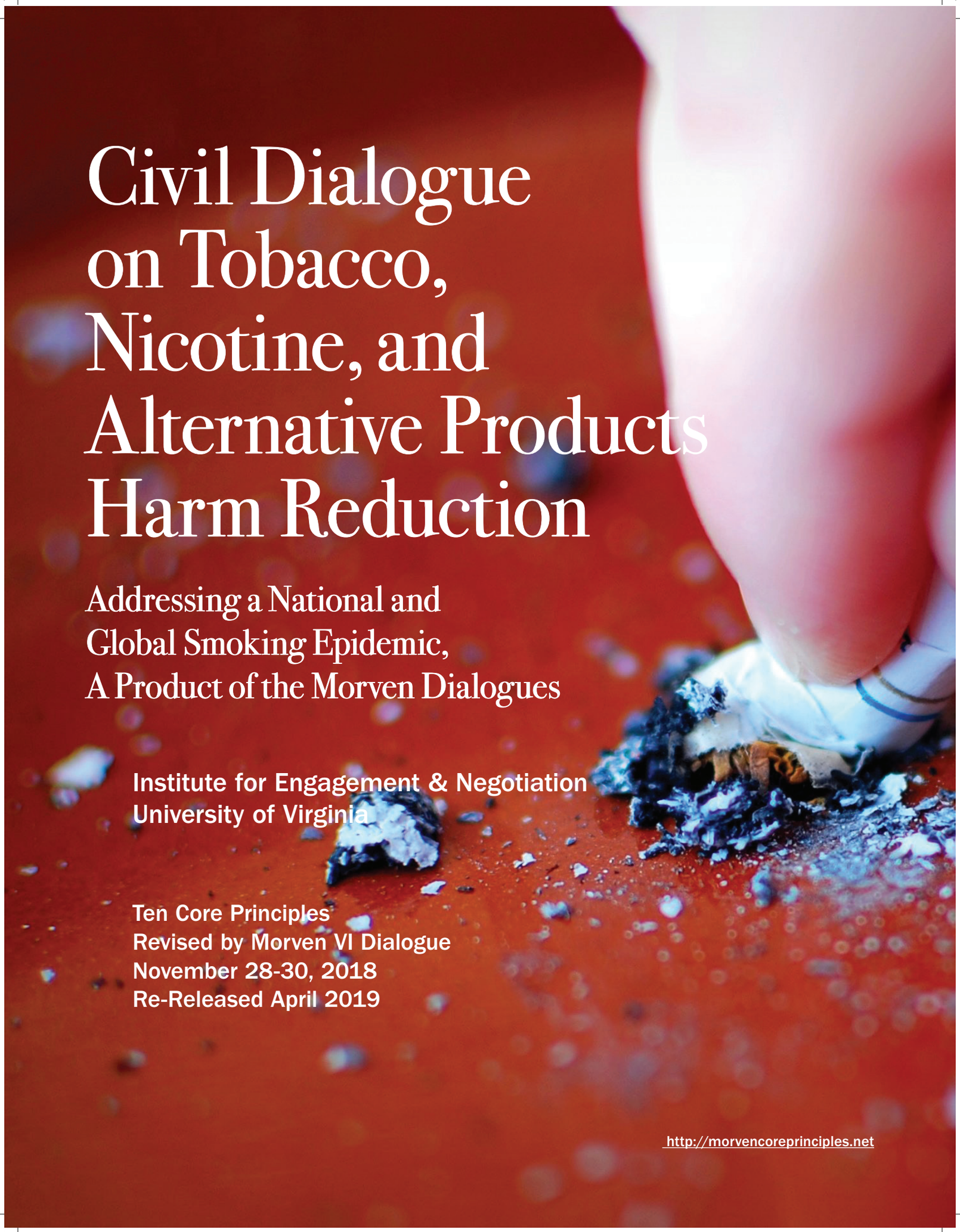

Civil Dialogue on Tobacco, Nicotine, and Alternative Products Harm Reduction

Addressing a National and Global Smoking Epidemic, A Product of the Morven Dialogues

Institute for Engagement & Negotiation
University of Virginia

Ten Core Principles
Revised by Morven VI Dialogue
November 28-30, 2018
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http://morvencoreprinciples.net

Report prepared by the
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The Morven VI Dialogue

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 to discuss a spectrum of issues pertaining to tobacco, nicotine, and alternative products harm reduction strategies. The dialogues were convened and facilitated by the UVA Institute for Engagement & Negotiation (IEN).[1] The first dialogue was held in March 2011 at Morven Farm, a historic retreat venue located outside of Charlottesville, Virginia. The second and third dialogues were also held at Morven, hence the name "Morven Dialogues." The forum and its dialogues recognize that some forms of harm reduction will be part of a viable strategy for reducing disease and death caused by tobacco use. Its focus is therefore less on whether harm reduction should be considered a viable strategy and more on how – and with what protections – it may be effectively implemented, not only in the United States but globally as well.

The fourth and fifth dialogues were held in 2014 and 2015 at the National 4-H Center in Bethesda, Maryland, and built on the earlier dialogues which resulted in a revised set of Core Principles released in January 2016. Because of what has been a dynamically changing environment, both in the US and globally, it was decided that a sixth dialogue should be held, this time again at Morven in November 2018, to review the Core Principles and to modify and amend them appropriately. As with all previous dialogues, the sixth Morven Dialogue focused on updating the Core Principles in a way that can be used by all stakeholders to help guide ongoing and future important discussions to develop and implement effective and workable policies and objectives.

The IEN has appreciated the input of many individuals who have participated in the Morven Dialogues over the years and who came to the table prepared to engage in civil discussions.

**Prior to the Morven Dialogues, 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 facilitated the eventual passage of the FDA tobacco legislation as well as a tobacco "buyout."*

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[1] The IEN was formerly the Institute for Environmental Negotiation. Its new name, given in 2019, better reflects its evolving mission.

“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

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Executive Summary

There are an estimated one billion smokers worldwide, with the overwhelming majority living in low and middle-income countries. A staggering seven million of these smokers will die prematurely this year. If not confronted aggressively and with innovative policies, an estimated one billion people will die of smoking related causes during the 21st century. Today, there are a growing number of science-based significantly lower risk tobacco, nicotine, and alternative products being developed and put on the market that could have a notable impact in reducing the devastating disease and death caused by cigarette smoking. These include but are not limited to a growing range of products such as snus, gums, lozenges, and a variety of electronic delivery systems. The Core Principles were originally produced and published in October 2013, amended in January 2016, and now in February 2019.

April 2019

The Ten Core Principles that have been Identified by the Morven VI Dialogue Participants

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

There is an urgent need to better define and understand the growing number of tobacco, nicotine, and alternative products on the market (and being developed) and to communicate truthful and accurate information about these products to all stakeholders in a more consistent manner – including their risks, relative risks, and intended uses.

2. Smoking Replacement Products (SRP's): Recognize, Understand, and Act on the Significant Differences Between Combustible and Non-Combustible Products

A growing spectrum of tobacco and nicotine products being introduced into the global market place need to be more appropriately defined (see Core Principle #1). Although these products have differing characteristics, they all can be considered lower risk non-combustible products. This Core Principle further suggests that non-combustible products be collectively classified as Smoking Replacement Products (SRP's) to further distinguish them from the more traditional forms of harmful combustible smoked products such as cigarettes.

3. Regulatory Oversight: Develop Consistent, Science- Based, Consumer Friendly, and Incentive-Based Regulatory Framework

All tobacco, nicotine, and alternative products should be regulated based on the risks, relative risks, and intended uses of the products (continuum of risk). This should include such areas as labeling, marketing, sales and distribution, and product standards and taxation. Consideration should be given to regulating products under a single regulatory authority (or at a minimum with close collaboration between authorities). Legislative and regulatory policies should be consumer-friendly and based on sound science.

