**Is Civil Dialogue and Engagement Between Diverse Stakeholders with Respect to Tobacco Harm Reduction Feasible? A Review of the Past, Present and Future**

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**Abstract**

With a billion smokers in the world and an annual toll of 7 million premature deaths, more can be done to significantly reduce or even eliminate the use of combustible products. Part of that effort involves the development of science-based consumer acceptable products. The public health community, policy makers, and regulators are very much divided as to whether harm reduction is a viable strategy. Part of these differing views have deep roots in the distrust of the tobacco industry that for decades denied that its products caused serious harm and then developed unregulated products which made implied claims of safety (i.e. low tar and nicotine). This personal essay will explore the past, present and future as a means of determining whether there may be a path forward in making ‘harm reduction’ a part of the solution rather than being seen as part of the problem. The first area reviewed will be starting in the 1950’s until about 2000 focusing on tobacco industry tactics and strategies to misuse science and to deny that their products caused cancer, heart disease and other harms. The second period will cover the time from the Master Settlement Agreement (1998) through the passage of the Tobacco Control Act in 2009 and up until the present day. The third area will be on whether it is possible in a regulated environment for diverse stakeholders to engage in a civil dialogue that focuses on making harm reduction a legitimate way of significantly reducing disease and death from cigarettes.

**Introduction**

There are currently one billion smokers in the world. This year it is estimated that seven million people will die prematurely from smoking and the use of tobacco products, many living in low to middle income countries. The tragedy is that these premature deaths are preventable. Rather than do an extensively footnoted ‘paper’, the following is more of a commentary and observational piece on how this epidemic might be better confronted, something that involves not only the use of traditional tobacco control measures, but also, in terms of the subject of this commentary, a change and shift in the tobacco and nicotine industry itself and the products they produce. This can only happen if the players are willing and able to engage in serious civil dialogues. My thoughts are based on more than four (4) decades of involvement in tobacco and nicotine related policy issues - which I have addressed and written about in a number of ‘white papers’ as far back as 2006 (see suggested list of readings).

From my perspective, ‘engagement’ between stakeholders in a regulated environment remains critical. In what is and has been a rapidly changing environment, it becomes essential for all stakeholders to share information so that we can deal with ongoing challenges that we face as well as taking advantage of opportunities.

Many ask why is it that there seems to be a renewed ‘polarization’ that exists between many stakeholders today? A polarization that seems in some ways to be widening rather than shrinking in both the US and globally. A polarization that suggests that the ‘tobacco wars’ of the 1970’s, 80’s and 90’s have returned as the ‘tobacco and nicotine wars’. An important twist in the scenario is that this is not just about the divide between public health and industry but includes divisions within the public health community as well as divisions within the tobacco and nicotine manufacturing sectors. The kinds of concerns that were raised in the 20th century about the ‘industry’ are now being raised today. While *seemingly* the same they are very different. And while the polarizing seems to be widening, as we shall see, there are also a growing number of venues where dialogue is actually taking place. This would never have occurred in the second half of the 20th century.

We should remember that the ‘cigarette’ is a man-made product dating back more than 100 years-the result of technologies that allowed for the very profitable mass production of cigarettes. They are products that have addicted and prematurely killed hundreds of millions of people. Today we have the technologies and the innovation to make science-based significantly lower risk products available to the adult smoker. Are we collectively up to the challenge?

This commentary will focus on the *past, present and future* as we consider the importance of civil engagement on important issues related to tobacco harm reduction (THR) in today’s environment.

**Part I ---A Half a Decade of Deceptions- c.1950-2000**

Without an understanding of the early history it makes it difficult to fully get a handle on where we are today and why there is such distrust on the part of many in the tobacco control community of tobacco and nicotine manufacturers.

The evidence suggesting that smoking caused cancer had been accumulating during the late 1940’s at a time when the sale of cigarettes was becoming more and more popular. At mid-century approximately 50% of the adult population smoked. Life style advertising and the use of celebrities including people like Ronald Reagan, Humphrey Bogart, Lucille Ball, and many others was rampant. Tobacco companies became sponsors of major television and radio shows. Doctors appeared in advertisements to tell smokers that certain brands were smoother and milder and the brand that ‘more doctors smoked’. Even cartoon character Fred Flintstone became a ‘spokesperson’ for Winston.

During World War II, cigarettes had been widely distributed to the troops. Hospitals routinely provided cigarettes to many of their patients. Smoking was encouraged everywhere, and seen as an integral part of society. The tobacco industry was alive and well.

**A Frank Statement to Smokers (1954)**

But behind the scenes by about 1950, the tobacco industry was becoming ‘worried’ that their businesses would be severely damaged if they did not address the growing health concerns about the use of their products. In December of 1953, an extraordinary meeting took place at the Plaza Hotel in New York City. The meeting, partly prompted by the release of a major study by Ernst Wynder and colleagues at Sloan Kettering that year, was nothing less than an effort on the part of the companies to plot their strategies to counter the allegations being made about their products. It would start a 50-year effort by the tobacco industry to mislead the country, the public and its customers about the dangers associated with their products, probably one of the most significant cover ups in American history. As the industry executives debated and discussed what they should do, John Hill of the prestigious public relations firm Hill and Knowlton, suggested that the industry question the scientific findings. Within about a month (January 1954) the tobacco industry published an advertisement in approximately 400 newspapers across the country, entitled, **A Frank Statement to Cigarette Smokers**. It was an extraordinary document that among other things proclaimed:

* We accept an interest in people’s health as a basic responsibility, paramount to every other consideration in our business.
* We believe that the products we make are not injurious to health.
* We have and always will cooperate with those whose task it is to safeguard the public health.

