University of Virginia | Institute for Engagement & Negotiation
Shaping Our World Together

Accelerating Actions to Clear the Smoke:
Finding Common Ground in a Polarized World

CIVIL DIALOGUE ON TOBACCO, NICOTINE, AND ALTERNATIVE PRODUCTS HARM REDUCTION

July 1, 2024

The Morven VII Dialogue

Addressing a National and Global Smoking Epidemic

REPORT PREPARED BY THE INSTITUTE FOR ENGAGEMENT & NEGOTIATION

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A NOTE FROM THE DIRECTOR

Dear Friends,

Over the last 20 plus years, the Institute for Engagement & Negotiation (IEN) at the University of Virginia has had the pleasure and honor of convening and facilitating discussions concerning what has been and will continue to be a dynamically rapidly changing environment. The seven Morven Dialogues have provided a "'safe haven'" venue where diverse stakeholders have been willing to set aside their organizational titles and enter into discussions and dialogue with other willing participants, to come to the table in an effort to take on one of the most important continuing public health challenges of our time – not only in the U.S. but also globally.

"...in an effort to take on one of the most important continuing public health challenges of our time..."

The following set of Core Principles, while semi-comprehensive, are not fixed in stone and will continue to evolve. New challenges will be faced and, more importantly, new opportunities will continue to arise and will need to be seized.These principles are intended to provide both guidance and encouragement to all stakeholders to commit to engage and work together in a more transparent and collaborative way. Preventing disease and death of millions of people around the world depends on it. These principles are owned by no one and are intended to be used by all.

I wish to thank all of the many people who have been involved in this ongoing journey and the many perspectives that have been shared around the table. I hope those who were not able to participate will use and widely share the Core Principles, contributing to something that could be historical in its ability to reduce the long-term harm and deaths from combustible products.

A NOTE FROM THE DIRECTOR

Continued

The Institute for Engagement & Negotiation (IEN) wishes to suggest that in addition to the findings and suggestions synthesized from the Morven Dialogues and contained in the 10 Core Principles detailed in this report, several broadly defined areas of common ground may exist, and there may be general agreement on the following:

a. Stepped up efforts are urgently needed to **significantly curtail the use of combustible tobacco products** both in the U.S. and globally;

b. **Children and adolescents should not use any tobacco and nicotine products** and that this audience should not be targeted to use any form of tobacco and nicotine;

c. Development and use of **significantly lower risk alternative products to serve as replacement alternatives to the combustible cigarette** is needed, and these products should be made available as quickly as possible to adult users.

d. **High-quality peer reviewed science is essential** and there needs to be greater engagement between stakeholders and the scientific community.

e. A **workable and flexible science-based regulatory framework** is needed to evolve and adapt to a rapidly changing environment.

f. **Truthful and accurate information about the risks and relative risks** concerning the use of tobacco and nicotine products must be provided to the public, consumers, medical professionals, retailers, the media, and others.

g. Meeting the challenges and taking opportunities to reducing disease and death from tobacco will require **greater engagement and collaboration** by a broad spectrum of stakeholders and interests.

Tanya Denckla Cobb
Director, Institute for Engagement & Negotiation, University of Virginia

“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 it is vital that we pursue common ground…

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.”

- FDA press release and comments of FDA Commissioner Gottlieb, July 2017

“It is important to see the one across from you – who may be your enemy – and see him as a friend waiting to be made.”

- Archbishop Desmond Tutu

“Do I not destroy my enemies when I make them my friends?”

- Abraham Lincoln

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I. MORVEN DIALOGUES: HISTORY & PURPOSE

What are the Morven Dialogues?

In today's increasingly complex, fast-paced, social media driven world we are seeing societies and communities becoming more and more polarized, unwilling to listen or engage with those who may have differing views on a particular issue. Civil dialogue and engagement increasingly have been replaced with strong and often emotional rhetoric. Group-think has become predominant. The tobacco and nicotine space has, unfortunately, not been immune from this trend.

The purpose of the forum for Civil Dialogue on Tobacco, Nicotine, and Alternative Product Harm Reduction and its series of dialogues is to bring stakeholders together in a safe haven environment to discuss a spectrum of issues pertaining to tobacco, nicotine, and alternative harm reduction strategies. The series of dialogues have been convened and facilitated by the UVA Institute for Engagement & Negotiation (IEN). The first, second, and third dialogues were held at Morven Farm, a historic retreat venue located outside of Charlottesville, Virginia (2011-2013). Hence the name, Morven Dialogues. The fourth and fifth dialogues were held in 2014 and 2015 at the National 4-H Center in Bethesda, Maryland. It was decided that a sixth dialogue was needed which was convened in 2018, that time again at Morven.

The forum and its dialogues recognize that some forms of harm reduction should be considered as a viable and urgently needed strategy for reducing disease and death cause by tobacco use. **Its focus has therefore been less on whether harm reduction should be considered a viable strategy, and more on how and with what protections harm reduction may be effectively embraced and implemented, not only in the United States, but globally as well.**

Morven VII (held March 14-15, 2024) was convened to build on the extensive work contained in the Morven VI report. The Dialogue discussed what has changed in terms of the previously identified Core Principles, what new priorities have emerged, and how might the original Morven VI Core Principles (and any changes to them) be more effectively and broadly adopted and implemented.

IEN has appreciated the willingness and input of many individuals who have participated in the Morven Dialogues over the years and who came to the table prepared to not only provide their expert views but to listen to others and engage in civil discussion.

Prior to the Morven Dialogues, the IEN sponsored a series of dialogues in the 1990's between the public health community and tobacco growing communities called the "Southern Tobacco Communities Project" that influenced and facilitated the eventual passage of the Tobacco Control Act legislation (FDA) as well as a tobacco "buyout" that benefitted tobacco growing communities.

II. TOBACCO HARM REDUCTION: WHY IS IT NEEDED?

While progress has been made over the last several decades, the stark reality is that not enough is being done nationally or globally. In the United States, some sixty years after the release of the landmark 1964 Surgeon General's Report:

- Cigarette smoking remains the nation's single most preventable cause of death and disease, accounting for approximately 480,000 premature deaths each year. The are 30 million Americans who still smoke, many of whose lives will tragically be cut short.

- It is estimated that smoking costs the United States approximately $600 billion each year in health care costs and lost productivity.

On the global level:

- There are more than one billion smokers in the world, with an increasing number (80%) of these smokers living in low- and middle-income countries.

- Each year approximately seven million people will die prematurely, making cigarette smoking the single most preventable cause of disease and death globally.

- The United Nations and other domestic and international bodies have made prevention of non-communicable diseases (NCD's), including cancer, heart disease, diabetes, and lung disease, a major global health priority.