4. Research and Science: Encourage Transparent, Collaborative Research of the Highest Integrity to Reduce Risks

Scientific research will be increasingly essential to the development and implementation of effective and workable regulatory policies for overseeing all tobacco, nicotine and alternative products. Greater collaborations between the broader research community that includes academic research institutions, public health authorities, product manufacturers, and governmental agencies should be promoted. Research should be made available and disseminated, including publication in scientific journals, using the highest standards of research, transparency, and peer review.

5. Innovation and Technology: Encourage and Incentivize Lower Risk Products

New technology and innovation should be encouraged in both the public and private sectors. This should include a commitment from governmental bodies and manufacturers to devote a greater amount of financial resources to developing science-based lower risk products. It should also include providing concrete incentives (such as tax credits, patent extensions, and flexible regulatory policies) to tobacco growers, tobacco, nicotine, and alternative products manufacturers, entrepreneurs, and research institutions.

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

Regulatory oversight of all tobacco, nicotine, and alternative products should require that the sale, distribution, and marketing of these products be monitored and evaluated to assess the health and behavioral effects of using such products on both the individual and the broader population. This is particularly important to preventing the initiation and use of tobacco and nicotine products by underage populations. Science-based lower risk products should be allowed on the market if there is a reasonable expectation that the product will reduce exposure to tobacco toxicants and/or reduce the risk of tobacco related disease. Rigorous monitoring, surveillance, and enforcement can provide an effective bridge to address concerns with the potential fast-tracking of reduced-risk products.

7. Consumers and the General Public: Involve Those Impacted by Decisions in Developing Communication and Regulatory Framework

Consumers and the general public should be provided with accurate, science-based, and understandable information to better understand the risks, relative risks, and intended uses of the various spectrum of products on the market. Consumers who are at risk of disease and death need alternatives that are affordable, accessible, and acceptable. Consumers should also be actively consulted and involved in the development of policy and regulations.

8. Nicotine: Communicate Truthful and Accurate Information About the Risks, Relative Risks, and Possible Benefits About the Use of Nicotine

As part of any effort to communicate truthful information about the risks and relative risks of tobacco and nicotine products, special attention should be given to include the communication of truthful information with respect to nicotine. While nicotine is highly addictive and not benign, and no child or adolescent should use any nicotine product, a large portion of the both the public and of smokers continues to believe that all tobacco and nicotine products are equally harmful, and that nicotine is the major cause of cancer. Adult smokers are entitled to know more about the availability of “cleaner” and safer forms of nicotine products to help break their addiction to cigarettes.

9. Tobacco Agriculture: Involve Agriculture Stakeholders in Developing Communication and Regulatory Framework

Tobacco producers should be actively involved in working with public health authorities, agriculture authorities, and other policy makers in both the public and private sectors. This includes the development of science-based quality controls and health and safety standards to produce tobacco. A more concerted and cooperative effort should be undertaken to help growers transition out of the production of tobacco and/or assist growers in transitioning to a new system of production that makes risk-reduction a priority.

10. Engagement and Dialogue: Encourage Civil Dialogues with Broad Stakeholder Involvement

There is a need for greater civil engagement between a growing number of stakeholders and experts that includes governmental agencies, public health organizations, tobacco, nicotine and alternative product manufacturers, researchers, consumers, health care professionals, laboratory testing facilities, retailers and wholesalers, and agricultural interests. Engagement should be encouraged in both public and private sector venues.

A full copy can be found online at: www.virginia.edu/ien/tobacco

Preamble

According to the World Health Organization, 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. This year alone, a staggering seven million of those people will die prematurely from cigarette smoking, 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, and diabetes, a major global health priority. The growing use of combustible tobacco, a major risk factor in all these conditions, requires urgent attention at national and global levels.

The global epidemic in smoking is alarming in both its magnitude and its escalating prevalence. Despite considerable public health effort, the reduction in disease and death has been slow, and rates of cessation success, even with nicotine replacement therapy (NRT) assistance, tend to be disappointingly low. If not confronted aggressively and with innovative policies, an estimated one billion people will die of smoking-related causes during the 21st century. It is particularly critical to address youth and combustible tobacco products.

Recognizing that nicotine,[2] though addictive and habit-forming for some, is not itself a significant factor in the causation of disease, addicted smokers urgently need access to significantly lower risk tobacco, nicotine, and alternative products. In order to achieve this goal, it is necessary to inform the general public, consumers, policy makers, healthcare providers, and other stakeholders about the benefits that can be obtained by switching from a combustible/smoked tobacco product to a significantly lower risk noncombustible product.

Today's products include not only the more traditional tobacco and nicotine products, but newer innovations including gums, lozenges, vaping products often referred to as e-cigarettes, heat-not-burn products, and inhalers. This expansion presents new challenges, but it also creates new opportunities for reducing the devastating disease and death caused by using tobacco on both a national and global scale. 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 the products are labeled, sold, marketed, and used.

The development and implementation of consistent, effective global public health policies that significantly reduce disease and death from tobacco use is going to require the involvement of numerous stakeholders, interests, and disciplines, working both independently and together, as well as transparently. This includes government agencies and regulators; public health officials; researchers and scientists; manufacturers of tobacco, nicotine, and alternative products; consumers of these products; farmers and entrepreneurs. Everyone has a critical role to play.

[2] See "The Health Consequences of Smoking- 50 Years of Progress: A Report of the Surgeon General", 2014 at http://www.surgeongeneral.gov/library/reports/50-years-of-progress/

Research over the last twenty years continues to shape and reshape the public health community's understanding of the core problem. While there are differing opinions about what should be done based on this understanding, there is an emerging recognition of the following key findings:

- The overwhelming harm from tobacco use comes from tobacco products that are combustible/smoked.
- Nicotine, although addictive, is not carcinogenic and at relevant exposures presents reduced health risks.
- The spectrum of harm is not a continuous curve, but rather a "cliff," reflecting the high level of toxicity of specific combustible smoking products at the "top of the cliff" with noncombustible products at the "bottom of the cliff."
- Existing efforts to reduce the toll of tobacco are failing to meaningfully change the projections of expected early death.
- With the advent of long-sought more visionary regulatory frameworks, there is a new opportunity to reduce the incidence of disease and death from tobacco products.
- The new regulatory approaches should coincide with the development of new nicotine-delivery products and other alternative products such as gums, lozenges, e-cigarettes, and other devices.
- All tobacco, nicotine, and alternative products should be evaluated based on both individual risk and relative risk.
- Preventing access by children and adolescents under legal age – the purchase, sale, initiation, use and possession of all tobacco, nicotine and alternative products – should be a high priority harm reduction strategy.
- Public policy should promote the development, use, and continuing evaluation of reduced-risk products.
- Measures need to be taken to inform, educate, incentivize, and drive consumers to lower risk products to reduce the use of cigarettes and other dangerous combustible tobacco products.
- Whatever strategies are used to achieve this goal, they must serve both the individual and the population as a whole.
- The engagement of stakeholders in civil dialogues and in the development of new visionary policies is essential.

To provide focus for what a successful effort to reduce the global burden of disease and premature death from tobacco products might encompass, these Core Principles have been developed.

Harm reduction is something that is common to many activities in our society and is not unique to the area of tobacco and nicotine. We see harm reduction/minimization being applied to our foods, drugs, automobile safety, and environmental pollution, and increasingly being considered in the area of marijuana production and use. Although the support for harm reduction policies continues to grow there is also a growing concern by some who fear that new products, such as the e-cigarette, may have unintended consequences.

These Core Principles are an effort to address some of these fears and also to provide guidance for the creation and implementation of harm reduction policies that will significantly reduce the devastating disease and death, caused nationally and globally by combustible products, and in particular cigarettes.

These Interrelated Core Principles are owned by none, yet belong to and can be embraced by everyone.

They serve as guiding principles for 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 and, most importantly, should prevent all youth access, initiation, and use of any tobacco and nicotine products.

Individuals or representatives of organizations and businesses, consumers, academic institutions and other entities who believe that they can conceptually embrace these Core Principles are encouraged to conceptually support them.