As part of the announcement, a quasi- scientific/ public relations group, the Tobacco Industry Research Committee (TIRC) was formed, later to be renamed the Council for Tobacco Research. In 1958, the tobacco industry established the Tobacco Institute which complimented the efforts of the CTR but served a much broader purpose than merely the scientific arena, including dealing with lobbying and public relations. And when the issue of second hand smoke was raised as a public health problem, the industry created another public relations front group in 1988.

But the evidence about the serious health consequences of smoking kept mounting. In 1964 the landmark Surgeon General’s Report, *The Health Consequences of Smoking* was released by Surgeon General, Dr. Luther Terry. Surgeon Generals’ reports, many released by probably the most well recognized Surgeon General in US history, Dr. C Evert Koop, would follow over the years including reports on cardiovascular disease, chronic obstructive lung disease, nicotine addiction, and second hand smoke.

In addition, the public health community, that had demonstrated little to no significant public policy efforts in the 1950’s, 60’s and early 70’s established the Coalition on Smoking OR Health (ACS, AHA, ALA) in the late 1970’s and began working at the federal, state and local levels on tobacco related issues. The agenda covered a spectrum of issues all of which are familiar today – excise taxes, clean indoor air laws, advertising and marketing restrictions, improved labeling etc. As part of that agenda the public health organizations began efforts to seriously call for tobacco products to be regulated by the Food and Drug Administration, petitioning the agency to regulate tobacco products under the agency’s ‘drug’ authorities.

But the tobacco industry kept up its onslaught of deceptions, developing and aggressively marketing products that were ‘suggested’ as being safer and lower in risk while arguing at the same time that it still had not been scientifically proven that cigarettes caused disease or that they caused addiction. In the 70’s and 80’s they focused on the reduction of ‘tar’ and created competitive marketing campaigns to keep smokers smoking and to encourage others to take up the addictive habit. Marketing themes using descriptors words such ‘Lights’, ‘Low’, ‘Reduced’ became the norm. They exploited the use of governmental measurements of ‘tar’ to further give legitimacy to their marketing. The role and marketing of special filters such as the use of ‘charcoal’, and the Kent ‘micronite’ filter also gave people a false sense of safety. Women increasingly become the target of the tobacco giants with the most well remembered cigarette campaign being Virginia Slims. And RJ Reynolds would reinvent ‘Camels’ by creating a cartoon character named ‘Joe Camel’ a brilliantly conceived and executed campaign that appealed to the younger generation. And equally of concern was that the industry would also focus on the African American community particularly with menthol cigarettes such as Kool. A May 1,1972, memorandum from Tobacco Institute VP Fred Panzer to Horace Kornegy, the Institute’s President, described the industry’s success as follows:

“It is my strong belief that we now have an opportunity to take the initiative in the cigarette controversy, and start to turn it around.”

He described what had been a holding strategy that was focused on:

* Creating doubt about the health charge without actually denying it;
* Advocating the public’s right to smoke without actually urging them to take up the practice;
* Encouraging objective scientific research as the only way to resolve the question of health hazard,

By the 1980’s the public health community, with very limited resources, was fighting back. Warning labels had been added to cigarette packs and advertisements and advertising was banned on television and radio in the 1970’s. But there was more to be done. The Coalition on Smoking OR Health would file a number of petitions with the Food and Drug Administration arguing that cigarettes, and especially those products making implied health claims should be regulated as ‘drugs’. But for a period, the request fell on deaf ears in part because of the political clout of the industry. This would change with the appointment of David Kessler as Commissioner of the FDA. It was under President George H.W. Bush, and in part because of the leadership of Assistant Secretary for Health James O. Mason that the idea would finally get legs, then to be taken up under the Clinton Administration. In February of 1994, Commissioner Kessler would respond to the Coalition’s request indicating that the agency was considering regulating tobacco products. The agency would later, not surprisingly, be challenged by the tobacco industry, a challenge which eventually found its way to the US Supreme Court where it was narrowly decided that the agency did not have statutory authority to regulate tobacco products- eventually returning the issue to Congress to deal with. **FDA v Brown and Williamson Tobacco Corporation, 529 U.S.120 (2000)**

Other important events took place. Hearings were held in Congress by a House Subcommittee under the chairmanship of Henry Waxman (D-CA). On April 14, 1994, the seven CEO’s of the tobacco companies were sworn in and presented with challenging questions, the most well-known question being whether nicotine was addictive. One by one they all said NO… nicotine is not addictive.

Whistle blowers from industry came forward to expose what the industry knew about the dangers and addictiveness of their products. In 1996, a former B&W senior employee, Jeffrey Wigand, would appear on CBS’s **60 Minutes** telling what he knew, in spite of efforts by the company to silence him.

