies (tobacco, pharmaceutical, biotech) the incentives to developed science based lower risk products that were strictly regulated? What if we had developed a regulatory model that set standards and regulations based on risks and relative risks? I would suggest that we would have been able to seriously reduce the use of combustible products, as well *incentivze* the development of products that would have

been useful to consumers of tobacco products seeking to significantly reduce their risk. But we did not and we preferred to continue to fight the more traditional tobacco wars, which in retrospect I think has been a disservice to advancements in public health and product regulation.

Regulating Tobacco, Pharmaceutical and Alternative Products Based on Risks and Relative Risks- Moving Users Down the Continuum of Risk

As many are aware, tobacco, nicotine and alternative products are now regulated in different Centers within the FDA depending on the product, what its product base is and how it is used. This schizophrenic approach to regulation of these products is an example of the outdated 1980's and 1990's thinking and the failure to bring the Family Smoking and Tobacco Control Act up to date and into the 21st century. But in Congress serious discussions about improving and restructuring the legislation were unwelcome. I can't even begin to recall how often I heard the "chorus", 'we can't changed anything in the legislation'. I recall that some years ago when Philip Morris had been pushing a version of their own bill, the health community chanted, 'no bill is better than a bad bill' but in the end that is what transpired. Maybe not 'bad' but certainly not reflective of the significant changes that have taken place in tobacco and nicotine science and in the development of significantly lower risk products. So we need to be honest and willing to talk about the short comings of the legislation especially when measured against the Principal Recommendations of the IOM report **Clearing the Smoke** --- a report that had actually been done at the request of the FDA. We have to get over this idea that all tobacco is equally harmful and to accept that we are very close to having some tobacco based products as low in risk as are many of the NRT products currently on the market. Not only is such a statement (that all tobacco products are equally harmful) scientifically inaccurate but it is disingenuous for people who speak as public health experts to continue to make such statements.

Tobacco is in essence, an agricultural based product, having naturally occurring nicotine. **It is what is done to the tobacco how it is grown , processed, cured, manufactured and most importantly used that determines the level of risk.** For the noncombustible products, which I call 'smokefree' products and which range from traditional forms of smokeless (often very high in TSNA's) to NRT it might be more useful to consider employing a regulatory based 'food model' rather than a pharmaceutical or medical device model. Today there are smokefree tobacco based products that are 90% plus lower in risk than combustible cigarettes and there is a range of risks for tobacco based 'smokefree' products. Thus classifying all such products as equally toxic or dangerous is disingenuous, and misleading to the public and we need to get beyond it.

When discussing the pros and cons of using tobacco- based 'smokefree' products versus NRT, some, especially those it seems with ties to the pharmaceutical interests will only

make a risk comparison between the two categories of smokeless tobacco and NRT. Why is that? The risks and relative risks for products should be assessed along the entire continuum of risk that includes combustible products as well, so that users of any and all tobacco, nicotine, and alternative products can make a truly informed judgment about the spectrum of products on the market. We shouldn't be *selectively* withholding information that could have a significant impact on public health.

Each product should be given a 'risk' profile, based on a scientific evaluation. Labeling and marketing requirements (and even taxation requirements) should be determined based on the risk profile and the science that supports it. Products for which additional science becomes available (ie changes the risk profile) can then be reevaluated. I don't think it is too far off in the future when we will see some tobacco based products being sold as therapeutics, and the more traditional NRT products being sold as consumer products rather than 'drugs'. And let's not forget that GMO tobacco, often referred to as the 'white rat' of the plant world, is being looked at for developing medicines and industrial enzymes.

The whole debate swirling around the e-cigarette is a fascinating one to follow and has all the components and attributes for a detailed academic case study. It brings to the forefront many of the complex and important issues that need to be addressed including consideration for changes in the current FDA law that would bring all tobacco, nicotine and alternative product regulation under the same umbrella, and setting standards and regulations for these products based on risks and relative risks. But it also presents ideological challenges to many in tobacco control as well as industry (tobacco, pharmaceutical and biotech). Many in tobacco control see this as a natural extension for continuing the 'war' with the tobacco industry. They, in spite of the science or the need for further dialogue and evaluation of the science, or given that none of the various more diverse companies have anything to do with Big Tobacco, want these products banned all together. And as usual with many in tobacco control there is a tendency to assume that all of the various companies are the same and that their products are the same and have the same risk profile. They are not. Clearly these products (whether tobacco based or nicotine based) should be carefully evaluated by the FDA and risk profiles established. If in the interim, people want more information about the various products, such as in one case where a tobacco control advocate wanted to know where the nicotine in the e-cigarette comes from, why don't they just ask? Instead, there is a tendency to act and react as if the developers of these products have something to hide. Maybe some do maybe some don't? All the more reason for engagement. All the more reason for scientific evaluation and fair regulations.