Further, individuals and organizations are encouraged to use and disseminate these Core Principles to help move the Tobacco, Nicotine, and Alternative Products Harm Reduction Dialogue agenda forward.

Therefore, Be It Resolved: That in order to address the global burden of disease and death caused using cigarettes and other dangerous combustible tobacco products, and in the furtherance of promoting public health through product modification and the development and availability of significantly lower risk tobacco, nicotine, and alternative products, the following interrelated principles be embraced and implemented. These interrelated Core Principles fall within ten (10) categories:

1. Definitions and Terminologies
2. Smoking replacement Products (SRP's)
3. Regulatory Oversight
4. Research and Science
5. Innovation and Technology
6. Monitoring and Surveillance
7. Consumers and the General Public
8. Nicotine
9. Tobacco Agriculture
10. Engagement and Dialogue

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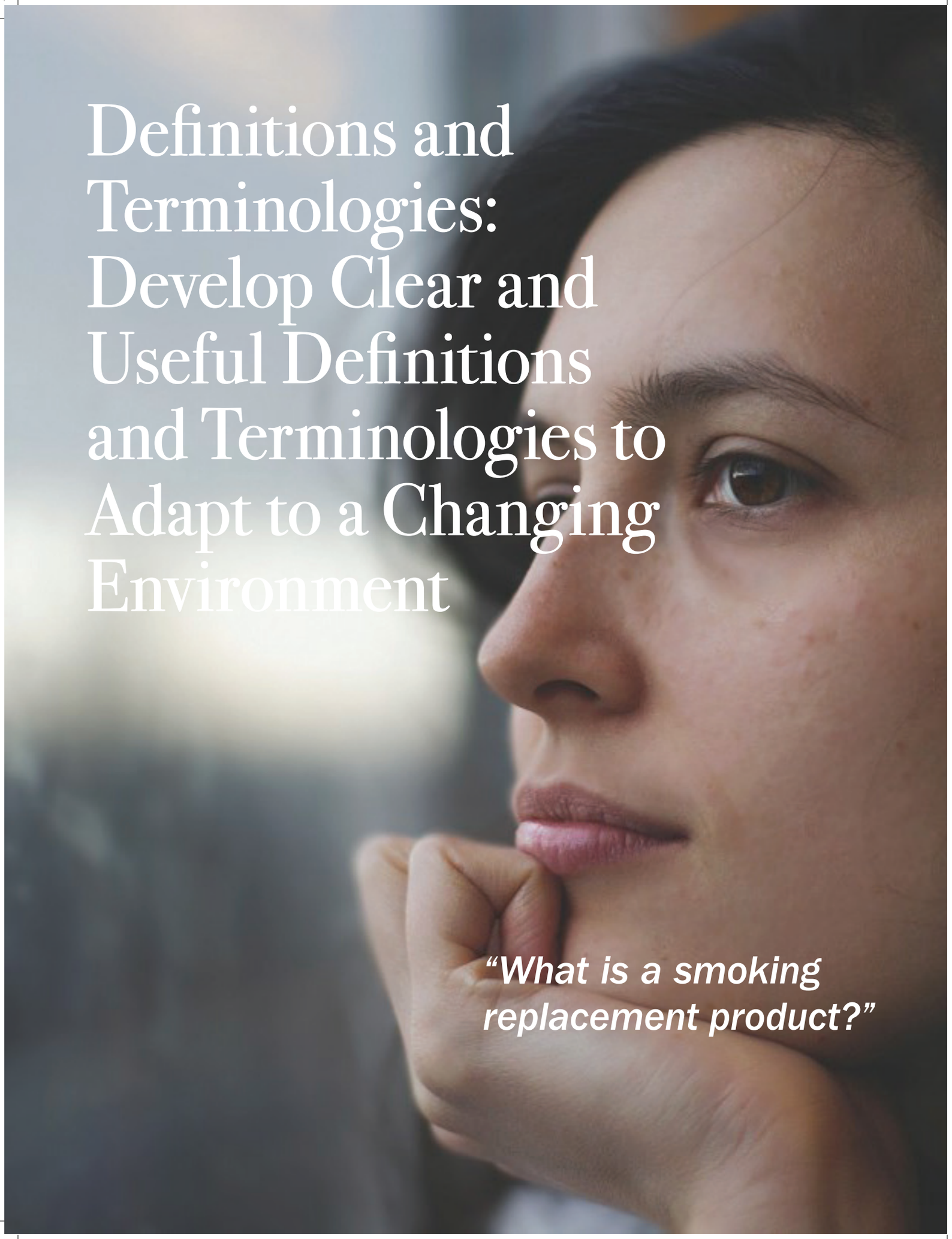
Definitions and Terminologies: Develop Clear and Useful Definitions and Terminologies to Adapt to a Changing Environment



Core Principle 1

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

Today's global marketplace continues to have a rapidly growing number of products and manufacturers. It is no longer a marketplace where new products are or can be evaluated only in terms of black and white, but instead the evaluation yields multiple shades of gray. In an evolving and confusing marketplace like this, with so many lives hanging in the balance, the goal of achieving harm reduction requires that clear and truthful communication about the risks and benefits be disseminated. Additionally, a complete understanding of supply chain sources needs to be transparent and communicated to the general public and consumers. This should include that:

- All tobacco, nicotine, and alternative products including cigarettes, smokeless tobacco, nicotine replacement products (NRT), noncombustible products, vaping products (e-cigarettes), gums, lozenges, snus, inhalers, and heat-not-burn products are more clearly defined for purposes of public understanding, statutory definition, regulatory consistency, and relevance;
- Terms such as cessation, innovative products, tobacco industry, combustible and non-combustible industry, therapeutic products, alternative products, smoking/vaping, harm reduction, addiction, smoking replacement products, modified risk tobacco products, current user, experimentation, and others are more clearly defined for purposes of public and user understanding, statutory definition, and regulatory consistency and relevance;
- Governmental agencies, 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;
- To accomplish these goals and objectives, consideration should be given to the establishment of a process to develop a glossary and set of recommendations for defining and clarifying terms that could serve all stakeholders including the general public.

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Smoking Replacement Products (SRP's):[3] Recognize, Understand and Act on the Significant Differences Between Combustible and Non-Combustible Products

Core Principle 2

Smoking Replacement Products (SRP's):[3] 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 into the market place need to be more appropriately defined (See Core Principle #1). These products have differing characteristic as well as differing "risk profiles," but all of them can be considered non-combustible products that are significantly lower in risk when compared to combustible/smoked products. (Combustible products include cigarettes, cigars, pipes, hookah, roll your own, etc.) These non-combustible products should be collectively classified as Smoking Replacement Products (SRP's) to more clearly differentiate the non-combustible from combustible/smoked classifications. SRP's need to be considered a part of comprehensive public health strategies to discourage and prevent the use of combustible products, especially cigarettes, which are by far, in the US and globally, the leading cause of disease and death. This Core Principle articulates some general principles for how SRP's should be manufactured, sold, labeled, and marketed. (More specifics can be found throughout this document). This should include that:

- All tobacco, nicotine, and alternative products should be proportionately regulated based on their risks and relative risks. The differences in risks between combustible/smoked and non-combustible products (SRP's) are significant;
- The public, consumers, and all stakeholders are entitled to truthful, accurate, and non-misleading information about the risks, relative risks, and intended uses of SRP's, and should be provided such information by governmental agencies, public health organizations, researchers, manufacturers, and the media;
- It should be unlawful for all tobacco and nicotine products (including SRP's) to be sold, made available to, or used by anyone under the age of 18/21. Advertising and marketing of these products must not be targeted to those under the age of 18/21;
- SRP's should be consumer acceptable and readily available to adults over the age of 18/21. Consumer acceptability of SRP's should allow the use of flavors. Flavors are not inherently bad, but they can cause appeal. Therefore, companies should specifically avoid using flavor descriptors or target-marketing that may significantly impact youth;

• 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);

• The cooperative development of fair, workable, flexible, and enforceable product standards should be given a high priority by regulators. SRP innovation should be encouraged, not stifled (See Core Principles #3 & 4);

• The scientific/regulatory standards for allowing SRP's on the market should be made with the view that there is a reasonable expectation that the product is lower in risk based on the current availability of scientific evidence. A more collaborative transparent approach to the scientific review of SRP's should be undertaken involving academic research institutions, public health authorities, regulatory authorities, and manufacturers. (See Core Principle #3);

• SRP's should not be actively marketed or promoted to recruit new users of nicotine;

• There must be a coordinated effort to educate the public and consumers, health care professionals, policy makers, regulators, and the media about SRP's and the potential role they can play in reducing disease and death caused by combustible tobacco products.