The domestic and global epidemic in smoking is alarming in both its magnitude and its escalating prevalence. Despite considerable public health efforts, the reduction of disease and death has been slow, and rates of smoking cessation success, even with nicotine replacement therapy (NRT) assistance, tend be disappointingly low. **If not confronted aggressively and with innovative policies and products, an estimated one billion people will die of smoking related causes during the 21st century. New strategies are urgently needed, and it will take new leadership and visionary thinking to end the smoking epidemic.**

Recognizing that nicotine, though addictive and habit forming for some, is not itself a significant factor in the causation of disease, smokers urgently need access to science-based regulated, lower risk tobacco, nicotine, and alternative products. To achieve this goal, it is necessary to provide the general public, consumers, policy makers, health care professionals, the media and many other stakeholders, with truthful and accurate information about the risks and relative risks, and benefits that can be obtained by switching from a deadly combustible (smoked) tobacco product to a significantly lower risk non-combustible alternative product.

A Sense of Urgency

Just over 20 years ago, the prestigious Institute of Medicine (IoM) released a landmark report entitled "CLEARING THE SMOKE – Assessing the Science Base for Tobacco Harm

WHY IS IT NEEDED?
Continued

Reduction." Amongst the many detailed recommendations in the 500-plus page report were some principal recommendations that remain very relevant to today's environment. Included was a recommendation for the inclusion of harm reduction as a viable strategy for reducing disease and death caused by the deadly cigarette.

Harm reduction is common to many behaviors and activities in our society where we face potential daily risks and is not unique to the area of tobacco and nicotine. We see harm reduction being applied to our foods, legal and illicit drugs, alcohol, automobile safety, environmental pollution and increasingly being considered in the area of marijuana production and use. For many in tobacco control, resistance to harm reduction being applied to the tobacco and nicotine space comes from a deep mistrust of "Big Tobacco" for its decades of lies and deceptive behaviors. Today, the tobacco and nicotine space has changed dramatically. Regulatory oversight of the industry is now in place, serious research is being done, innovation has resulted in the development of new products by a growing spectrum of different manufacturers, and consumers preferences for lower risk products have shifted. As one highly respected public health expert so succinctly put it, "…the past should not be the future in tobacco control."

Today's products in the tobacco and nicotine space not only include the traditional forms of tobacco and nicotine products, but newer innovations including gums, lozenges, vaping products (e-cigarettes), heat-not-burn products, inhalers, and pouches. This ongoing expansion presents new challenges but more importantly new opportunities for reducing the devastating disease and death caused by tobacco at both a national and global level. Applying harm reduction principles can have an impact at many points along the tobacco and nicotine chain – from the growing, curing and processing of the leaf; to the complex manufacturing processes; to the use of new technologies and innovation; and to how a product is regulated, labeled, sold, marketed, and used.

The development and implementation of consistent and effective national and global public health policies that significantly reduce disease and death from tobacco use is going to require the active involvement and leadership of numerous stakeholders, interests, and disciplines working both independently and collaboratively, as well as transparently. This includes government agencies and regulators (such as the FDA, NIH, CDC); public health officials; researchers and scientists; public health NGO's; manufacturers; consumers; policy makers; health care professionals; entrepreneurs; retailers; farmers; and many others. Everyone has an important role to play. Unfortunately, we have seen greater and greater polarization in the tobacco and nicotine space. Change is urgently needed. It's time to consider resetting and reconsidering our efforts.

III. MORVEN VII DIALOGUE: EXECUTIVE SUMMARY

The Institute for Engagement & Negotiation (IEN) at the University of Virginia organized and convened the seventh (7th) Morven Dialogue on tobacco, nicotine, and alternative products harm reduction, held March 14-15, 2024. The dialogue was hosted at Morven Farm, a retreat venue located outside Charlottesville. This Morven Dialogue, like the others before it, was intended to provide a safe haven environment, using a version of the Chatham House Rule, so that the approximately 30 participants could express their views, listen, and civilly engage with each other. The dialogue was managed by professional facilitators from the Institute who have worked on tobacco harm reduction for over twenty years.

The Morven VI report (April 19, 2019), Civil Dialogue on Tobacco, Nicotine, and Alternative Products Harm Reduction, was the product of the first six dialogues, and was used as the primary document for adaptation. Participants were asked to do homework before attending, including reading the Morven VI report to identify what has changed since the Morven VI Dialogue, what new priorities and concerns have emerged, who will be instrumental in implementing the Core Principles, as well as giving some thought to a number of other topics. The IEN also requested that invitees who could not attend provide any thoughts they might have in terms of the dialogue's objectives.

During the day and a half discussion of the Morven VII Dialogue, all of the Core Principles and the details contained in each were reviewed and suggestions made for updating them in many areas. Several areas received a great deal of attention, in part driven by the currently changing environment. (For more details, see Section D: The Core Principles). The following brief summaries reflect some of the key issues and questions that participants discussed.

Definitions and Terminologies (Core Principle # 1)
Much of the discussion focused on the need for better and more consistent definitions and terminologies related to what nicotine is and isn't. Additional thoughts included the need to better define what "addiction" is and isn't, what is meant by "appropriate for the protection of public," as well as many other definitions and terminologies. It was clear that much more needs to be done in this area.

FDA's Center for Tobacco Products/Regulatory Oversight (Core Principle # 3)
There was a great deal of discussion and concern about the ability of the FDA's Center for Tobacco Products (CTP) to do its job in what has been a rapidly and dynamically changing environment. Concern and criticism were not targeted at the hard-working staff of the Center but rather with the lack of leadership needed to develop a more visionary,

modernized regulatory framework to advance the Center's ability on a number of fronts, including harm reduction. While the Reagan-Udall Foundation report made important recommendations for CTP's operational improvements, many participants felt there was a great urgency to do more. The CTP's July 2017 comprehensive plan was something raised by a number of people, suggesting that it should be revisited. Others brought up the need for an independent NASEM report that would update the landmark "Clearing the Smoke" report.

Science and Research (Core Principle #4)
Discussion focused on a number of key points, including how relevant and focused priorities need to be established for scientific research; research should be of the highest quality; bias needs to be removed; misinformation curtailed; there needs to be greater collaboration between both public and private sectors; good science should drive policy decisions; greater attention needs to be given to harm reduction research; and there needs to be greater transparency from governmental agencies such as the FDA, NIH, and CDC, as well as manufacturers.

Innovation and Technology (Core Principle # 5)
Innovation and technology were discussed as major drivers in the development of newer lower-risk alternative products. Many suggested that innovation should be encouraged, not stifled, by the CTP, other governmental agencies, policy makers, or even academic research institutions. The role and needs of consumers were seen as important considerations for where innovation should be focused. The use of new technologies to help prevent youth access to all tobacco products was also raised as something very positive.

Misinformation and the need to provide truthful and accurate information (Core Principle # 7, and also encompassed in numerous other Core Principles)
Discussion focused on the critical need for dissemination of truthful, accurate, and non-misleading, consistent information that will reach all stakeholders including consumers, policy makers, regulators, medical professionals, lower-income underserved populations, the general public, the media, and more. Many emphasized that there needs to be a major collaborative educational effort about what tobacco harm reduction can do to save lives.