Concerns were also being raised about increased adolescent smoking which jumped from 28 percent to 35 percent over about a three-year period in the early 1990’s.

**The Master Settlement Agreement (MSA) and the Department of Justice Lawsuit**

In the 1990’s a number of States Attorney Generals filed lawsuits against the tobacco companies seeking to recoup the health care costs associated with smoking, which was estimated to be $ 50 billion in 1993.

In November of 1998, 46 states, as well as several territories entered into the Master Settlement Agreement (MSA) with the major tobacco companies. The MSA was comprehensive and required the tobacco companies to make substantial payments to the states in perpetuity, as well as agreeing to restrict certain advertising, promotion and marketing practices for cigarettes. The MSA released the participating manufacturers from past and future claims for costs incurred from smoking related illness but did not include the limiting the ability of individuals to sue. It also required the termination of the Tobacco Institute and for the establishment of the American Legacy Foundation (today called the TRUTH Initiative) which was given authorities to conduct tobacco control programs using tobacco industry payments provided through the settlement.

Right on the heels of the MSA was the filing of a major lawsuit by the US Department of Justice in **US v Philip Morris** in September, 1999. The lawsuit brought serious charges against the tobacco industry under the Racketeer Influenced and Corrupt Organization (RICO) Act. The findings and opinion of the court by Judge Gladys Kessler detailed the 50 years of deceptions and coverup and was another major ‘nail in the coffin’ of the tobacco industry. The opinion and documentation was 1,700 pages in length and provided in depth details about the tobacco industry’s 50 years of deceptions and corruption in their efforts to deceive the American public about the dangers of their products including nicotine addiction (**United States v. Philip Morris USA.,9F.Supp.2d1, D.DC. 2006** ). As Doug Blanke, Executive Director of the Tobacco Control Legal Consortium would sum it up:

“After six years of litigation, nine months of trial, hundreds of depositions and thousands of exhibits, the verdict is in. A highly respected impartial jurist, the Honorable Gladys Kessler of the US District Court for the District of Columbia has studied the evidence and rendered the definitive ruling on the tobacco industry’s fifty-year conspiracy to defraud American and the world.”

Even with all this activity going on, the tobacco companies had been quietly working to develop new ‘safer’ tobacco and nicotine products. In 1988, RJ Reynold’s introduced **Premier** a ‘technologically advanced’ product that heated the tobacco and delivered nicotine as an aerosol. Their problem was that the product tasted horrible and did not provide the satisfaction that smokers expected. **Premier** was followed by **Eclispe** in the 1990’s and is probably the most well-known example of a prototype of some of the tobacco heat- not- burn harm reduction products on the market today. While Reynold’s was spending hundreds of millions of dollars to develop the product, they still were reluctant to voluntarily take the product to an agency like the FDA and were reluctant to engage directly or provide information about their products with those of us in public health. Today I wonder if things might have developed differently if the companies were more *transparent* about their products and willing to share the science and findings. Concerned that these products would be nothing more than another effort by Big Tobacco to again mislead the public, the Coalition on Smoking OR Health (ACS,AHA,ALA) filed petitions with FDA to have them regulated as ‘drug delivery devices’.

**Efforts at early engagement and dialogue**

While the tobacco companies stonewalled even as they worked to develop and market ‘harm reduction products’, the idea of real dialogue and engagement was not totally silenced and important precedents were set. In 1985, former President Jimmy Carter, as part of his decision to establish the Carter Center, invited a small group of stakeholders to be a part of what was, I believe, the first dialogue held by the Center. As President, Carter had not been able to move very far in dealing with the challenges related to tobacco use, as the industry controlled both the legislative and regulatory bodies in Washington. The dialogue was an eye-opening experience for me at the time. But true to form, missing from the dialogue was Big Tobacco who in spite of personal calls to the CEO’s from the President, refused to participate. In a letter of thanks (September 20, 1985) from the President to those of us who did attend, he noted: “The success of the meeting was largely due to the willingness of the parties to put aside their official titles and deal with each other as individuals.” – a sentiment that is critically important today.

In the 1990’s another important series of dialogues took place, organized and conducted by the University of Virginia’s Institute for Environmental Negotiation (today the Institute for Engagement & Negotiation). Called the **‘Southern Tobacco Communities Project’ (1994-2001),** this project would bring the tobacco growers and the public health community into the same room from all of the tobacco states. It was a significant breakthrough and a precedent-setting series of meetings for all involved. But once again the representatives of Big Tobacco refused to attend. Many growers knew that there might be consequences from the tobacco manufacturers for sitting down with the public health community but they proceeded anyway. Many of them knew they were being used as pawns by the companies to help fight legislation that would hurt the cigarette business. In one scenario the companies organized campaigns with growers with the theme of ‘Keep FDA off the farm”. In spite of those efforts the dialogues would lead to a set of *Core Principles* as well as to the establishment of the President’s Commission on Tobacco and the release of a report, **Tobacco at a Crossroad (May 2001**) that would allow the public health community and the growers to move forward with a common policy agenda, one that would support FDA oversight of tobacco as well as providing a ‘tobacco buyout’ for tobacco producing communities.