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[3] This new Core Principle was added by the Morven VI Dialogue.


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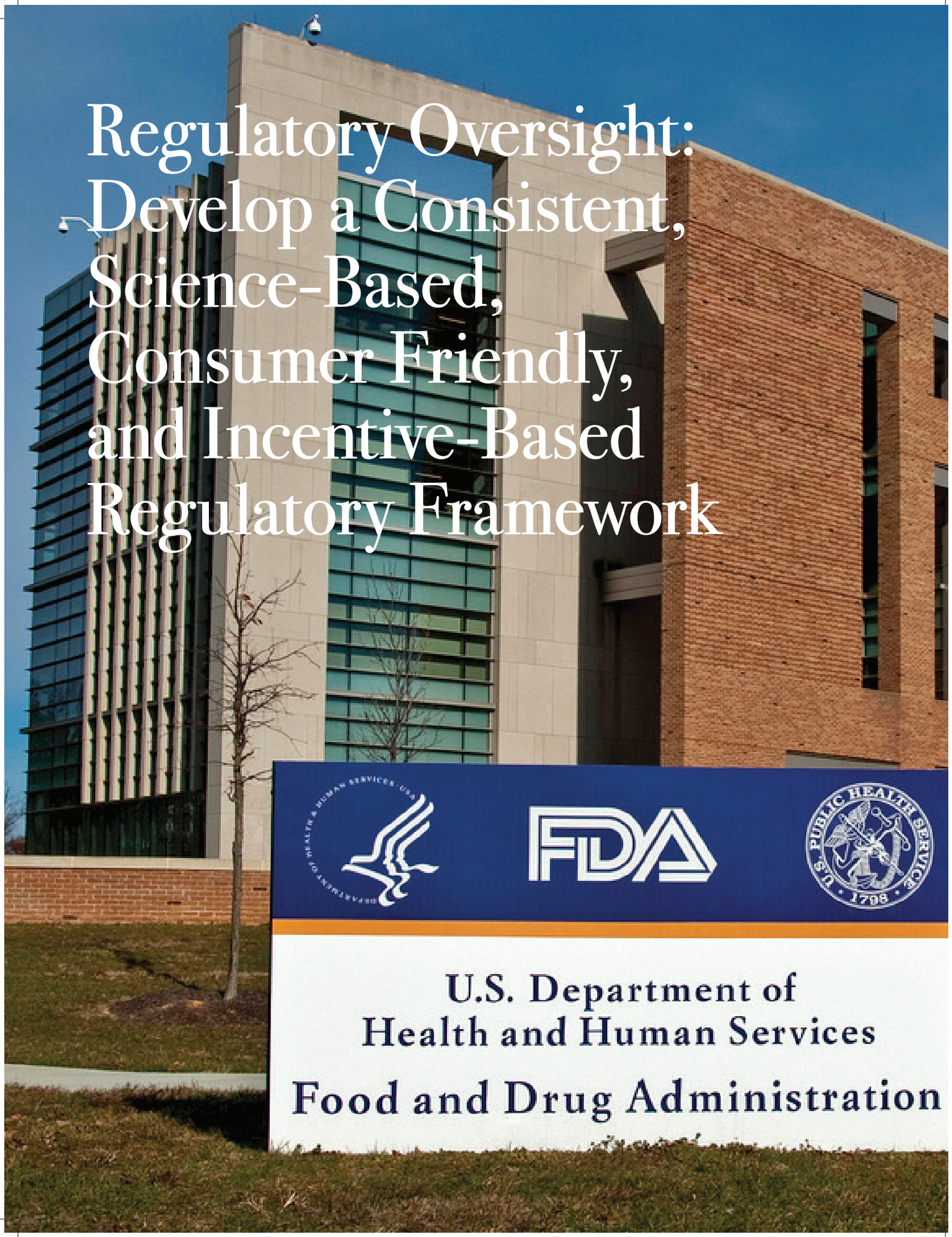
Regulatory Oversight: Develop a Consistent, Science-Based, Consumer Friendly, and Incentive-Based Regulatory Framework



Core Principle 3

Regulatory Oversight: Develop a Consistent, Science-Based, Consumer Friendly, and Incentive-Based Regulatory Framework

A critical aspect for implementing successful tobacco, nicotine, and alternative products risk reduction policies, domestically and globally, is to regulate these products in a more comprehensive, inclusive, coherent, proportional, and consistent manner. This should include that:

- Governmental regulatory bodies should regulate the manufacturing, labeling, distribution, sale, and marketing of all tobacco, nicotine, and alternative products based on risks, relative risks (continuum of risk), and intended uses with a key goal of benefiting public health;
- Sound science, transparently developed and communicated, has global implications and should provide the basis for regulations and standards, including the regulations and standards governing harm reduction and alternative products;
- Those regulations and standards should take into consideration the interests and needs of the consumer and users of products, including environmental regulatory measures for agriculture, child labor laws, and sustainability principles;
- Consideration should be given to regulating all tobacco, nicotine, and alternative products under a single regulatory authority, or ensuring that there is close coordination, cooperation, and alignment between one or more regulatory bodies within government;
- The combustible cigarette should be used as the "reference product" for evaluating the risks and relative risks of other tobacco, nicotine, and alternative products;
- Legislative and regulatory bodies should develop consumer/user-friendly policies and regulations for all tobacco, nicotine, and alternative products that ensure that the public, consumers, and users can fully understand the risks and relative risks of products, and that deceptive labeling and advertising practices are prohibited;
- Tobacco, nicotine, and alternative products that are significantly lower in risk than the combustible cigarette, based on sound science, should be given a high priority for approval as viable, non-combustible alternatives/SRP's to combustible/smoking cigarettes. This could include the fast-tracking approval of harm reduction products as well as pricing and taxing lower risk products at lower levels;
- Statutory and regulatory policies should stimulate and encourage the development of significantly lower risk tobacco, nicotine, and alternative products to reduce the incidence of smoking;
- The broad scientific community in the US and globally, including the combustible and non-combustible industry, should be invited and encouraged to participate in the development of policies and regulations for all tobacco, nicotine, and alternative products.

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Research and Science: Encourage Transparent, Collaborative Research of the Highest Integrity to Reduce Consumer Health Risks

Image © https://commons.wikimedia.org/wiki/File:Scientists_are_working_in_the_lab.9.jpg

Core Principle 4

Research and Science: Encourage Transparent, Collaborative Research of the Highest Integrity to Reduce Consumer Health Risks

Scientific research will be increasingly essential to the development and implementation of effective and workable regulatory policies for overseeing all tobacco, nicotine, and alternative products and the development of lower risk products. This should include that:

- Research into the development of significantly lower risk, science-based tobacco, nicotine, and alternative products should be given a high priority in both the public and private sectors;
- Manufacturers of tobacco, nicotine, and alternative products should make non-proprietary research readily available to regulators, academia, and the public by engaging in transparent dialogues and communication instruments, such as scientific journals and press releases;
- Manufacturers of tobacco, nicotine, and alternative products have an obligation and responsibility to conduct and use world-class science, and to follow the appropriate scientific protocols used by other industries;
- There should be greater interaction, including data sharing and collaborations (consortia) and a commitment to open science, between all researchers and scientists, regardless of institutional affiliation;
- Research, and the validation of the research by a third party, should be a shared responsibility of governmental oversight agencies, tobacco, nicotine, and alternative product manufacturers, academic research institutions, public health authorities, and others;
- Publication originating from any source should be encouraged, so long as the highest standards of research, transparency, and peer review are applied;
- In the case of funding to researchers, scientists, and academic institutions (including but not limited to corporate research funding), there should be appropriate and necessary safeguards in place to ensure that the research and the results of such research are held to and conducted with the utmost independence and integrity, including transparency in the financing, researching, and reporting process.