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EXECUTIVE SUMMARY
Continued

It was felt that despite FDA Commissioner Califf's effort to make the issue of misinformation a major priority for the FDA, the Center for Tobacco Products has been slow in providing truthful and accurate information to the general public, consumers, medical professionals, and others.

Adolescents and Youth (Referenced and incorporated in numerous Core Principles)
There was recognition and acceptance that the concerns about adolescent use of tobacco and nicotine products are a priority and that this should continue to be a major priority for the CTP, mainstream tobacco control NGO's, manufacturers, retailers, and policy makers at the federal, state, and local levels. Nevertheless, there is also is a need to realistically balance the youth priority issues with addressing the needs of the 30 million smokers in the U.S. This represents a return to the recommendations made in the FDA/CTP July 2017 comprehensive plan.

Global (Referenced and incorporated in numerous Core Principles)
Throughout the two days of discussions many participants reminded the group that the Core Principles should not be seen or applied only in terms of national tobacco harm reduction policies and efforts in the U.S. but applied globally as well, especially in the low to middle income countries (LMICs).

All of the above topics, along with many others, are reflected in greater detail in the refreshed and updated **10 CORE PRINCIPLES** that follow.

IV. MORVEN VII DIALOGUE: CORE PRINCIPLES OVERVIEW

The general public – as well as many stakeholders – lack information and understanding of what is meant by "tobacco harm reduction." Some feel it's a continuation of the decades-long unethical behavior and harmful, disingenuous tactics of Big Tobacco that led to litigation by the attorneys general of 46 states and, ultimately, the Master Settlement Agreement (MSA) in 1998; they fear that "tobacco harm reduction" is a way for the tobacco companies to continue their unethical behavior under the guise of doing good. Others feel that tobacco harm reduction is a moral and ethical imperative for research, innovation, and the development of science-based oriented regulatory polices to significantly reduce premature disease and deaths from smoking both in the United States and globally.

These Core Principles are an effort to address the concerns associated with tobacco harm reduction, while also providing guidance for the creation and implementation of harm reduction policies that can significantly reduce the devastating disease and death caused nationally and globally by combustible tobacco products.

A key aspect of the Morven Dialogue process is that the outcomes of the dialogue are not owned by anyone: i.e., the dialogues are not held in response to a request from a specific client or for use by one specific group. Rather, the following Core Principles represent the collective thinking since 2011 of dozens of scientific, public health, and policy experts who have participated in the dialogues in the hope of reducing premature and preventable disease and death. They are intended for broad use and consideration. To the point, the Core Principles are owned by no one, yet belong to and can be embraced and used by everyone. It is important to see them as not only standalone topics but as *complimentary and interrelated* to one another.

They serve as guiding principles for what are urgently needed on-going efforts to reduce the harm associated with smoking. They represent a framework for moving forward and should be seen as complementary to other existing tobacco control efforts, including preventing all youth access and initiation of any tobacco and nicotine products.

Individuals or representatives of organizations and businesses, researchers, academic institutions, manufacturers, medical professionals, public health NGO's, policy makers, regulators, the media, and many others who believe they can conceptually embrace the Core Principles – all are encouraged to actively and publicly support them, in whole or in part, and to disseminate them to others.

CORE PRINCIPLES OVERVIEW
Continued

The Morven VII Core Principles

Core Principle 01: Definitions and Terminologies: Develop Clear, Useful Definitions and Terminologies to Adapt to a Changing Environment

Core Principle 02: Smoking Replacement Products (SRPs): Recognize, Understand, and Act on the Significant Differences Between Combusitible and Non-Combustible Products

Core Principle 03: Regulatory Oversight: Develop a Regulatory Framework that is Consumer Friendly, Flexible, and Based on Sound Science and Incentives

Core Principle 04: Research and Science: Encourage and Ensure Transparent Collaborative Research of the Highest Integrity to Reduce Consumer Health Risks and Shape Regulatory Policies

Core Principle 05: Innovation and Technology: Encourage and Incentivize the Development and Availability of Science-Based Lower Risk Products

Core Principle 06: Monitoring, Evaluation, and Accountability: Balance Rigorous Oversight with Regulatory Incentives, Flexibility, and Fast-Tracking for Lower Risk Products

Core Principle 07: Truthful and Accurate Information: Consumers, the General Public, and Other Important Stakeholders Deserve Truthful and Accurate Information About Risks and Other Relative Risks of All Products

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Core Principle 09: Tobacco Agriculture: Involve Agricultural Stakeholders in Developing a Communication and Regulatory Framework

Core Principle 10: Civil Dialogue & Stakeholder Engagement

"...the Core Principles are owned by no one, yet belong to and can be embraced and used by everyone. It is important to see them as not only standalone topics but as complimentary and interrelated to one another."

“If you meet a sectary, or a hostile partisan, never recognize the dividing lines, but meet on what common ground remains - if only that sun shines, and the rain rains for both, the area will widen very fast and ere you know it on the boundary mountains, on which the eye has fasted, have melted into air.”

- Ralph Waldo Emerson

“If I always do what I’ve always done, then I’ll always get what I’ve always got.”

- Anonymous

Core Principle 01

Definitions and Terminologies: Develop Clear, Useful Definitions and Terminologies to Adapt to a Changing Environment

Today's domestic and global marketplaces continue to have a rapidly changing environment driven by scientific research, innovation, and technology, the development of new lower risk alternative products, changing consumer preferences, and new entrants into the marketplace.

With these shifting conditions comes the need to constantly review definitions and terminologies. What was once black and white, is today many different shades of gray. In an evolving and often confusing and competitive marketplace like this, and with so many lives hanging in the balance, the goals of achieving harm reduction require that there be clear, accurate, and truthful communications disseminated about the risks and benefits to society. There should be **consistency in definitions and terminologies for purposes of public understanding**, statutory and regulatory consistency, and general relevance – something that is lacking in today's environment.

a. **All tobacco, nicotine and alternative products** including cigarettes, smokeless tobacco, nicotine replacement products (NRT), noncombustible products, vaping products(e-cigarettes), gums, lozenges, snus, inhalers, heat-not-burn products, pouches, tobacco-free nicotine products, **need to be more clearly defined for purposes of public understanding, statutory and regulatory consistency, and general relevance.**

b. **Terms and definitions** such as cessation, nicotine, synthetic nicotine, addiction, habit-forming, therapeutic, smoking, vaping, harm reduction, smoking replacement placement products, safe/safer, modified risk products, current user, dual use, tobacco industry, human rights, youth use, "appropriate for the protection of public health," need to be more clearly defined for purposes of public understanding, statutory and regulatory consistency, and relevance.

c. Governmental agencies (such as the FDA, NIH, CDC), policy makers, non-governmental organizations, health care providers, manufacturers, and consumer organizations **need to work cooperatively and transparently to develop more useful definitions and terminologies**, as well as to transmit and communicate that information in a more consistent manner to consumers, the general public, patients, and other stakeholders.