Another area of relevant interest is what some are referring to as dissolvables. Again the rhetoric makes for good press but it is hardly scientific or carefully thought out. Many of these products are for the most part not only significantly lower in risk than combustible cigarettes but there are also probably varying degrees of risk between them. The 'candy for kids' arguments, while having some merit and having worked in years past, also have been distorted and hyped in order to gain press attention reminiscent again of the 1980's and 90's. I can understand that but I also take exception to it in this new era. Why for

example hasn't there been similar questions raised about the NRT dissolvable lozenges made by the pharmaceutical companies that are advertised on television, radio, in magazines and in drug and grocery stores and which come in an assortment of flavors including things like "fruit chill", "cherry", "lime", "mocha", etc. Aren't these dissolvable products similar in form and substance (including containing nicotine) to the dissolvable tobacco products? Couldn't they, as some would argue, easily be concealed and won't they lead to the use of other tobacco products by children? FDA has recently reinstated the 1996 Rule and I think that we should first look to the effective implementation of that rule by the states to ensure that tobacco and nicotine products don't fall into the hands of kids. We should simultaneously look at the science of the dissolvables (both nicotine and tobacco based) and set standards that are based on the science on not on speculation. All tobacco and nicotine products should (again as recommended by the IOM report) be carefully monitored and corrective actions taken when and if necessary.

Harm Reduction

Some suggest that the attention being focused on the issue of tobacco harm reduction is a sinister plot of the tobacco industry – a clever way for the industry to continue to profit at the expense of public health. If one takes the time to give some thought to the importance and concepts of harm reduction, one will realize that it is something that has actually been embedded in tobacco control in one way or another for more than 30 years. As long as we focus on the public health objectives and there is an effective regulatory structure in place, we should be elated that we can now 'force' changes on the industry and the products they manufacture, and that we can drive those who wish to ignore or manipulate science off the playing field.

When I was first working with several members of Congress in drafting a very early version of the FDA legislation, one of the basic and important goals was to ensure that all products were labeled and marketed in a truthful, accurate and non misleading way. Users and potential users of products had the right to be completely informed about the products they were using. They had a right to information that would give them the tools to make decisions about the use of differing products, including total cessation. This was one of the basic tenets and positions of the public health community in arguing for FDA oversight in the first place. Ironically today some in tobacco control would seek to withhold truthful and non-misleading information because it doesn't concur with their views that all tobacco is equally harmful. And there are others who have vested interests in the pharmaceutical industry and who, rather than giving incentives to all companies, wish to keep any competitive products off the market.

In 2001 the Institute of Medicine, at the request of the Food and Drug Administration, issued a landmark report, **Clearing the Smoke** that concluded that harm reduction is a feasible and justifiable public health strategy if implemented carefully. In the principal recommendations the IOM noted that to implement a successful harm reduction strategy the following objectives needed to be met:

- Manufacturers have the necessary *incentive* 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;
- Consumers are fully and accurately *informed* of all the know, likely, and potential consequences of using these products;
- Promotion, advertising and labeling of these products are firmly *regulated* to prevent false or misleading claims, explicit or implicit;
- Health and behavioral effects of using PREPS are *monitored* on a continuing basis;
- Basic, clinical and epidemiological *research* is conducted to establish their potential for harm reduction for individuals and populations;
- Harm reduction is implemented as a *component* of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment.

Harm reduction is a public health strategy that has also been used successfully in many other areas. In democratic societies there are often tradeoffs to be made and harm reduction is a significant public health alternative to outright prohibitions and bans. Below are several examples:

- The use of condom's and other preventive measures for dealing with HIV and other STD's
- Needle exchange programs to reduce disease and deaths for drug users
- Availability of low fat, cholesterol, sodium, and sugar foods (rather than seeking an out right prohibition or mandated reduction in those elements)
- Using birth control and condoms in preventing unwanted pregnancies especially among youth, rather than relying on abstinence only as the only solution.
- Reducing environmental emissions and discharges (not total elimination) as steps to controlling and improving air and water quality, including providing industry with *incentives* for reducing such emissions.
- Requiring the use of seatbelts and other safety requirements in automobiles.