For more information, please refer to the 2011 “Core Principles Concerning Corporate Funding for Tobacco, Nicotine, and Alternative Product Harm Reduction Research”, available at: www.virginia.edu/ien/tobacco

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Innovation and Technology: Encourage and Incentivize Lower Risk Products

Image © Master Sgt. Kimberly Yearyean-Siers

Core Principle 5

Innovation and Technology: Encourage and Incentivize Lower Risk Products

As is happening in other manufacturing sectors, the development of lower risk products, new technology, and innovation should be encouraged and supported in both the private and public health sectors. Historically, established industries have been transformed or eliminated when innovation flourishes. Innovation, in the form of novel nicotine delivery devices, smoking replacement products (SRP's) and in the application of technology to mitigate the problem of combustible/smoked tobacco use and nicotine dependence, must be actively encouraged in both the private and public health sectors. This should include that:

- Governmental research bodies, manufacturers of tobacco, nicotine, and alternative risk-reduction products should be encouraged to commit increasing amounts of financial resources to developing innovative lower risk products. Those manufacturing combustible products, such as cigarettes, should be incentivized to reprioritize their corporate goals and objectives away from combustible cigarettes;
- Concrete incentives (e.g., tax credits, patent extensions, regulatory prioritization) should be provided to nicotine product manufacturers, alternative product manufacturers, entrepreneurs, research institutions, and tobacco growers to develop non-combustible smoking replacement products (through advances in technology and innovation) that are significantly lower in risk than combustible products;
- New investment capital should be acquired to develop new technologies and innovations to reduce the devastating toll caused by combustible tobacco products;
- Regulations should be flexible and adaptable to allow new science-based, lower risk products into the marketplace in a more expeditious manner.

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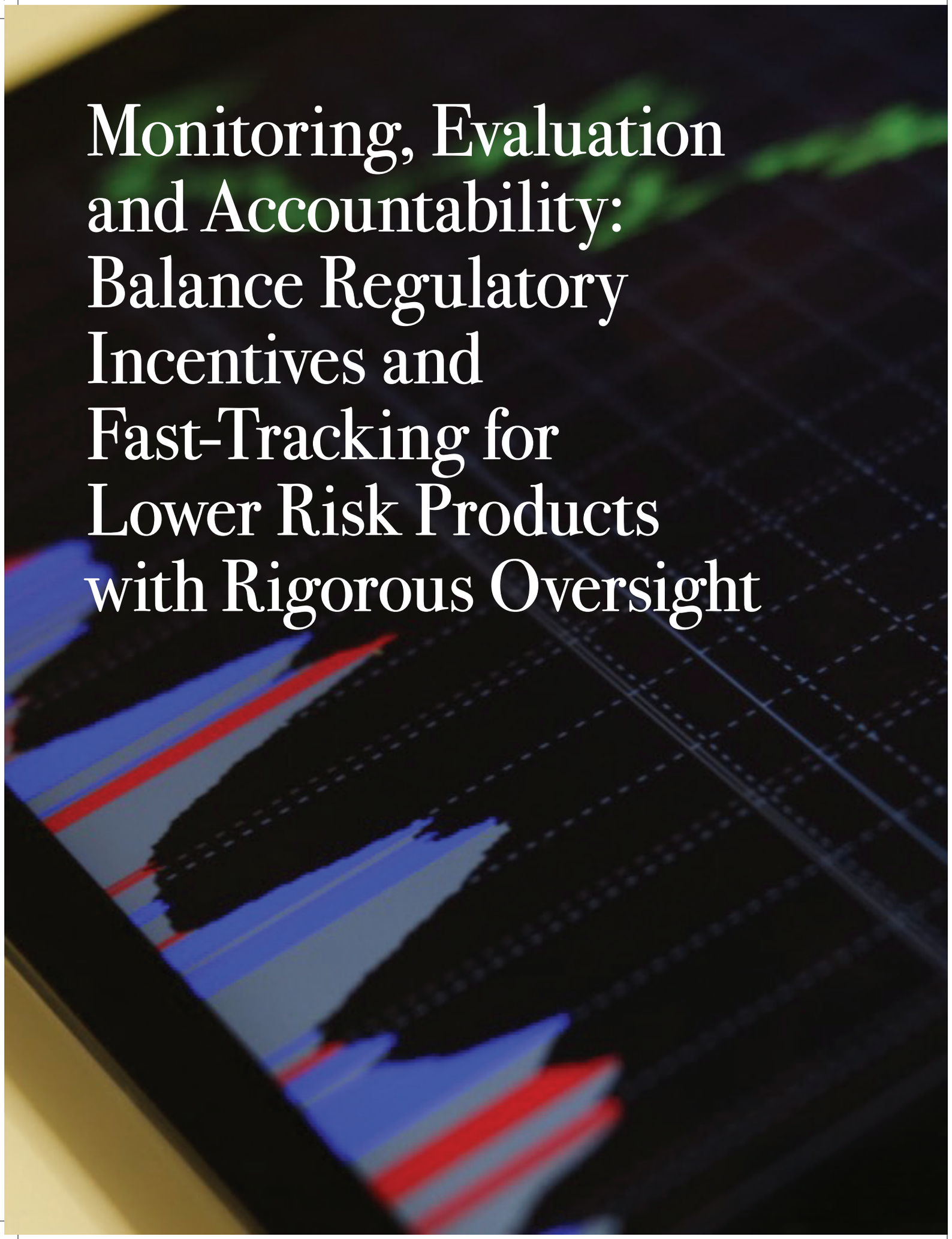

Monitoring, Evaluation and Accountability: Balance Regulatory Incentives and Fast-Tracking for Lower Risk Products with Rigorous Oversight

Core Principle 6

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

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 reduced-risk products. This oversight process should include that:

- All tobacco, nicotine, and alternative products must be monitored in order to assess the health and behavioral effects of using such products, including the effects on the individual and the broader population;
- Regulatory bodies should provide leadership for developing a rigorous monitoring and surveillance system, conducted with governmental regulatory oversight, and including cooperation and collaboration with various stakeholders including tobacco, nicotine, and alternative products manufacturers, labeling and marketing experts, non-governmental organizations, and others;
- Coordinated and cooperative efforts to monitor the use of all tobacco and nicotine products by those under the age of 18/21 is given a high priority;
- Science-based, lower risk products should be allowed on the market (under the purview of regulatory oversight) if there is a reasonable expectation based on the available science that the product will reduce exposure to tobacco toxicants and/or reduce the risk of tobacco-related disease;
- 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 marketplace;
- Where it is determined that a manufacturer has intentionally not met its obligations under a statute or regulation, enforcement measures must be quickly implemented, and appropriate penalties must be assessed.