<u>Recommendation:</u> Consideration should be given to the establishment of an independent working group to undertake this work, composed of individuals representing the scientific and public health communities, consumers, medical professionals, manufacturers, and governmental agencies.

“At first people refuse to believe that a strange new thing can be done, then they can begin to hope that it can be done, then they see that it can be done and all the world wonders why it was not done centuries ago.”

- Frances Hodson Burnett,
A Secret Garden

Core Principle 02

Smoking Replacement Products (SRPs): Recognize, Understand, and Act on the Significant Differences Between Combustible and Non-Combustible Products

A growing spectrum of tobacco, nicotine and alternative products being introduced in both domestic and global markets need to be more appropriately defined (See Core Principle # 1). These products have differing characteristics as well as differing risk profiles, but the majority of the non-combustible products are considered significantly lower in risk when compared with combustible/smoked products. Combustible products include cigarettes, cigars, pipes, hookah, roll-your-own, etc. The non-combustible products should be classified as "Non-combustible Tobacco Nicotine Products" or as "Smoking Replacement Products (SRPs)" to more clearly differentiate them from combustible/smoked classifications. Non-combustible products include but are not limited to smokeless products, Snus, e-cigarettes, gums, patches, lozenges, inhalers, heat-not-burn products, pouches, and tobacco-free products.

SRPs need to be considered as part of comprehensive public health strategies to discourage or prevent the use of combustible products – particularly the cigarette, which is by far in both the US and globally the leading cause of preventable disease and death. This Core Principle articulates some general principles for how SRPs should be manufactured, regulated, sold, labeled, and marketed.

a. All tobacco, nicotine and alternative products should be **proportionately regulated** based on their risks and relative risks (Continuum of Risks). The difference in risks between combustible/smoked products and non-combustible products (SRPs) are significant.

b. Scientifically reviewed lower risk alternative products, which are properly regulated, labeled, distributed, marketed and used, should be considered **"appropriate for the protection of the public health,"** when compared to the combustible cigarette.

c. The public, consumers, and all stakeholders are entitled to **truthful, accurate and non-misleading information** about the risks, relative risks and intended uses of lower risk alternative products, and should be provided such information by governmental agencies, public health organizations, researchers, manufacturers, health care professionals, and the media.

d. It should be **unlawful for all tobacco and nicotine products (including SRPs) to be made available to anyone under the age of 18/21** (in the U.S. age of enforcement is 21). **Marketing and advertising** of these products must **not** be targeted to those under the age of 18/21.

Core Principle 02

Continued

e. SRPs should be **consumer acceptable** and readily available to adults over the age of 18/21. Consumer acceptability of SRPs should responsibly allow the use of flavors. Flavors are not inherently bad (as in the case of flavored NRT products as an example) but they can cause appeal. Therefore, manufacturers coupled with regulatory oversight should specifically, actively, and responsibly avoid using flavor descriptors or target marketing that may impact on youth.

f. **Monitoring and surveillance** of who is using a product and how it is used must be given a high priority by all stakeholders (See Core Principle # 5).

g. The **cooperative development of product standards** should be given a high priority by regulators. SRP innovation should be encouraged not stifled (See Core Principles #3 and #4).

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h. The scientific/regulatory standards for allowing SRPs on the market should be made with the view that there is a reasonable expectation that the products are lower in risk based on the currently availability of scientific evidence. **A more collaborative, transparent approach to the scientific review of SRPs** should be undertaken involving academic research institutions, public health authorities, governmental regulatory and research authorities (Such as the FDA/NIH), and manufacturers.

i. SRPs should **not be actively marketed or promoted** to recruit new users of nicotine.

j. There must be a **coordinated effort to educate** the public, consumers health care professionals, policy makers, regulators, and the media about SRPs and the potential role they can play in reducing disease and death caused by combustible cigarettes. (See Core Principle # 7).

“Two roads diverged in a wood and I - I took the one less traveled by and that has made all of the difference”

-Robert Frost

Core Principle 03

Regulatory Oversight: Develop a Regulatory Framework that is Consumer Friendly, Flexible, and Based on Sound Science and Incentives

A critical aspect for implementing a successful tobacco, nicotine, and alternative product risk reduction program, both domestically and globally, is to regulate these products in a more comprehensive, inclusive, coherent, proportional, flexible, and consistent manner. The role of the FDA's Center for Tobacco Products (CTP) is therefore critically essential. It has been over twenty years since the Institute of Medicine (now a part of NASEM) issued the landmark report "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction."

Much has changed following the issuance of that important report and many believe it may be time for NASEM to do a comprehensive follow-up report, or for CTP or Congress to conduct their own reviews that will bring regulatory policies into the modern world. There was some hope of progress in July of 2017 when a visionary comprehensive tobacco and nicotine plan was announced by then FDA Commissioner Scott Gottlieb and then CTP Director Mitch Zeller. But progress on the numerous recommendations has languished and seven years later stakeholders still find themselves struggling with what a modernized visionary CTP should look like and when that will happen. At the request of the current FDA Commissioner Robert Califf, an operational review of the CTP was conducted by the Reagan-Udall Foundation, but the review only went so far. The staff of the CTP are dedicated employees who do their jobs as effectually and efficiently as they can, in an environment in need of a new, more efficient regulatory framework. Moving forward should take into consideration that:

a. Governmental regulatory bodies (such as the FDA) should **regulate the manufacturing, labeling, distribution, sale and marketing** of all tobacco, nicotine, and alternative products **based on risks and relative risks** (Continuum of Risk) and intended uses with a key goal of benefiting public health.

b. **Sound science**, transparently and in some cases cooperatively developed and shared (as well communicated), has global implications and should provide the **basis for regulations and standards** including the regulations and standards governing harm reduction.

c. Those regulations and standards should **take into consideration the interests and needs of all stakeholders**, including the general public, consumers of tobacco, underserved and minority populations, as well environmental regulatory measures for agriculture, child labor, and sustainability principles.

Core Principle 03

Continued

a. Consideration should be given to regulating all tobacco, nicotine, and alternative products under a **single regulatory authority** (such as FDA styled authority) but ensuring that there is close coordination, cooperation, interfacing, and alignment with other bodies within government.

b. The combustible cigarette should be used as the "**reference product"** for evaluating the risks and relative risks of other tobacco, nicotine and alternative products.

c. Legislative and regulatory bodies should develop **consumer friendly policies and regulations** that ensure that the public, consumers, and users can fully understand the risks and relative risks of products and that deceptive labeling and marketing practices are prohibited.

d. Products that are scientifically established as significantly lower in risk than the combustible cigarette, should be given high priority for **authorization** by the CTP. This would entail **streamlining the approval processes** allowing products meeting certain product standards to be **fast-tracked.** Simultaneously, the CTP should increase its efforts, in coordination with other federal, state and local governmental agencies (as well as those in the private sector), to work cooperatively to **remove illegal unauthorized products** (such as e-cigarettes) flooding the market and **increase fines and penalties** on those who are violating the law.

e. Regulatory oversight must entail both developing and implementing programs designed to reduce and **prohibit youth and adolescent use** of tobacco and nicotine products but in parallel with programs and policies designed to reach adult smokers and other underserved populations.

f. Statutory and regulatory policies should seek to **stimulate and encourage innovation and research**, not stifle it, in developing next generation products designed to reduce disease and death.

g. Regulatory oversight should include **involving a broad spectrum of stakeholders** to participate in open conferences, forums, workshops, and dialogues that will help in designing more effective policies and programs for reducing disease and death.