As the opening paragraph of the report noted, “Tobacco Farmers and their communities are in the midst of an unprecedented economic crisis. At the same time, public concern over the health hazards of using tobacco products is at an all time high. Resolving these two crises will require new, visionary tobacco policy in this country.” For me it was an another ‘enlightening’ moment and important development, as I continued to realize that former and current ‘adversaries’ could in fact sit down and find areas of common ground.

There was another notable meeting/conference involving engagement. That was the conference entitled: **Tobacco Dependence: Innovated Regulatory Approaches to Reduce Death and Disease**, convened by the Georgetown University Center for Drug Development Science and the Food and Drug Law Institute in April of 1998. Included in the conference were a spectrum of stakeholders including Doctors Koop and Kessler (by phone) Others attending the conference were ‘tobacco dependence experts, other interested scientists and clinicians, lawyers, policy makers, representatives from relevant government agencies, and from Congress, pharmaceutical industry representatives, tobacco industry representatives, and members of the press’. These ‘meetings’ and dialogues would suggest possible paths forward for discussing and implementing new approaches for the regulation of tobacco and for tobacco harm reduction.

At no time during this 50-year period did the tobacco companies, very much controlled by their lawyers, express any *serious* interest in having any kind of transparent, honest dialogue, although there were several people from the companies who were ‘intrigued’. They had gone too far down the road of deceptions to go back. Time and time again opportunities were presented but all were rejected. The promises made in the **Frank Statement** were nothing more than meaningless words. It was a ‘war’ that they believed they were winning. A high-level Executive at Philip Morris would later describe their behaviors to me as having a ‘bunker mentality’. They would challenge any and all comers in the courts and would oppose any and all efforts to have themselves or their products regulated.

But ‘change’ and a renewed interest in tobacco harm reduction also seemed to be in the air at the turn of the 20th century.

**Part II – ‘The Times They Are a Changing’- 2000 – 2019 and Beyond**

It is against the backdrop of the previous 50 years that we consider what has happened since the turn of the 20th century and what the coming years might bring in terms of advancing and supporting tobacco harm reduction, or whether we will find ourselves in a continuation of the ‘tobacco and nicotine wars’. I intentionally spent time looking at that 50-year period because those events are deeply ingrained in the minds of many in the tobacco control community (as well as policy makers and the public) not only in the US but globally as well and we can indeed draw some parallels between what happened then and *concerns* being raised about what *might* happen now.

While we have come a long way since 1950 when 50% of the adult population smoked and which is now down to less than 15%, that still leaves over 30 million adults smoking in the United States. And when one looks at the global level, we continue to be confronted with nothing short of a global epidemic.

Following the Master Settlement Agreement in 1998, many felt that a ‘corner’ of sorts had been turned. Some felt it was the beginning of the end for the tobacco companies as they had operated for 50 years. The tobacco industry’s half a century of falsehoods and coverups that had taken the lives of millions of Americans was exposed and the call for regulating the tobacco industry by the FDA and holding the industry accountable grew louder. However, it would be some years before that goal would finally be accomplished (June of 2009).

At the turn of the 20th century one company, Philip Morris, USA (now Altria Client Services) took an unprecedented step and announced that it would support FDA oversight in some form. That announcement, that came in early 2000, took the tobacco control community, policy makers, others in the industry and even the general public by surprise. The announcement of this major shift by one of the tobacco companies who had vehemently opposed FDA oversight, came at a conference at the Reagan Library put together by former Secretary of HEW Joseph Califano in early 2000, where Steve Parrish of Philip Morris and former FDA Commissioner David Kessler actually participated in a program together. From that day on and because of the willingness of two people, who had very differing conflicting views, to ‘engage’ would help change the dynamics of the discussions. It turns out that Mr. Parrish would also meet with numerous leaders on Capitol Hill and at the White House, much to the chagrin of the rest of the tobacco industry.

‘Tobacco harm reduction’ was gaining attention in discussions in the tobacco control community, governmental bodies, and within industry. Technology and innovation were seen as a way of possibly making products less harmful, including reducing or significantly reducing the cancer-causing agents in smokeless non-combustible products. The need for an agency like the FDA to provide the necessary regulatory oversight of tobacco was gaining strength from multiple sides. Growers had come onboard in support of it in the late 1990’s and now one of the major tobacco companies had as well.

**“Clearing the Smoke” - Institute of Medicine Report (2001)**

A landmark report (requested by the Food and Drug Administration) from the prestigious Institute of Medicine, entitled **Clearing the Smoke- Assessing the Science Base for Tobacco Harm Reduction (2001),** would bring the topic of harm reduction front and center. I believe that the issues and topics discussed in that report are as relevant today as they were when the report was released. The Committee appointed ‘to assess the science base for tobacco harm reduction’ was impressive. The report gave credence to the essential need to have all tobacco products regulated including both conventional ones as well as tobacco harm reduction products, referred to in the report as PREPS (potentially reduced exposure products). Stakeholders from all sides provided comments and testimony. The report noted on page 7 as part of the Principal Recommendations that:

* “The committee believes that harm reduction is a feasible and justifiable public health policy – but only if it is implemented carefully to achieve the following objects:

- 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 known, 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 program that emphasizes abstinence -oriented prevention and treatment.