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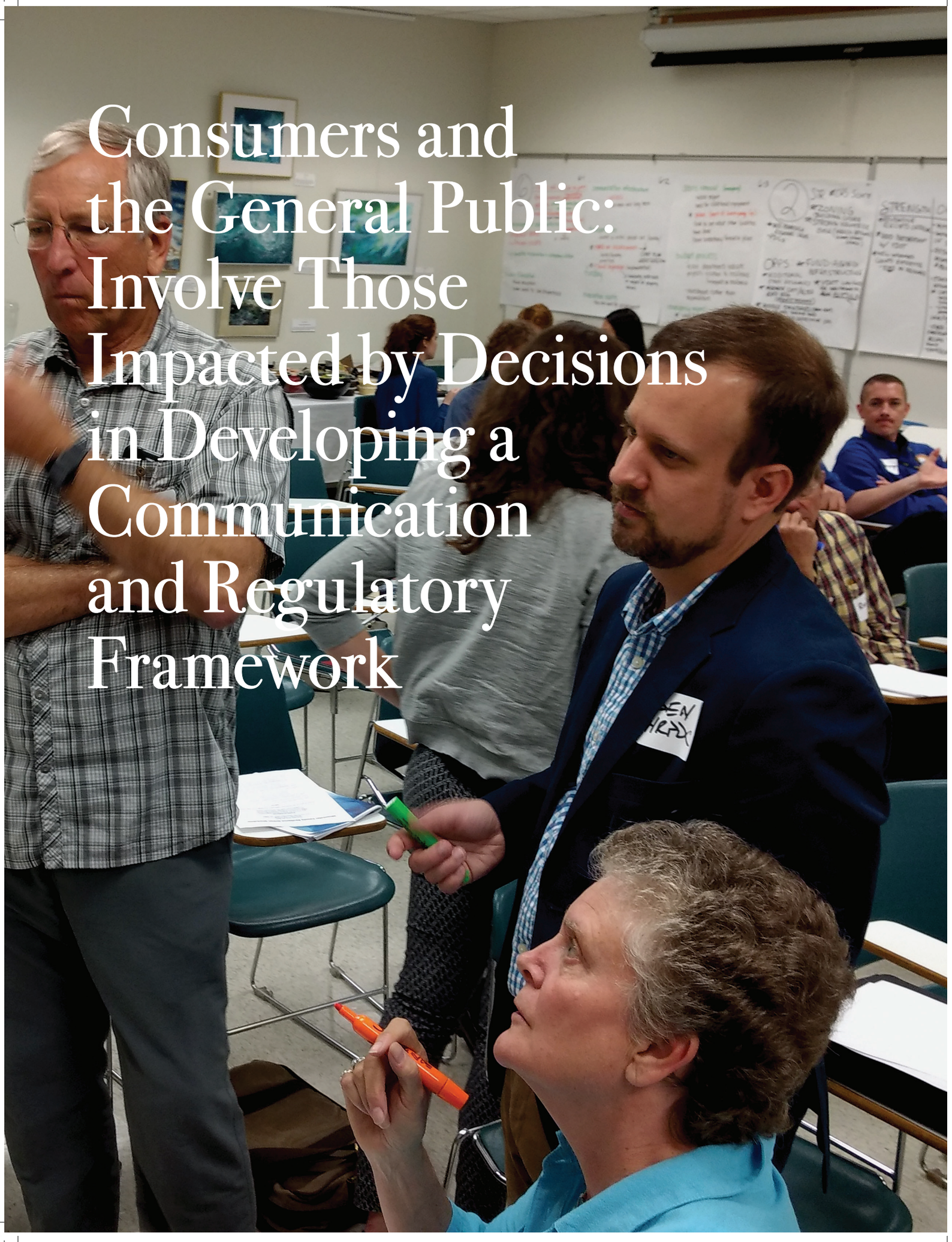


Consumers and the General Public: Involve Those Impacted by Decisions in Developing a Communication and Regulatory Framework

Core Principle 7

Consumers and the General Public: Involve Those Impacted by Decisions in Developing a Communication and Regulatory Framework

Consumers and users of tobacco, nicotine, and alternative products and the general public must always be provided with the science-based information necessary to understand the risks, relative risks, and intended uses of the various products currently on the market. Despite substantial efforts to promote cessation, many users of combustible/smoked tobacco products continue to smoke. Many consumers (and the general public) continue to believe that all forms of tobacco and/or nicotine are equally hazardous. Those consumers who are at the greatest risk for disease and death need non-combustible smoking replacement alternatives that are affordable, accessible, acceptable, and scientifically demonstrated to be significantly lower in risk. Closing this gap in understanding is important, and should include that:

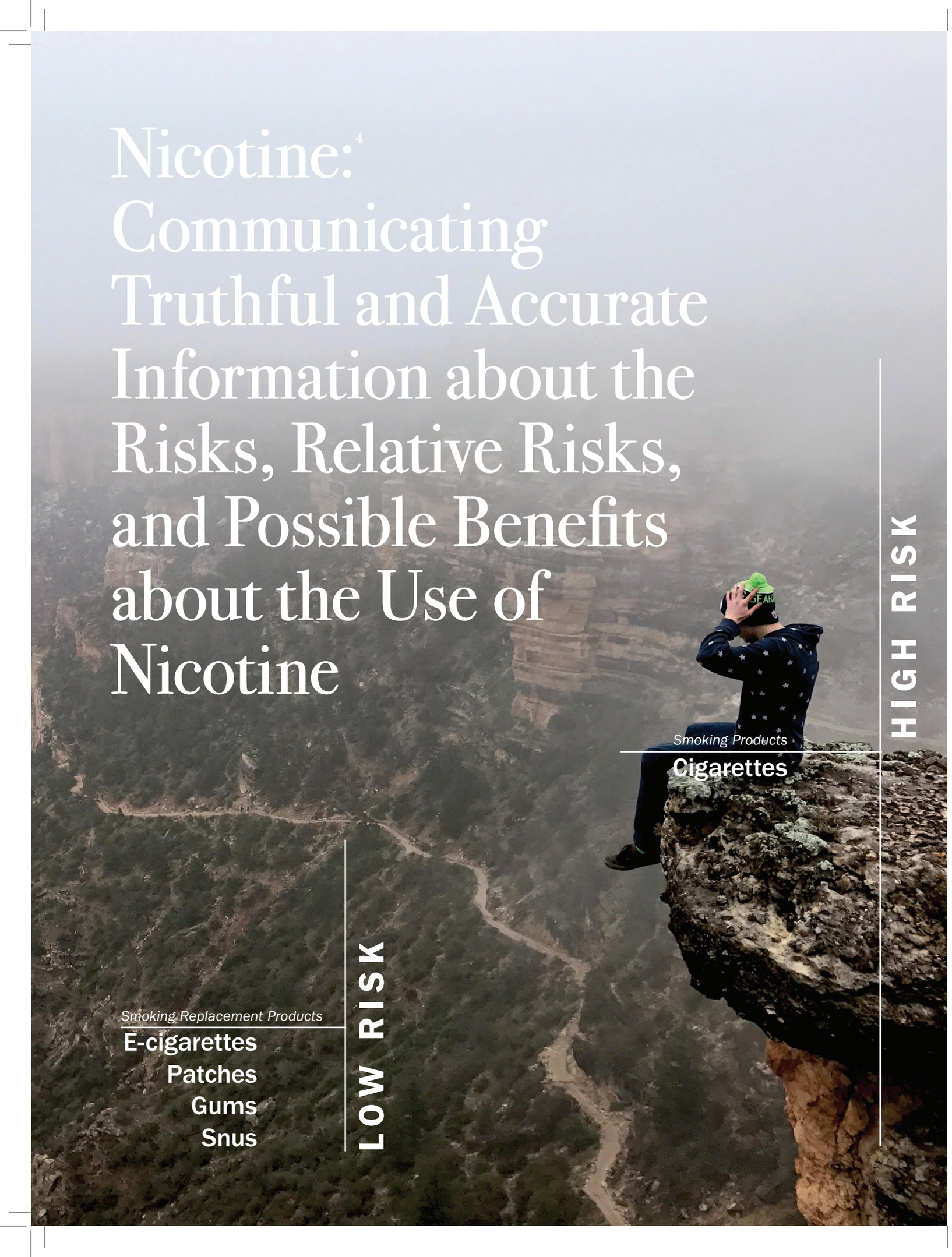
- The general public, health care providers, and consumers and users of tobacco, nicotine, and alternative products should be provided with accurate, science-based, and understandable information about the risks, relative risks, intended uses and effectiveness of all tobacco, nicotine, and alternative products. This information should be made available through consumer-oriented outlets such as social media, industry publications, governmental publications and sources, public health NGO's, university information distribution systems, and traditional advertising mechanisms, etc.;

- Users and potential users of tobacco, nicotine, and alternative products should be actively consulted and involved in the development of policies, in the setting of regulations, in the implementation of policies and regulations, and in identifying what kinds of information are most useful for them. In addition, consumers must be instructed on how these products should be used to achieve a measure of effectiveness. Efforts to reach consumers must include enabling and actively facilitating their participation to ensure their perspectives are heard;

- Governmental agencies at the global, national, state, and local level (as well as other public and private stakeholders) should have an active role in ensuring that the information provided to the consumer, health care providers, the general public, and other stakeholders is scientifically accurate, science-based, and is provided in a manner appropriate to the target audience.