"Nothing in life is to be feared, it is only to be understood. Now is the time to understand more, so we may fear less."

- Marie Curie

Core Principle 04

Research and Science: Encourage and Ensure Transparent Collaborative Research of the Highest Integrity to Reduce Consumer Health Risks and Shape Regulatory Policies

Sound scientific research has been and will continue to be increasingly essential to the development and implementation of effective regulatory policies governing all tobacco, nicotine, and alternative products – including the development of lower risk, Smoking Replacement Products (SRPs). Concerns have been expressed that there has been an unfortunate increased bias in research, for which peer review has been insufficient. Concerns also have been raised that governmental agencies (such as the FDA/CTP, NIH) are not giving enough attention to the priority-setting processes needed to meet the rapidly changing tobacco and nicotine environment. Additional concerns relate to the misuse of findings of a scientific study (misinformation), such as when they are cherry-picked and used intentionally more for public relations and often predetermined advocacy goals rather than ensuring that sound policy decisions are made. It benefits no one – whether the regulator, consumer, public policy maker, public health community, academic research community, manufacturers, the public, or the media – when the quality of research and the findings fail to meet the necessary high standards.

a. Manufacturers of tobacco, nicotine, and alternative products have an obligation and responsibility to **conduct and use world-class science**, and to follow appropriate scientific protocols used by other industries such as the pharmaceutical industry.

b. In the case of funding to researchers, scientists, and academic institutions in both the public and private sectors, there should be **appropriate and necessary safeguards and protocols** in place to ensure that the research and its results are held to and conducted with the **utmost independence and integrity, including transparency.**

c. Research into the **development of significantly lower risk, science-based products** should be given a high priority in both the public and private sectors.

d. Manufacturers of tobacco, nicotine, and alternative products should make non-proprietary research readily available to regulators, academia, policy makers, the public, and the media by **engaging in transparent dialogues and other communication instruments**, such as scientific journals, press releases, and websites.

Core Principle 04

Continued

e. Research and the **validation of research** by a third party should be a shared responsibility of governmental oversight agencies, tobacco, nicotine, alternative product manufacturers, academic research institutions, public health authorities, and others.

f. There should be greater interaction, including **data sharing and collaborations and a commitment to open science**, between all researchers and scientists, regardless of institutional affiliation.

g. **Publication originating from any source should be encouraged**, so long as the highest standards of research, transparency, and peer review are applied.

“Creativity is thinking up new things. Innovation is doing new things.”

- Theodore Levitt

“Scientists have become the bearers of the torch of discovery in our quest for knowledge.”

- Steven Hawking

Core Principle 05

Innovation and Technology: Encourage and Incentivize the Development and Availability of Science-Based Lower Risk Products

As is happening in other manufacturing sectors, the development of lower risk products, new technologies, innovation, and competition should be encouraged in both the public and private sectors. Historically established industries and new entrants into the marketplace flourish when innovation is encouraged and supported. Innovation, in the form of novel consumer acceptable nicotine delivery devices and products, can play a significant role in reducing the devastating disease and death caused by the combustible cigarette both nationally and at the global level. The visionary comprehensive tobacco and nicotine plan announced by former FDA Commissioner Scott Gottlieb and former CTP Director Mitch Zeller made innovation an important part of the plans of the July 2017 announcement. Yet instead of actively supporting innovation, the FDA/CTP seems to have, knowingly or unknowingly, stifled it. More needs to be done in both the public and private sectors to encourage and promote innovation.

a. Governmental research bodies, manufacturers of tobacco, nicotine, and alternative risk reduction products, and academic research centers should be encouraged to commit increasing amounts of **financial resources for the development of innovative lower risk products**. Those manufacturing significantly more harmful combustible products, such as cigarettes should be incentivized to reprioritize their corporate goals and objectives away from cigarettes.

b. **Concrete incentives** (e.g., tax credits, patent extensions, regulatory support, and prioritization) **should be provided** to nicotine product manufacturers, alternative product manufacturers, the pharmaceutical industry, entrepreneurs, research institutions, and even tobacco growers in the development of noncombustible, science-based smoking replacement products.

c. **Regulations should be flexible** to allow new science-based lower risk products into the marketplace in a more expeditious manner.

d. **New investment capital should be sought** and acquired to support the development of new technologies and product innovations to help reduce the devastating disease and death toll caused by combustible tobacco products.

e. In addition to product development, both innovation and new technologies are now allowing for new ways to **ensure that children and adolescents cannot purchase** tobacco and nicotine products. Such innovations need to be supported by both the public and private sectors, including by the FDA/CTP, public health authorities, policy makers, convenience and vape store owners, and many others.

“Success has nothing to do with what you gain in life or accomplish for yourself. It’s what you do for others.”

-Danny Thomas, Entertainer and Founder of St. Jude’s Hospital for Children, Memphis TN

“Knowledge is what we get when an observer, preferably a scientifically trained observer, provides us with a copy of reality that we can all recognize.”

- Christopher Lasch

Core Principle 06

Monitoring, Evaluation, and Accountability: Balance Rigorous Oversight with Regulatory Incentives, Flexibility, and Fast-Tracking for Lower Risk Products

Regulatory oversight of all tobacco, nicotine, and alternative products will require that the sale, distribution, and marketing of these products be consistently monitored and evaluated, with results providing assurance of efficacy and reduced risk. Rigorous monitoring, evaluation, and enforcement can provide an effective mechanism to address concerns with fast-tracking the approval of science-based reduced risk products. There continues to be concern that the FDA's Center for Tobacco Products (CTP) has been slow in reviewing, evaluating, and authorizing the allowance of science-based noncombustible products into the marketplace – products that when used as intended could provide smokers access to significantly lower risk products when compared to the combustible cigarette. Consideration should be given to the following principles.

a. All tobacco, nicotine, and alternative products should be **rigorously monitored in order to assess the health and behavioral effects** of using such products, including the effects on adults, as well as on adolescent use.

b. Science-based lower risk products should be considered for **fast-tracking authorization and approval** where there is a reasonable expectation, based on the science, that the products will reduce exposure to tobacco toxicants and/or reduce the risk of tobacco related disease.

c. Regulatory bodies (FDA/CTP) should provide the leadership for **developing a rigorous but flexible monitoring and surveillance system,** conducted with governmental oversight and including the active involvement, cooperation, and collaboration with various stakeholders. This includes tobacco, nicotine, and alternative product manufacturers, wholesalers and retailers, public health authorities at the state and local, other governmental agencies such as the Centers for Disease Control (CDC), the Federal Trade Commission (FTC), consumers, labeling and marketing experts, and others.

d. **Coordinated and cooperative efforts should be given high priority to monitor** the use of tobacco and nicotine products by children and adolescents. These efforts must also include looking at how these products are being used by the adult smoking population who cannot quit and are looking for other viable lower risk products.