**Food and Drug Administration Oversight of Tobacco becomes a Reality- Entering a ‘New Era’ ?**

In 2009 and after hearings in both the Senate and House and behind the scenes negotiations in Congress for several years, The Family Smoking Prevention and Tobacco Control Act (PL 111-31) was signed into law by President Obama on June 22, 2009, giving the FDA long overdue authorities to regulate tobacco. The passage of this law was nothing short of being truly historic and something that many of us had worked on for several decades. It was partially written and crafted to ‘punish’ and keep the industry ‘in-check’, an industry that had for so many decades knowingly inflicted so much disease and death on society. I have long contended however, that in many areas, including in particular the area of harm reduction, the statute was outdated before the President’s signature was dry and failed to incorporate many suggestions that had been outlined in the IOM, **Clearing the Smoke** report. Section 911, dealing with modified risk tobacco products, seems upside down, making it extremely burdensome to bring new science- based lower risks products into the market while in many ways protecting the cigarette market. Ten years after its enactment, much has been done by the FDA’s Center for Tobacco Products (CTP). But it is clear to me that the statute is in need of review and ***modernization*** after 10 years. Some of what CTP is trying (or required to do by statute) to accomplish in the harm reduction area is like trying to put a square peg into a round hole. I suggest that the FDA/CTP convene a major public dialogue to solicit ideas and views as to how the TCA and CTP’s functions can be *modernized* and streamlined. Such a dialogue could also be convened by a neutral entity like the University of Virginia’s Institute for Engagement and Negotiation.

It cannot be stressed enough that the environment is very different than what we experienced and faced in the second half of the 20th century. The players have changed, the products have changed and will continue to change. Innovation and technology, new entrants into the market place, consumer demands, and competition are forcing us to consider new ideas and new options that can better address the devastating health consequences caused by the deadly toxic cigarette not only in the US but globally as well. We now have regulatory oversight that must continue to evolve and adapt.

As we collectively work to ensure the protections of children and adolescents and to curtail abuses by those who would once again target that audience, we need to also focus our attention on the millions of adult smokers by giving them viable science-based lower risk alternatives**. It is no longer acceptable for anyone to say that that all tobacco (and nicotine) products carry the same risk.** And it hasn’t been for some time. We must be willing to recognize that it is not the ‘tobacco’ (or the nicotine) that kills but rather what one does with the tobacco. Non-combustible forms of tobacco are generally considered to be 90% lower in risk than cigarettes. Yet that information is not being provided to smokers or to the general public.

**FDA announces its new visionary tobacco and nicotine focus (July 28, 2017)**

On July 28th of 2017, the FDA announced long-anticipated changes in the way in which the Center for Tobacco Products would regulate tobacco and nicotine products in a rapidly changing environment. In announcing a new ‘visionary’ nicotine policy, the FDA called for increased engagement and dialogue among stakeholders. They have used such terms as ‘crossroads’, the need to ‘encourage innovation’, the need to regulate products based on the ‘continuum of risk’,the need to ensure that children and adolescents are not targeted or encouraged to use any tobacco or nicotine product, and the need to provide adult smokers with lower risk alternatives. In the press release, the agency said:

“Envisioning a world where cigarettes would no longer create or sustain addiction and where adults who need or want nicotine could get it from less harmful alternative sources, needs to be the cornerstone of our efforts – and we believe its vital that we pursue common ground.”

As part of his remarks outlining the FDA’s new visionary approach to tobacco and nicotine, FDA Commissioner Gottlieb noted:

“To succeed, FDA must be strategic about how to use its tobacco and drug authorities. *To succeed, participants from all sectors in the ongoing harm reduction debate need to take a step back and work together to reach greater common ground*.”

While some progress has occurred, much remains to be done and some feel, including myself, that two years after the July 2017 announcement major pieces of the vision have not gotten the attention they deserve.

**Civil Engagement and Dialogue**

After the passage of the Tobacco Control Act in 2009, many, including myself, saw this as a ‘New Beginning’ or a ‘New Era’. The tobacco wars as we knew them in the 20th century were seemingly over but at the same time there were and still are many battles to be fought and challenges to be confronted. Could/can we avoid the mistakes and missteps of the past and, if so, how? What is the role of the growing spectrum of interests and how could they better engage? At the FDA’s Center for Tobacco Products, the first few years were spent focusing on Congressionally mandated tasks and trying to build the infrastructure of the Center to do its work.

In opening remarks at an FDA/CTP, Tobacco Products Scientific Advisory Committee meeting on March 30,2010, Dr. Lawrence ‘the Bopper’ Deyton, the Director of the CTP, 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.

I also remember in 2013, within a handful of days after Mitch Zeller became the second Director of the CTP, when a question was raised by some in the tobacco control community as to whether the ‘industry’ should be allowed to participate in a scientific workshop that the agency was holding. Tremendous pressure was brought to bear to keep the industry out. Mitch Zeller appeared at the workshop and told those gathered that it was the agency’s position that all stakeholders had a right to be present, express their views and to participate. To his credit and that of the CTP, that is the position that has continued to be pursued.