To add your individual or organizational name of conceptual support, please go to: https://virginia.az1.qualtrics.com/jfe/form/SV_2c11xduiaMjUaQl

Nicotine:[4] Communicating Truthful and Accurate Information about the Risks, Relative Risks, and Possible Benefits about the Use of Nicotine



Smoking Products

Cigarettes

HIGH RISK

LOW RISK

Smoking Replacement Products

E-cigarettes
Patches
Gums
Snus

Core Principle 8

Nicotine:[4] Communicating Truthful and Accurate Information about the Risks, Relative Risks, and Possible Benefits About the Use of Nicotine

As part of any effort to provide the public, consumers, health care professionals, and others with truthful information about the risks and relative risks of tobacco, nicotine, and alternative products, special attention should be given to include the communication of truthful information with the respect to nicotine. While nicotine is highly addictive and not benign, and no child or adolescent should use any nicotine product, a large portion of consumers and the general public continues to believe that all tobacco and nicotine products are equally harmful, and that nicotine is the major cause of cancer. Adult smokers are entitled to know more about the availability of "cleaner" and safer forms of nicotine to help break their addiction to cigarettes.[5] As US Federal Drug Administration (FDA) Commissioner Scott Gottlieb has noted in articulating the FDA's new visionary nicotine policy announced in July 2017, "*While it's 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.*" A more useful educational framework related to nicotine should include that:

- Nicotine, naturally occurring in the tobacco leaf, is a highly 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 for other diseases;
- Because of concerns about the effects on 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 sales and distribution of these products are strictly enforced and that marketing of these products is not targeted at adolescents;
- It is the method of nicotine delivery that causes the overwhelming disease and death from tobacco use. Combustible/smoked products are accountable for the overwhelming disease burden both nationally and globally. Cigarettes are the most appealing, most addictive, and most toxic of all nicotine containing products. "Cleaner" forms of nicotine delivery in noncombustible forms have been developed, and should be made available to adult smokers as both cessation therapies and as non-combustible smoking replacement products. If such consumer-acceptable products are made readily available, a complementary strategy for reducing the levels of nicotine in combustible products should be considered and pursued;

• Nicotine derived from tobacco has long been used in patches, gums, lozenges, inhalers, and other "Nicotine Replacement Therapy" (NRT) products, as a means of helping cigarette smokers quit the use of cigarettes. The evidence related to the safety of nicotine use in these products is significant;

• 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. This information should be provided to all users in a consistent and truthful manner, by all stakeholders including governmental agencies (such as Federal Drug Administration, Centers for Disease Control, and World Health Organization), manufacturers, policy makers, public health organizations, academic institutions, health care professionals, the media, and others;

• Educational efforts on the risks and relative risks of alternative nicotine products should include the enhanced truthful labeling of products (including package inserts) and public educational/media campaigns, such as the responsible use of social media and various websites and publication in scientific journals;

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

• For some users, nicotine may have a positive effect on cognitive processes, motor coordination, concentration, and memory;

• Governmental agencies, both nationally and globally, should be encouraged to establish more flexible, visionary regulatory frameworks like the one articulated by the US Food and Drug Administration in July 2017.[6]

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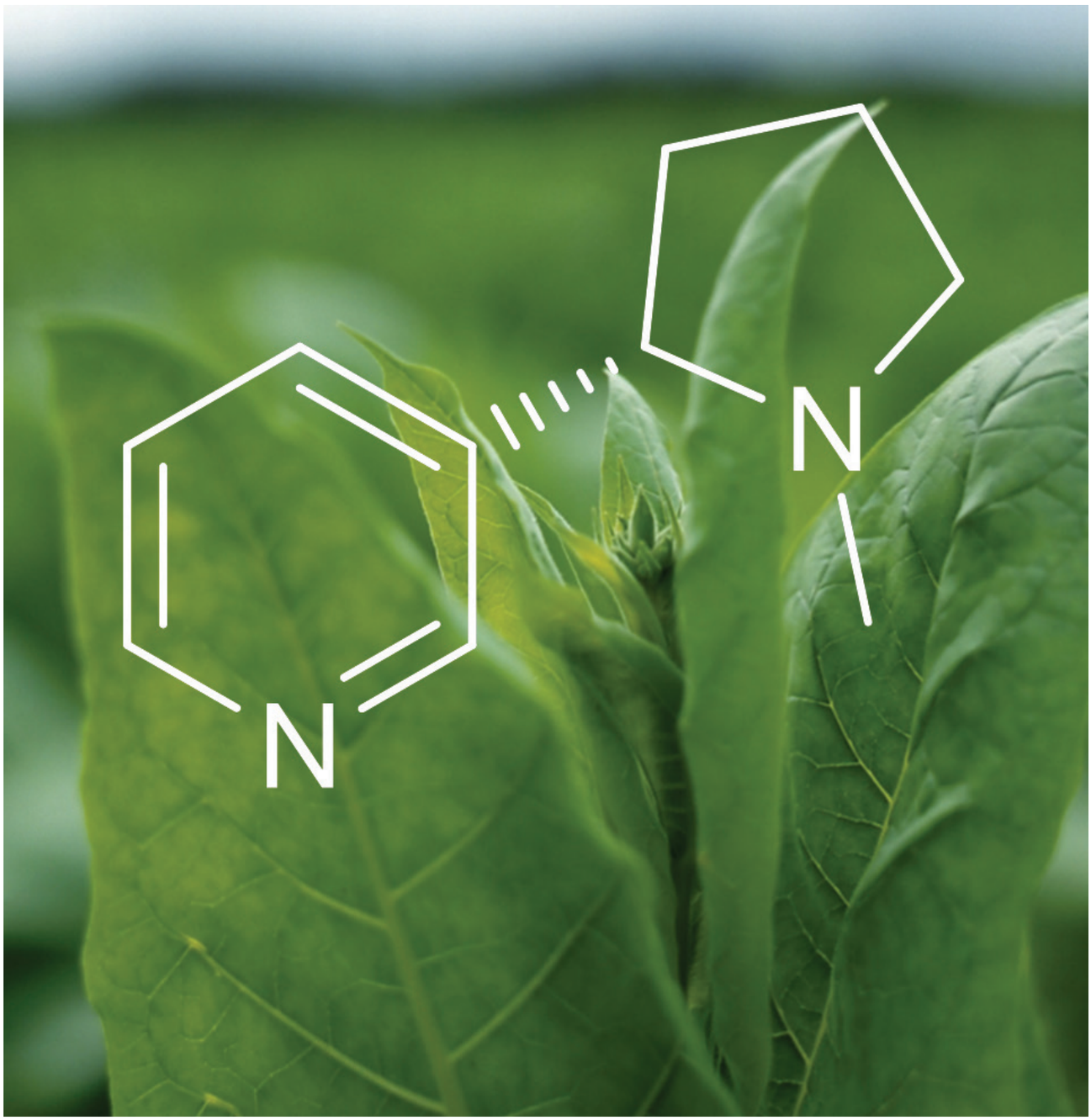
[4] This new Core Principle was added by the Morven VI Dialogue.