Core Principle 06

Continued

e. Where scientific evidence, such as well-designed and analyzed survey data, demonstrates that the sale and marketing of a product is having unintended consequences leading to increased harm, appropriate steps should be taken to **expeditiously correct such unintended consequences**, including the removal of the product from the market if necessary.

f. Where it is determined that a manufacturer has intentionally not met its obligations under a statute or regulations, **enforcement measures must be quickly implemented** and appropriate penalties assessed.

“Do not follow where the path may lead, go instead where there is no path and make a trail.”

- Ralph Waldo Emerson

Core Principle 07

Truthful and Accurate Information: Consumers, the General Public, and Other Important Stakeholders Deserve Truthful Information About Risks and Relative Risks of all Products

In today's social media-driven environment and with society increasingly polarized over many different issues, misinformation has become an important issue, urgently needing to be addressed. This is the case for the tobacco and nicotine space where confusion continues to reign. Consumers and users of tobacco, nicotine, and alternative products should be provided with trustworthy science-based information necessary to understand the risks and relative risks of the wide spectrum of tobacco and nicotine products on the market. Despite substantial efforts to promote cessation, many users of combustible, smoked tobacco products continue to smoke. Smokers and tobacco users, the public, the medical profession, many public health organizations, policy makers, and the media – all continue to believe that all tobacco and nicotine products are equally harmful, and that nicotine is a major cause of cancer, cardiovascular disease, and other ailments.

Misinformation has become so serious that FDA Commissioner Robert Califf has made correcting misinformation and providing the public with truthful and accurate information a major agency priority, with the expectation and hope that public confidence in the agency can be restored. To date, however, the FDA's Center for Tobacco Products (CTP) has done little in this area. The concerns are not just for misinformation in the U.S. but apply equally to misinformation being spread around the globe. Closing the deep divide of access to truthful information is important for public health and should reflect the following principles.

a. The general public, health care professionals, users of tobacco and nicotine products, policy makers, and the media are **entitled to accurate truthful, science-based and understandable information about risks, relative risks, intended uses, and benefits of switching away from the deadly combustible cigarette**. The combustible cigarette remains the single most preventable cause of death and disease in the U.S. Moving away from the combustible cigarette to "cleaner" forms of nicotine offers an order of magnitude lower risk than the cigarette, and in some cases reduces risk of death and disease by more than a 90%.

b. **Consistent messaging of information should be provided** by governmental agencies at the federal, state and local levels, by public health organizations, and by the medical profession. The messaging can be achieved through convenience stores and vape shops, consumer-oriented outlets such as pharmacies and grocery stores, manufacturers, academic institutions, and many others.

Core Principle 07

Continued

c. **Users and potential users** of tobacco, nicotine, and alternative products – including underserved populations – **should be consulted and actively involved in the development of policies and programs**. This would include but not be limited to determining what kinds of information would be most useful to them and how that information might be effectively transmitted.

d. Governmental agencies at the global, national, state, and local levels – along with other public and private sector stakeholders – should provide urgently needed **leadership** to correct the damaging misinformation campaigns that are doing more harm than good. Everyone has an **ethical responsibility for ensuring that information is truthful, accurate, science-based,** and is provided in a manner appropriate to the target audience.

"The greatest leader is not necessarily the one who does the greatest things. He is the one that gets people to do the greatest things."

-Ronald Reagan

"Leadership and learning are indispensable to each other."

- John F. Kennedy

Core Principle 08

Nicotine: Communicating Truthful and Accurate Information about the Risks, Relative Risks, and Possible Benefits of Use of Nicotine

The issue of nicotine, what it is and what it isn't, has become a hot topic in recent years. As part of any effort to provide the public, consumers, health care professionals, policy makers, and others with truthful information about the risks and relative risks (i.e., the continuum of risk) of tobacco, nicotine, and alternative products, special attention should be given to ensuring the communication of truthful information with respect to the difference between smoking the combustible cigarette and nicotine.

Nicotine is known to be highly addictive for some people, and considered by many as not benign. There is broad agreement that nicotine should not used by any youth or adolescent. However, it is not widely understood that the major cause of death and disease is the combustion of tobacco, i.e., the combustible cigarette. A very large portion of consumers and the general public, along with expert policy makers, and even medical professionals, continue to mistakenly believe that all tobacco and nicotine products are equally harmful, and that the major cause of cancer and other diseases is the nicotine.

Adult smokers are entitled to know about the availability of significantly lower risk forms of nicotine, delivered through cleaner, noncombustible products, including the use of synthetic nicotine, to help break their addiction to cigarettes. As former U.S. FDA Commissioner Scott Gottlieb has noted in articulating the FDA's comprehensive visionary announced in July of 2017, **"While it is the addiction to nicotine that keeps people smoking, it is primarily the combustion, which releases thousands of harmful chemicals into the body at dangerous levels, that kills people."** Unfortunately, the FDA's Center for Tobacco Products (CTP) has been slow in its efforts to educate the public, consumers, and other stakeholder about nicotine. An urgently needed more useful regulatory and educational framework related to nicotine should include the following.

a. Nicotine, naturally occurring in the tobacco leaf, or synthetically produced, is an addictive substance and in high doses can cause significant harm. However, **in doses that are currently used by consumers, evidence indicates that nicotine is not a cause of cancer nor a significant factor in other diseases.**

b. Because of concerns about the effects of nicotine on children and adolescents, **no one under the age of 18/21 should use nicotine in any form**. This includes ensuring that laws and regulations governing the sale and distribution of these products are **strictly enforced** and that the marketing of these products is not targeted at adolescents.

Core Principle 08

Continued

c. It is the method of nicotine delivery that causes the overwhelming disease and death from tobacco use. **Combustible, smoked products account for the overwhelming disease burden both nationally and globally**, making cigarettes the single most preventable cause of disease and death. Cigarettes are unfortunately the most available, most addictive, and most toxic of all nicotine containing products.

d. Cleaner forms of **nicotine delivery in noncombustible forms** have been developed, with more in the pipeline; these **should be made available to adult smokers as both cessation therapies and as noncombustible smoking replacement products**. If such consumer-acceptable products are made readily available, a complementary strategy for reducing the levels of nicotine in combustible products to nonaddictive levels should be considered and implemented.

e. Nicotine derived from tobacco has long been used in patches, gums lozenges, inhalers, and other "Nicotine Replacement Therapies" (NRT) products, as a means of helping cigarette smokers quit the use of cigarettes. The evidence indicating the **relative safety of nicotine use in these products is longstanding and significant.**

f. The public, users of tobacco and nicotine products, and other stakeholders are **entitled to truthful and accurate information about the risks, relative risks, and intended uses of nicotine products** (i.e., a nicotine "continuum of risk"). This information should be provided to the public, consumers and other stakeholders in a consistent and truthful manner. Governmental agencies such as the FDA, CDC, WHO, public health organizations, policy makers, manufacturers, academic institutions, health care professionals, the media, and others should be involved in the dissemination and distribution of truthful information about nicotine;

g. A clearer assessment needs to be completed of **where nicotine fits into a "continuum of drug risks" of both legal and illegal drugs, and their health and behavioral impact on society** (e.g., alcohol, amphetamines, caffeine, cocaine, opioids, cannabis, heroine, sugar, prescription, and OTC drugs). Currently, the general public seems to have been given impression that nicotine may be far dangerous than other drugs.