In spite of the fact that over the last couple of years many in the tobacco control community have renewed and stepped up their efforts to oppose engagement with the tobacco and nicotine ‘industries’ both in the US and abroad, dialogues have continued to be held on many different levels. It seems however, that the more mainstream tobacco control organizations are the most resistant to engagement and almost oblivious to the important and constructive role they could/can play in dealing with challenging issues by participating in civil safe-haven discussions. In spite of that resistance we see an increasing number of different types of dialogues taking place. Here are a few examples.

1. **The Food and Drug Administration/ Center for Tobacco Products:** Numerous workshops on a spectrum of topics have been held and discussion has taken place in including in the Tobacco Products Scientific Advisory Committee (TPSAC). But engagement is an area where more can be done especially given the fact that we are dealing with a ‘rapidly changing environment’ as recently noted by Director Zeller. For example, it has been suggested that rather than having the issue of youth use of e-cigarettes (primarily driven by the attention on JUUL) played out in the media where hype and emotion have dominated the discussion, that a far better approach for discussing the broader issue could have been through a dialogue/ summit sponsored by the FDA, where using independent facilitators, stakeholders would have an opportunity to not only express their views but to also listen to the views of others in a civil way. Such an approach could benefit the rulemaking process not only on this highly charged issue but on other issues as well. Both former Commissioner Gottlieb and CTP Director Zeller have been vocal proponents for dialogue but more needs to and can be done.
2. **Tobacco Merchants Association:** It is interesting that some ten years plus ago it was at these meetings where ‘harm reduction’ started to get specific attention and where we saw not only those from ‘industry’ in attendance but also a significant number of science and health policy people participate - giving keynote presentations as well as participating in panel discussions. It also became routine for senior staff from the CTP to provide updates.
3. **The Food and Drug Law Institute:** When the FDA assumed regulatory authority over tobacco products under the Tobacco Control Act, it was obvious that FDLI would need to add tobacco to its list of topics (drugs, foods, medical devices, cosmetics, etc.) as part of its annual conferences. .Over the last 10 year or so FDLI has provided a safe- haven forum where diverse stakeholders can meet and discuss complex regulatory and policy issues revolving around the subject of tobacco and nicotine. The importance of these meetings and conferences has grown with over 200 people from the US and abroad attending each year, and with the active participation of the FDA itself.
4. **The E-cigarette Summits (London and Washington):** organized and facilitated by Smooth Events have become an important neutral forum for discussion and engagement between stakeholders on complex issues surrounding e-cigarettes. These meetings continue to grow and it is anticipated that they will continue to do so, helping shape policy and regulatory actions both in the US and abroad.
5. The Global Forum on Nicotine (GFN): Now in its sixth year and held annually in Warsaw Poland, the GFN ‘serves as a platform for the exchange and debate on topics’ related to the use of safer alternative forms of nicotine to help people switch from smoking. ‘All are welcome’ and includes ‘academics, researchers, politicians and policy makers, from all sides of the debate.’ This year (2019) more than 600 people from all over the world attended. It is expected that this meeting will continue to be place for civil debate and dialogue.
6. **The Global Tobacco and Nicotine Forum (GTNF):** The GTNF meetings, which began in 2008 and slowly evolved into becoming not just a trade association meeting but has become a meeting where government officials, public health researchers and policy makers, and the media can attend. The issue of tobacco harm reduction and discussions about a ‘changing’ industry continue to be a dominating topic and theme at the conferences.
7. **Society for Research on Nicotine and Tobacco (SRNT):** The SRNT has been in the forefront on bringing scientists and researchers together each year to discuss issues related to tobacco and nicotine. While tobacco and nicotine manufacturers and researchers are allowed to attend the meetings, their participation remains limited to mostly making ‘poster presentations’. Yet they are the ones that are doing a great deal of research on new products as required by an agency like the FDA and as part of its application approval process. One wonders, whether in the coming years, there *might* be carefully constructed panel discussions that include a broader spectrum of researchers and stakeholders.
8. **Coresta (Cooperation Centre for Scientific Research Relative to Tobacco):** Coresta is ‘an association founded in 1956, ruled by French law, the purpose being to promote international cooperation in scientific research relative to tobacco and its derived products’. Its meetings including the Tobacco Science Research Conference provide attendees the opportunity to hear and discuss a spectrum of scientific issues related to tobacco and nicotine. This is an organization that might consider playing a more active and transparent role in supporting dialogue on scientific related issues.
9. **The Institute for Engagement and Negotiation at the University of Virginia:** For a number of years the IEN has held a series of dialogues on issues pertaining tobacco and nicotine harm reduction (These six dialogues are commonly referred to as the *Morven Dialogues.*). I will take moment (below) to provide some details about the Institute’s efforts that began in the 1990’s with the public health community and growers but which then led to a series of six dialogues specifically focused on tobacco and nicotine harm reduction.