Not only does the IOM report serve as a reminder that harm reduction is an important and feasible public health strategy for reducing disease and death caused by tobacco use but there are many other examples, statements, and reports that strongly support it being incorporated into tobacco control efforts. The Royal College of Physicians for example noted in a major report on harm reduction, "Harm reduction is a fundamental component of many aspects of medicine, and in deed, everyday life, yet for some reason effective harm reduction principles have not been applied to tobacco smoking". For more on the topic of harm reduction, go to: www.tobaccoatacrossroads.com

The FDA and the Tobacco Products Scientific Advisory Committee

I want to take a moment to comment on the Food and Drug Administration's Tobacco Products Scientific Advisory Committee because I think it has the potential for really instigating change, not only in the United States but eventually at the global level as well. But it will require some serious shifting of the traditional view points including from some of the Committee members who have well entrenched public positions dating from the 1980's and 90's and formed at the height of the 'tobacco wars'. It will require those who have or have had close ties with other special interests such as the pharmaceutical industry to set those close ties aside, and to keep an open mind about the rapidly changing science in this 'new era'. The TPSAC may do well to learn from the process that was employed by the Institutes of Medicine in the preparation of its **Clearing the Smoke** report and to use that report to further guide its actions. Interestingly enough there are several members of the TPSAC who also served on the IOM panel. I am confident that they will be thoughtful, thorough and fair in undertaking their responsibilities.

In his opening comments to the TPSAC (March 30,2010), Dr. Lawrence Deyton the head of the FDA's Tobacco Center, talked (among other things) about the need for:

- Engagement with all stakeholders, including industry;
- The need to focus on the science in making sound policy decisions;
- The need for transparency and
- The need for civility

He reiterated these positions again in his remarks that closed the meeting.

I couldn't agree with him more. .

There may also be a tendency by some on the Committee members to merely ignore the non-voting members. That would in my view be a mistake. These non-voting members, just as the voting members, have an obligation and responsibility to be transparent and to provide the other committee members with their honest assessments of the various issues that will come before the Committee. They are there to bring their expertise to the table. They can therefore have a positive impact on the decision making process.

The TPSAC obviously has specific mandates and has some constraints on what it can and cannot do but there are many things that it can address as part of that mandate. One major priority for the TPSAC that I would suggest might be to consider helping develop a system by which each tobacco, nicotine, or alternative products is given a risk profile, that can then be used to develop truthful, accurate and non misleading labeling and

marketing parameters and developing a list (as the IOM has also suggested), **‘incentives’ to manufacturers to develop and market products that reduce exposure to toxicants and that have a *reasonable* prospect of reducing the risk of tobacco related disease.**

I believe however, and have said this in many of my white papers and presentations, that we also need a mechanism by and through which we can undertake important ongoing discussions and dialogues in a safe haven in the **private sector**. What follows are some general recommendations for establishing such a private sector dialogue --- a dialogue that could also be of real use to the TPSAC as it conducts its work in the coming months and years.

Civil Dialogue and Engagement

While I have saved this topic for last, it is in my view the most important topic to be addressed. It is the one that will help move us forward. For years now I have been talking about the need to find a better way, by and through which people can actually have a civil dialogue about a host of complex issues pertaining to tobacco and nicotine. The model that was used in the Southern Tobacco Communities Project that brought public health interests and growers together in a safe haven is good example of success. Unfortunately instead what continues to manifest itself in the tobacco arena today is the very thing that many have tired of with respect to their government and special interests. We don’t seem to be able to constructively and civilly face and deal with the many complex issues that we as a nation face. We have increasingly become an ‘adversarial’ society. Many like conflict for the sake of conflict. (i.e. positions of power and a way of getting attention). Others like conflict because it gives them a ‘raison d’etre’ and helps sustain their funding in a perceived (real or illusional) fight with an enemy. Such behaviors when taken to the extreme and to the exclusion of other ways of approaching challenging issues can actually negatively impact on public health goals. A recent commentary appearing in the **Journal of Public Policy**, entitled “Understanding the origins of anger, contempt, and disgust in public health policy disputes: Applying moral psychology to harm reduction debates” is worth reading.

I, respectfully, would suggest that those who may have differing opinions than others at least try to respect differing views. Two people who share similar goals but may have different approaches to achieving the goals, accomplish little when their time is spent trying to undercut or discredit the other person.