Core Principle 08

Continued

h. Educational efforts on the risks and relative risks of alternative nicotine products should include the **enhanced truthful labeling of products and public education/media campaigns** in both the public and private sectors, including package inserts, the use of social media and various websites, and publication in scientific journals. This should be an effort coordinated with all stakeholders in conjunction with the Center for Tobacco Products.

i. No nicotine product should be used during pregnancy except under advice of a health care practitioner.

j. For some users, nicotine provided in non-combustible delivery products **may have a positive effect on cognitive processes, motor coordination, concentration, and memory.**

k. And finally, governmental agencies, both nationally and globally should be encouraged to establish **more flexible, visionary regulatory frameworks** similar to the one articulated by the U.S. Food and Drug Administration in July 2017.

"People smoke for the nicotine, but they die from the tar."
- Scientist Michael Russell, 1976

"... 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 it is vital that we pursue common ground..."

-FDA Press release and Comments of FDA Commissioner Gottlieb, July 2017

“Never doubt that a small group of thoughtful committed citizens can change the world. Indeed, it is the only thing that ever has.”

- Margaret Mead

“You cannot shake hands with a clenched fist.”

- Indira Ghandi

Core Principle 09

Tobacco Agriculture: Involve Agricultural Stakeholders in Developing a Communication and Regulatory Framework

Agriculture is often left out of consideration at both the global and national levels when discussing harm reduction efforts, but it has an important role to play in how low-risk products are developed and manufactured. The growing and production of tobacco plays a critical role in the tobacco harm reduction movement. Consideration should be given to the following principles.

a. **Public health agencies and authorities** in both the public and private sectors, as well as manufacturers, **should work cooperatively with agricultural agencies and authorities** in developing fair but effective science-based quality controls and health and safety standards to produce tobacco (growing, curing, and processing).

b. Grower organizations, producers, agronomists, academic research institutions, and agricultural extension services, both nationally and globally, need to be actively involved in working with governmental organizations in efforts to **establish fair but effective standards that reduce the harm** caused by tobacco leaf and produce lower risk products.

c. Concerted and organized efforts must be undertaken to **assist growers in transitioning out of the production of tobacco** and/or in assisting growers into transitioning to a new system of production that makes risk reduction a priority.

d. Tobacco grown for harm reduction products **should be grown using Good Agricultural Practices 2 (GAP2)**, which are designed to ensure environmentally sustainable growing and labor practices. These practices must be consistent with national and international laws governing the use of child labor.

"Science and technology coupled with improved human capital have been powerful drivers of positive change in the performance and evolution of smallholder systems."

- Food and Agriculture Organization of the United Nations

“Please accept my thanks for participating in the Carter Center’s first symposium on conflict resolution....

The success of the meeting was largely due to the willingness of the parties to put aside official titles and deal with each other as individuals.

I was personally moved by the genuineness of spirit of cooperation. Our meeting at Calloway Gardens will be an experience long remembered by all of us.”

-Excerpt from a letter to participants in the first symposium from President Jimmy Carter (1985)

Core Principle 10

Civil Dialogue and Stakeholder Engagement: Engage in more frequent dialogues in both public and private sectors with broader representation

Reducing disease and death from the use of tobacco, and most importantly from the use of deadly combustible forms of tobacco on a national and global basis, will in part depend on a willingness of stakeholders to develop, maintain, and expand new relationships and provide the necessary leadership. Words and subsequent actions do matter. If understanding and possible collaborations are to be fostered and solutions found, then it is important that stakeholders avoid portraying difficult issues in an overly simplistic "us vs. them" manner. In this dynamically changing environment, there is a continuing need to civilly engage in more frequent dialogues in both the public and private sectors with a broader representation of stakeholders, at multiple levels and in multiple venues.

a. All stakeholders and other experts – including but not limited to governmental agencies, public health organizations, tobacco, nicotine, and alternative product manufacturers, consumers, academic researchers, and others – **should be encouraged to engage in civil dialogues** on a spectrum of issues.

b. It will require new **leadership and a willingness** on the part of participants to not only provide their views but to also be willing **to listen and learn** from the views of others.

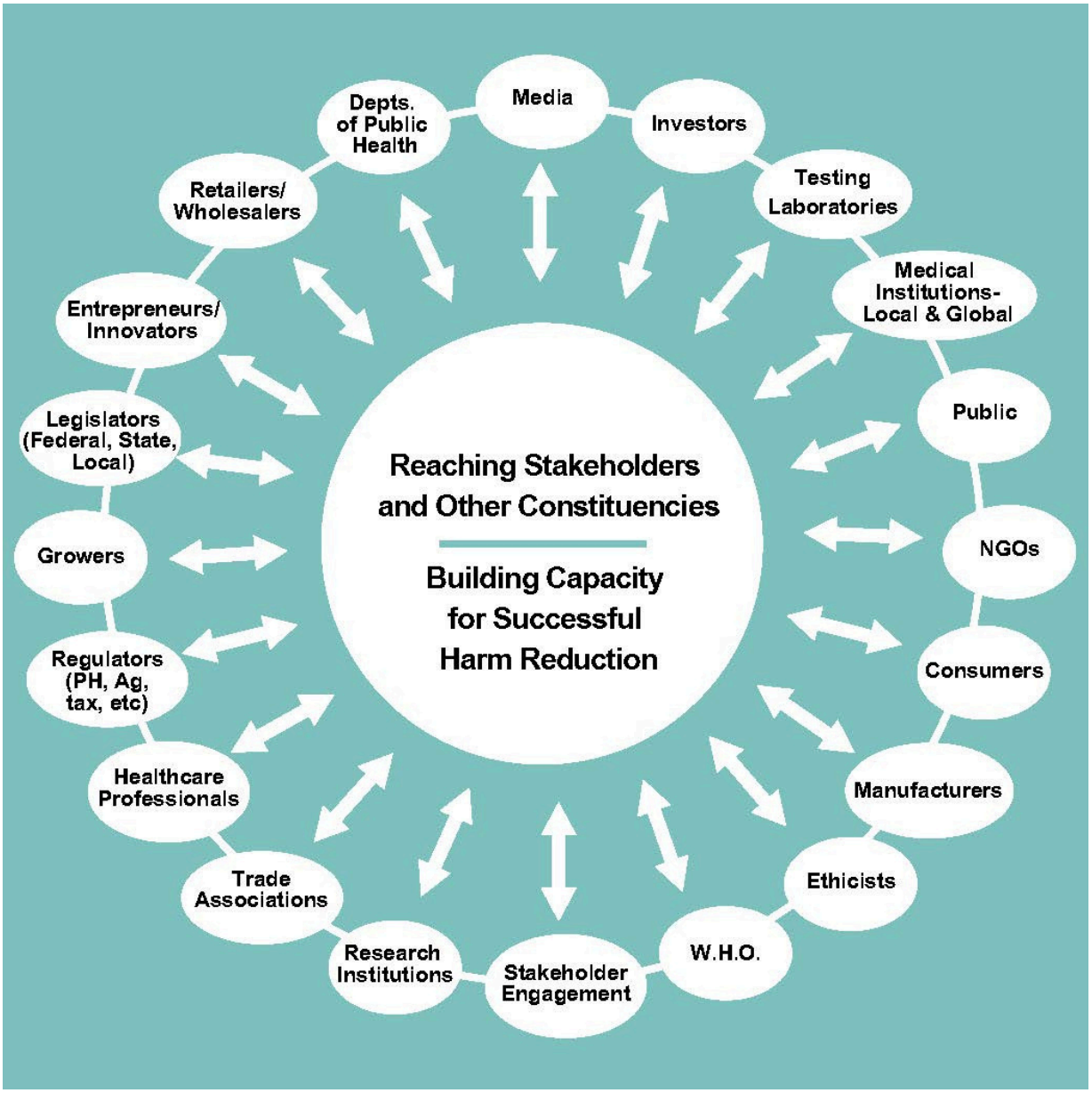
c. Where adversarial situations exist, such engagements should be in venues that are considered **safe havens for discussion,** and where transparency and civil dialogue can be applied with the assistance of unbiased facilitation.