**Moving Forward**

While much of the tobacco control community and especially the mainstream organizations both in the US and globally continue to focus on the more traditional and well tested and tried strategies, to the exclusion of accepting and embracing strategies related to harm reduction, I believe that we are indeed at a very important ‘crossroads’. For over ten years plus, we have been operating in an environment that is rapidly changing. Our focus in terms of tobacco harm reduction and regulation should include giving more of a legitimate focus on ‘product development’ and the innovation and technologies surrounding it and less on who is making the product. New non-traditional entrants into the market place, increased regulatory oversight, changes in consumer preferences, and competition are all forcing even the traditional tobacco companies to change their ways. These same elements are also impacting and challenging the traditional thinking of the tobacco control community as is evidenced by the emotional debate and divide over vaping and tobacco harm reduction in general. But as I and others have suggested (for a number of years) this is a ‘NEW ERA’ for which there are many unknowns, challenges and opportunities and which will be shaped by the interaction (or lack of interaction and engagement) of many differing stakeholders.

New leadership and more *transparency* are needed by all sides and should include some level of *‘respect’* for differing views, even if it is only to listen and ask important questions. I encourage colleagues in the tobacco control community to curtail their criticisms of those who have differing views on how to move forward. All share a common goal of reducing disease and death from tobacco use and in particular the combustible cigarette. All share a common view that children and adolescents should not use tobacco or nicotine products and that manufacturers should not target such audiences.

Globally the tobacco and nicotine industries should/must be willing to accept regulatory oversight of all their products based on the risks, relative risks and intended uses of those products (continuum of risk). They must demonstrate that they can and will do more to discourage the use of deadly cigarettes (not just talk about it) in ways that they are not currently doing. They need to commit to supporting efforts to ensure that tobacco and nicotine products are not used or targeted for use by children and adolescents. They need to be providing consumers with cost effective lower risk products as alternatives to cigarettes, especially in the developing world. In effect, they need to more rapidly ‘move the eggs out of their cigarette/combustible basket and put them in the ‘harm reduction basket’.

**(Side Note:** Unlike some, I do not see Article 5.3 of the Framework Convention on Tobacco Control (FCTC) impeding engagement or dialogue where manufacturers or others have an obligation or a need to ‘talk with’ regulators and others in terms of *product regulation and science*. I fully understand why many believe that 5.3 should be interpreted to limit or prohibit engagement, given the tobacco industry’s deceptive behaviors over the years, but there is sufficient flexibly in the language to allow for carefully constructed and focused dialogue to take place in this changing environment. In addition, ‘harm reduction’ is an important component of the FCTC and that should include supporting the development of science-based lower risk products.)

In a similar vein tobacco control must be willing to accept, and acknowledge the fact that THR or as some prefer to refer it, ‘harm minimization’, could, if properly but fairly and timely implemented, significantly reduce the burden of disease and death caused by smoking. They need to publicly acknowledge that not all tobacco products carry the same risks, that there is a significant difference in risk between combustible versus non-combustible products, that innovation should be encouraged and not stifled, and that users of tobacco and nicotine products are provided with truthful and accurate information.

As an example, I find it quite extraordinary that after more than 15 years and general agreement from almost all parties (including regulators) that some in tobacco control would still question the viability that products like Swedish Snus and other low TSNA non-combustible products could have in moving smokers away from the deadly cigarette. And now we are seeing a possible ‘repeat’ of history with vaping products. Vaping products clearly need regulation but we should be careful not to destroy an industry that could help accelerate the demise of the combustible cigarette.

It prompts me to ask, what comes first, the chicken or the egg? Who goes first? Does industry heed the demands of the tobacco control community to stop selling cigarettes before acceptance of lower risk products can be embraced? Or does tobacco control heed the requests of those in the tobacco and nicotine business to allow science- based regulated, lower risk products into the market place as combustible products are phased out? I believe they must happen simultaneously and one way to achieve that is to actually *engage* to see if common ground and a mutual path forward can be found.

Greater collaboration within the broader scientific community and the transparently sharing of ideas and research findings must be encouraged and fostered. Good unbiased science is what should be driving policy and regulatory decisions regardless of who is doing that science. Today’s environment is not as conducive to such collaboration as it needs to be and, unfortunately, there is a great deal of divisiveness even within the public health community itself. Those involved in the scientific research side of the tobacco and nicotine industries should, and must continue to make their science available to regulatory authorities, the public and to other researchers through their websites, through the publication of their research in scientific journals and through other means, including invitations to visit their research facilities. *Transparency* and the willingness to engage may help in building a better relationship in the future.

It would also be useful and helpful to seek agreement and buy-in on what the critical elements are for allowing a THR/harm minimization effort to move forward. This will require not only general ‘agreement’ on some principles but active participation as well. Words are not enough and there is far too much rhetoric on this important topic.

All of the various meetings and conferences I mentioned above are playing a role in fostering discussion on tobacco harm reduction. But there are clearly more opportunities for encouraging dialogue and engagement.