[5] For a more detailed review about nicotine and its pragmatic use in reducing disease and death from cigarette smoking, see "*Re-Thinking Nicotine and its Effects*" – by Raymond Niaura, PhD, formerly Director of Science and Training at The Steven Schroeder National Institute. https://truthinitiative.org/sites/default/files/ReThinking -Nicotine.pdf

[6] https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm

https://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm629412.htm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Tobacco Agriculture: Involve Agriculture Stakeholders in Developing a Communication and Regulatory Framework

Core Principle 9

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

Agriculture is often left out of consideration at both the global and national level 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. This should include that:

- 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);
- 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;
- 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;
- Tobacco grown for harm reduction products should be grown using Good Agricultural Practices 2 (GAP2),[7] 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.

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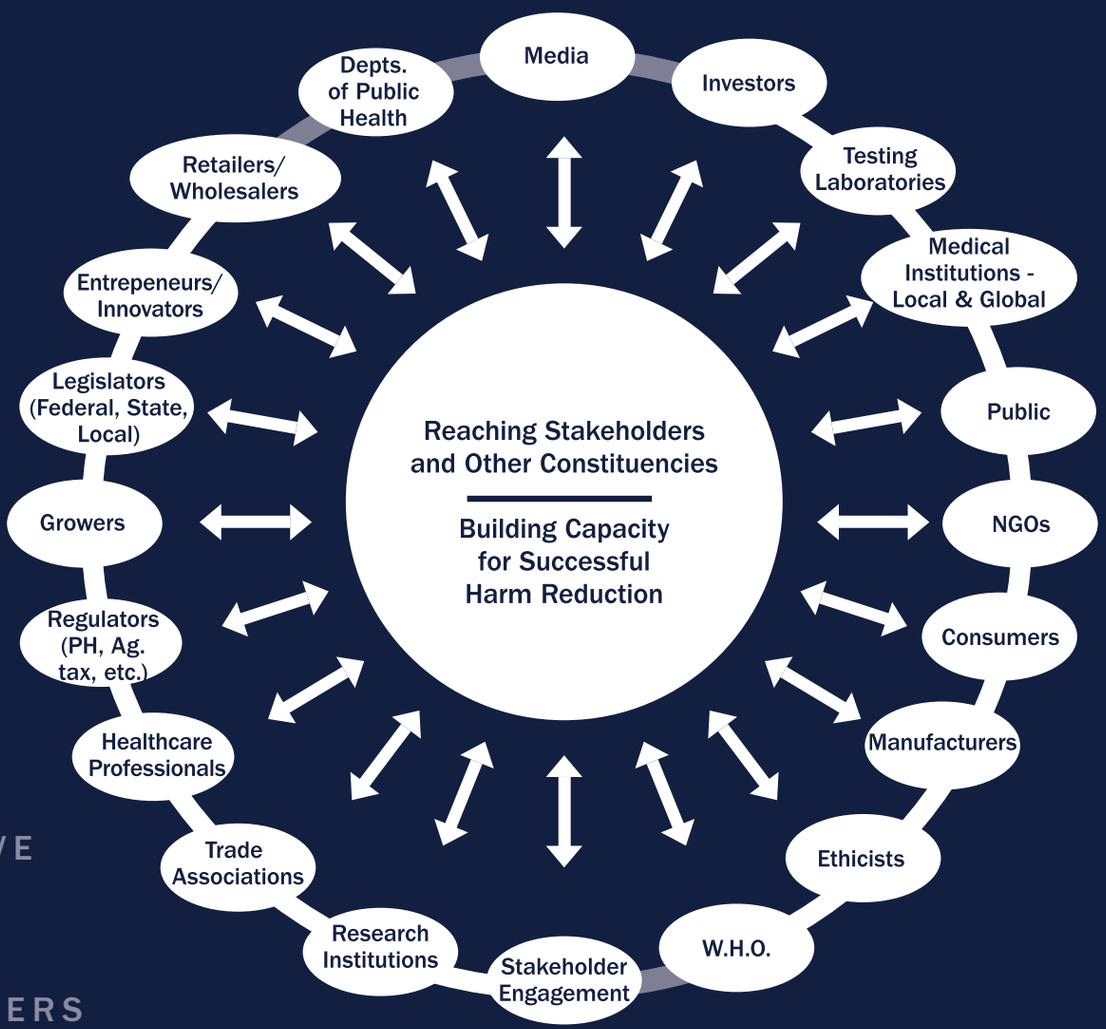
[7] The U.S Tobacco GAP program is an industry-wide program that aims at ensuring sustainable, economically viable production of useable tobacco and can be defined as: agricultural practices which produce a quality crop while protecting, sustaining or enhancing the environment regarding soil, water, air, animal and plant life as well as protecting and ensuring the rights of farm laborers.

http://www.gapconnections.com/Pages/US-Tobacco-GAP.aspx

Engagement and Dialogue: Encourage Ongoing Civil Dialogue with Broad Stakeholder Involvement



TOBACCO, NICOTINE, AND ALTERNATIVE PRODUCTS HARM REDUCTION STAKEHOLDERS

Core Principle 10

Engagement and Dialogue: Encourage Ongoing Civil Dialogue with Broad Stakeholder Involvement

Reducing disease and death from the use of tobacco, and most importantly the use of combustible forms of tobacco, on a global basis will depend on a willingness of stakeholders to maintain, expand, and develop new relationships. 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 versus them" manner. In this dynamically changing environment at both national and global levels, there will continue to be a need to engage in more frequent dialogues with a broader representation of stakeholders, at multiple levels and in multiple venues, both in the public and private sectors. This should include that:

- All stakeholders and other experts (including but not limited to governmental agencies; public health organizations; tobacco, nicotine, and alternative product manufacturers; researchers; consumers; tobacco agricultural interests) should be encouraged to engage in civil dialogues on a spectrum of tobacco, nicotine, and alternative products harm reduction topics;
- It will require 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;
- Where adversarial situations exist, such engagements should be held in venues that are considered "safe havens" for discussion, and where transparency and civil dialogue can be applied with the assistance of unbiased facilitation;
- 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; academic institutions; public health and scientific conferences such as the Society for Research on Nicotine and Tobacco (SRNT), and CORESTA; trade association meetings such as the Global, Tobacco and Nicotine Forum (GNTF), Global Forum on Nicotine (GFN), and E-Cigarettes Summits in London and Washington D.C.; organizations like the Food and Drug Law Institute (FDLI), and World Health Organization; and "safe haven" venues like the University of Virginia IEN Morven Dialogues. Opportunities for the promotion of engagement and dialogue abound;

These 10 Core Principles are intended to provide some guidance for those willing to initiate and or participate in civil dialogues related to tobacco and nicotine harm reduction. They are owned by no one but can be embraced and used by all.

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“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

Institute *for* Engagement & Negotiation

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IEN is a nationally recognized leader in fostering **collaborative change** across a broad range of environmental, social, and economic issues. IEN is a public service organization of the University of Virginia, with a team of facilitators and mediators that assists organizations, agencies, industry, and communities in making bold, sustainable decisions. Our work spans health, food and social equity; sustainable environment; resilient communities; and building capacity.

Team members are known for expertise in designing and facilitating collaborative problem-solving processes, consensus building, conflict resolution, and strategic planning; programmatic evaluation; mediation; training in leadership, conflict management and negotiation skills; and working to foster equity and justice in community processes and outcomes.

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IEN adheres to the Ethical Guidelines for Environment and Public Policy Members published by the Association for Conflict Resolution which include:

1. **Self-determination** of participants to make their own informed decisions.
2. **Impartiality** of the facilitator regarding ideas, content and recommendations.
3. **Conflicts of Interest** potentially held by the facilitator will be disclosed.
4. **Competence** of the facilitator to successfully complete the scope of work and support the overall effort.
5. **Confidentiality** of discussions outside of meetings (and per Virginia Code sections 3705.1(11) and 2.2-4119).
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