Those who have advocated dialogue and engagement have sometimes been called traitors (or worse) which in my view is both disrespectful and shortsighted. I look at what we are dealing with in tobacco with what occurred in the Cold War and how **change** was brought about by a few people willing to step outside their comfort zones to advocate change – often at their peril and the castigation of their colleagues. Let’s face it, for decades we lived in an environment in which we perceived the Soviet Union and its

empire as bitter evil enemies, advocates of views and ideologies that went against the very essence of our democratic principles. Some thrived on and relished that adversarial relationship with the evil empire. When leaders like Korbachov and others stepped forward to advocate ‘change’ they were roundly criticized in their traditional circles, as were many in the US. Many in this country opposed any efforts at engaging the ‘evil empire’ seeking to prolong the ‘cold war’ for many (often self-serving) reasons. But the Soviet Union and the communist countries that made up its allies were ‘changing’ and that change brought about new opportunities.

Today, in the tobacco environment there is a cautious movement for change that is happening in spite of the efforts of many to try and preserve the ‘status quo’. There are leaders in and outside government who recognize that this isn’t the 1980’s or 1990’s.

Conducting a civil dialogue in a ‘safe haven’ is very distinct from conducting ‘negotiations’. Civil and carefully managed dialogue is a way of giving people the opportunity to make their views and ideas known and provides a forum for others to ‘listen’ and ask questions. It provides an opportunity to bring experts to the process who have no vested interest in the outcomes. No one is being asked to give up anything. No one is being asked to sell their souls to the devil. We have models that demonstrate that civil engagement and dialogue can and does work. This is a process that was successfully and effectively used when the public health community and the tobacco producing community sat down in the Southern Tobacco Communities Project (through the University of Virginia), that was used by the Institute of Medicine in putting together the **Clearing the Smoke Report** and is today being used by the FDA, as recently exemplified by the Tobacco Products Scientific Advisory Committee.

I for one will continue to be an advocate for such engagement and civil dialogue not only between those within the public health and scientific communities but also beyond. Even though I would declare the ‘tobacco wars’ of the 80’s and 90’s over, I believe that there may be *some* merit in carrying on the ‘tobacco wars’ to keep the industry in check, especially overseas. But this should not be to the exclusion of other opportunities that exist today. Many of the battles and disputes that we face in today’s world should be open and transparent, civil, and based on facts.

Thomas Jefferson in a letter to his friend James Madison in 1787 wrote: **“I hold it that a little rebellion now and then is a good thing and as necessary in the political world as storms in the physical”**. I don’t profess to being a rebel but I do profess to challenging the ‘status quo’ way of thinking, especially when I believe that there is more than enough evidence to support the notion that carefully constructed dialogue can benefit public health. I challenged the ‘status quo’ in the 1980’s and 1990’s and I have done it in first decade of the 21st century.

This isn’t Kansas anymore.

*N.B. I fully recognize that what I have outlined and suggested may **not** (and in some cases **should not**) apply to what is occurring in many other countries and regions of the world. Each country and each region faces different challenges and opportunities, and tobacco control, public health advocates and policy makers need to determine what will work best for them in seeking to reduce disease and death caused by tobacco and how best to hold the tobacco industry more accountable. In other words, “If the shoe doesn’t fit, don’t wear it”.

Scott D. Ballin has spent more than 25 years involved in issues related to tobacco and public health. He has worked on a spectrum of tobacco issues ranging from labeling reforms on cigarettes and smokeless tobacco products, FDA regulation of tobacco, excise tax increases, clean indoor air laws and tobacco agriculture reforms. For more than 10 years he served as the American Heart Association’s Vice President and Legislative Counsel, as a Steering Committee member and two-time Chairman of the Coalition on Smoking OR Health (AHA,ACS,ALA etc.) which was the first truly active national coalition in the tobacco movement. He has provided advice and consulting services to the American Lung Association, the Campaign for Tobacco Free Kids, and Star Scientific. Recently, he has served and continues to serve on the Steering Committee of the Alliance for Health Economic and Agriculture Development (AHEAD), informal organization formed to bring parties together to work for the enactment of recommendations contained in the Presidential report, Tobacco at a Crossroad. He remains a strong advocate for bringing parties together in neutral forums in order to discuss controversial issues, to remove barriers, to foster constructive dialogue, to look for new opportunities, and to find common ground. He has written several papers on tobacco harm reduction that can be found at www.tobaccoatacrossroads.com .

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