**The ‘Morven Dialogues’ convened by the University of Virginia’s Institute for Engagement and Negotiations**

I want to take a moment to mention the dialogues that have been conducted by the University of Virginia’s Institute for Engagement and Negotiation – commonly referred to as the **Morven dialogues**. I do so as both a past participant in those dialogues as well as someone who has worked with the Institute for Engagement and Negotiations for a number of years. As a result of the six (6) dialogues held by the Institute on issues pertaining to tobacco harm reduction, an updated set of **Core Principles** for moving forward with a THR agenda have been recently published (April of 2019) and can be used by any and all stakeholders (**Civil Dialogue on Tobacco, Nicotine and Alternative Products Harm Reduction- Addressing a National and Global Epidemic, A Product of the Morven Dialogues**). They are not all inclusive but serve as guidance/food- for- thought for assisting those who wish to engage about issues surrounding tobacco harm reduction and who may wish to embrace them conceptually. The Ten Core Principles are:

1. Definitions and Terminologies;
2. Smoking Replacement Products;
3. Regulatory Oversight;
4. Research and Science;
5. Innovation and Technology;
6. Monitoring, Evaluation and Accountability;
7. Consumers and the General Public;
8. Nicotine;
9. Tobacco Agriculture;
10. Engagement and Dialogue.

I encourage all stakeholders who have a serious interest in tobacco harm reduction to review these principles and to consider adding their name to *conceptually* support them. The Core Principles can be accessed at:

<http://morvencoreprinciples.net>

**III Final Conclusions and Observations**

While there seems to be much to digest, what I have outlined is only the tip of the iceberg and is intended to hopefully stimulate further thinking about ***what we have learned from the past, what we are going through in present, and what we can do for the future.*** My forty plus years of involvement in the tobacco and nicotine ‘space’ tells me that we can in fact do more. That the pieces for advancement to significantly reduce the disease and death caused by combustible products are there (and have been) waiting to be assembled. The topic of this article is whether dialogue and engagement are **‘feasible’**. My conclusion is that not only are dialogue and engagement feasible but they have also been occurring for a number of years, and in a number of venues. Because of the rapidly changing environment and the complexities of the issues, they have important and critical roles to play in shaping policy for the future.

In the 21st century we have been dealing with new technologies, new entrants into the market place driven by competitive forces that have accelerated innovation. Adult consumers are demanding and deserve newer lower risk products. They are entitled to truthful and accurate information about those products. While many in mainstream public health seem to be more focused on reviving, reinventing and continuing the ‘tobacco wars’ of the past, I believe our focus should be more on the growing spectrum of **products** and how they can serve as science- based lower risk alternatives to smoking, rather than merely focusing our attention on the manufacturer. We need to get out of our silos and put aside our ‘tribal instincts’ and be more receptive to new opportunities and ideas. While there will be some (maybe many) who will continue to oppose engagement, they should not criticize those who believe that harm reduction dialogue and engagement need to be pursued.

Let’s consider several overlapping primary goals- ones that I believe a broad spectrum of stakeholders can share.

1. Agree that we need to focus our efforts to significantly curtail the use of combustible tobacco products both in the US and globally;
2. Agree that we should encourage the development and use of significantly lower risk alternative products (tobacco, nicotine and alternative products) to serve as replacement products and alternatives to the combustible cigarette and to make those products available as quickly as possible to adult users;
3. Agree that there needs to be a workable and flexible science- based regulatory framework that can adapt and evolve to the rapidly changing environment;
4. Agree that children and adolescents should not use tobacco and nicotine products and that this audience is not targeted to use any form of tobacco or nicotine;
5. Agree that meeting the challenges and taking opportunities for reducing disease and death from tobacco entails greater engagement by a broad spectrum of stakeholders and interests.

**A Personal Note of Thanks:**

While this observational piece highlights some of my own recollections of events, I would be very remiss if I did not acknowledge and thank the dozens and dozens of people who have helped move things forward and who took and are taking leadership roles, often in face of criticism, to make THR a part of the solution rather than be seen as part of the problem and who believe that ‘engagement and dialogue’ are critical components for moving forward. The list is long and diverse but includes many of my colleagues in the public health community, government officials, academic research organizations, manufacturers, tobacco growers, organizations such as the Food and Drug Law Institute, the UVA’s Institute for Engagement and Negotiation, trade associations such as the Global Tobacco and Nicotine Forum, the Global Forum on Nicotine and many more.

**A Few Sources and Suggested Readings for Background and Reference:**

Alliance for Health Economic and Agriculture Development (AHEAD) Ballin, Scott et al, [www.tobaccoatacrossroads.com](http://www.tobaccoatacrossroads.com) Several extensive white papers and presentations may be of interest including:

* “Tobacco and Tobacco Products et a Crossroads in the 21st Century-Reducing the Harm From Tobacco and Tobacco Products; Can Tobacco Modification play a Role?; Seeking Civil Solutions in an Uncivil Environment” (August 2006)
* “The Changing Regulatory Environment of Tobacco, Nicotine and Alternative Products – Time for a More Constructive Scientific Dialogue and Engagement on Modified Risk Tobacco and Nicotine Products” Keynote remarks of Scott D. Ballin before the Food and Drug Administration’s Workshop on the Scientific Evaluation of Modified Risk Tobacco Products (August 25-26 2011)
* “SMOKEFREE” TOBACCO AND NICOTINE PRODUCTS: A Constructive and Practical Road Map Towards a Civil Dialogue to Influence Public and Private Sector Policy Decisions”, November 2007)

Food and Drug Law Institute Journal, Special Issue: *The Conference on Tobacco Dependence: Innovative Regulatory Approaches to Reduce Death and* Disease, Volume 53 Supplement,1998

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