d. While there will be some who will oppose civil engagement and dialogue, they should do so while **respecting** those who legitimately believe that civil dialogue and engagement can make a difference.

e. **Dialogues can take place in many differing venues, and at many different levels in both the public and private sectors**. Such venues include governmental agencies such as the Food and Drug Administration (FDA) and the World Health Organization (WHO); academic institutions; public health and scientific conferences, such as the Society for Research on Nicotine and Tobacco (SRNT) and the Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA); trade association meetings such as the Global Tobacco and Nicotine Forum (GTNF); the Global Forum on Nicotine (GFN); E-Cigarette Summits in London and Washington DC; and venues like the Food and Drug Law Institute (FDLI) and the IEN's Morven Dialogues.

Opportunities abound.

Impacted and Influential Stakeholders To Be Engaged In Ongoing Civil Dialogue



Glossary of Acronyms

AHA - American Heart Association

ACS - American Cancer Society

ALA - American Lung Association

CDC - Center for Disease Control

CTFK - Center for Tobacco Free Kids

CTP - Center for Tobacco Products (FDA)

FDA - Federal Drug Administration

FDLI - Food and Drug Law Institute

FTC. - Federal Trade Commission

LMIC - Lower-to-Middle Income Countries

IEN - Institute for Engagement and Negotiation

GAP2 - Good Agricultural Practices 2

GFN - Global Nicotine Forum

GTNF - Global Tobacco and Nicotine Forum

NASEM - National Academy of Science, Engineering + Medicine
(formerly Institute of Medicine)

NIH - National Institutes of Health

NRT - Nicotine Replacement Therapy

MSA - Master Settlement Agreement

SRP - Smoking Replacement Products

SRNT - Society for Research of Nicotine and Tobacco

TCA - Tobacco Control Aact

WHO - World Health Organization

Mission

We facilitate shared solutions through equitable collaboration, research, and training.

Vision

We envision resilient, just, and healthy communities.

Values

Service ~ Justice and Equity ~ Conflict Transformation ~ Inclusive and Innovative Process Design ~ Education

Services

Consensus Building
Conflict Management
Equitable Collaboration Processes
Community + Stakeholder Engagement
Community-Based Research
Strategic Planning
Training

Professional Affiliations

US EPA, Conflict Resolution and Services Contract Roster
US DOI, Collaborative Action and Dispute Resolution Practitioner Roster
Association for Conflict Resolution
University Network for Collaborative Governance
National Coalition for Dialogue & Deliberation

IEN Core Team

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***Robierre Nderitu**, Fiscal & Project Mgr.*

A nationally recognized leader in fostering **collaborative change**, IEN is a public service organization of the University of Virginia. Our team of facilitators and mediators assists organizations, agencies, industry, and communities in making bold, sustainable decisions across a broad range of environmental, social, and economic issues.

IEN has deep experience designing and facilitating collaborative processes around community engagement, consensus building, multi-party mediation and negotiation, and conflict transformation. We are also experts in leadership training, strategic planning, programmatic evaluation, and participatory qualitative research. IEN is respected for our commitment to equitable processes and outcomes.

Philosophy

IEN seeks common ground to bring about uncommon solutions. Our collaborative processes lead to more creative and effective shared solutions to public issues. Our emphasis on equitable and inclusive processes also yields greater understanding and builds critical legitimacy for solutions. We help our clients engage impacted communities and broaden their networks. IEN practitioners are responsible to those who convene these processes, those who participate, and to the general public. IEN promotes openness, inclusion of all perspectives, and respect for the time and efforts of all participants.

Approach - Equitable Collaboration

IEN's approach ensures that all voices are heard in the process. We pay attention to which voices are privileged, how group dynamics shape decisions, and where productive conflict can be transformative. Our commitment to equitable collaboration means that we respect the time and expertise of all participants, strive for genuine inclusion, aspire to provide trauma-informed facilitation, flexibly adapt processes to changing contexts, and aim to support groups in reaching their outcome and process goals.

IEN's approach centers equity in the process. The six principles of Equitable Collaboration, a framework developed by IEN over the course of three years with input by a diverse array of experts and advisers:

Trauma-informed
Focus on relationships, and prepare and support people in ways that prevent, minimize, or mitigate renewed trauma

Inclusive
Reach all segments of a community, and account for racial, ethnic, gender, class and other dynamics to ensure meaningful participation

Responsive
Acknowledge and respond to community questions, needs, concerns and ideas in timely and meaningful ways

Truth-Seeking
Invite honest, complete histories, even when such histories are painful to hear and understand

Deliberative
Foster brave spaces where participants honestly and openly confront past and present, for learning, growing, and shared civic thinking

Adaptive
Develop appropriate goals and process for each situation, while adjusting as circumstances change

Professionalism IEN adheres to the *International Association of Public Participation (IAP2) Code of Ethics* and *Core Values*, and *Association for Conflict Resolution* (ACR) *Ethical Guidelines for Environment and Public Policy Members*.