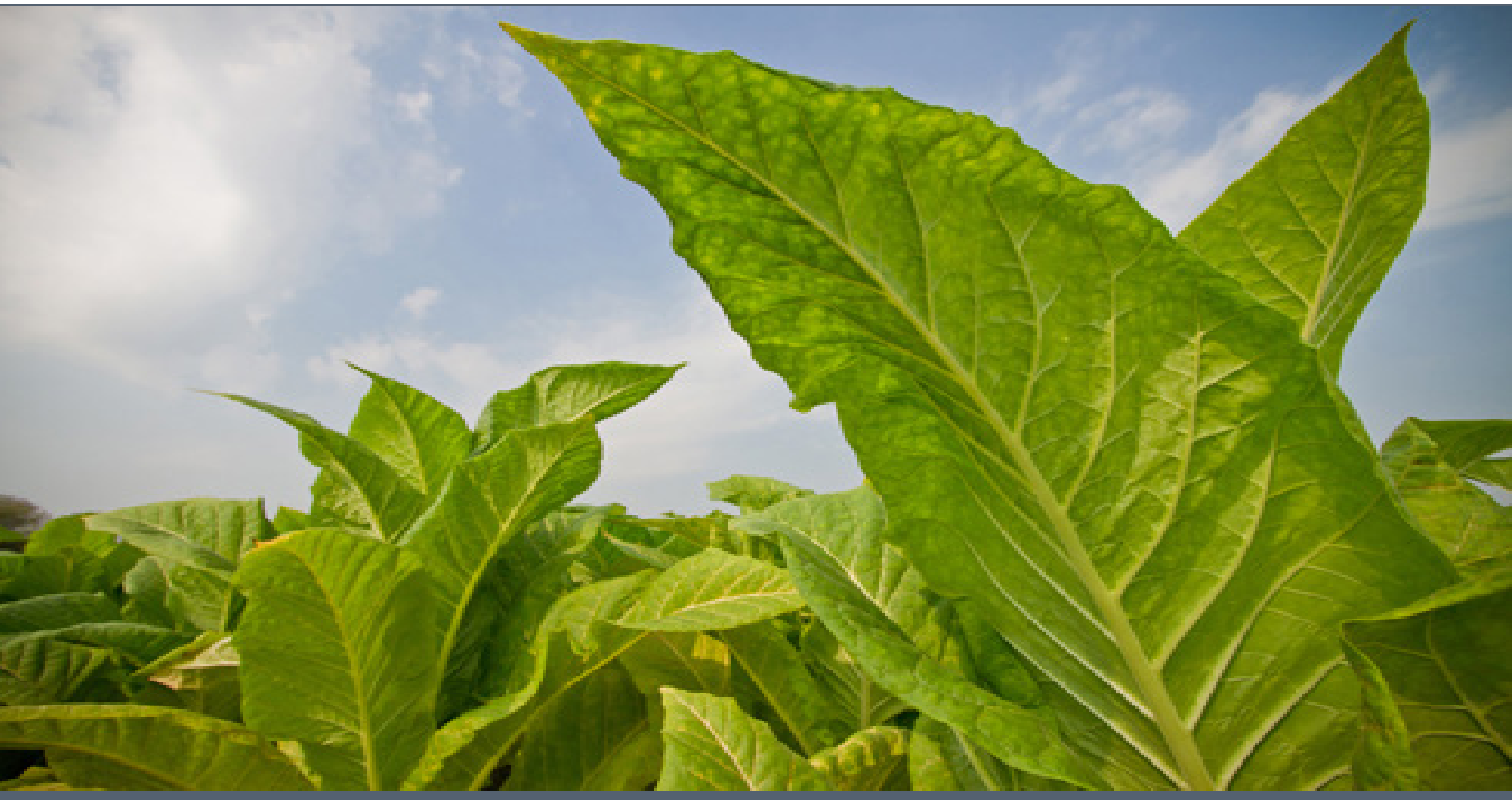
CORE PRINCIPLES
CONCERNING THE IMPLEMENTATION OF EFFECTIVE AND WORKABLE TOBACCO, NICOTINE, AND ALTERNATIVE PRODUCTS POLICIES FOR REDUCING DISEASE AND DEATH FROM TOBACCO USE

A National and Global Priority



A Product of the Morven Dialogues
Sponsored by the
Institute for Environmental Negotiation
University of Virginia

UNIVERSITY of VIRGINIA
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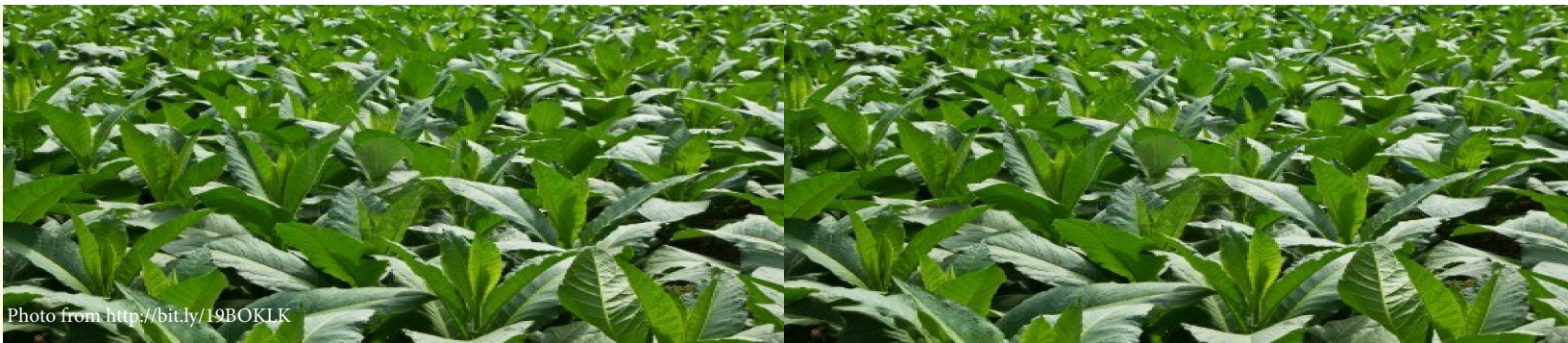
THE MORVEN DIALOGUES

The purpose of the Forum for Civil Dialogue on Tobacco, Nicotine and Alternative Product Harm Reduction and the series of dialogues at Morven is to bring parties and individuals together in a safe haven to discuss a spectrum of issues pertaining to tobacco, nicotine, and alternative harm reduction strategies. The first Morven Dialogue was held in March 2011. The forum and the 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 – with what protections -it may be effectively implemented, not only in the United States and Europe but globally as well.

In June of 2013, a diverse group of some two dozen individuals met at the University of Virginia's Morven, a retreat setting outside Charlottesville, Virginia, for a dialogue titled "Forum for a Civil Dialogue On Tobacco, Nicotine, and Alternative Product Harm Reduction"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PREAMBLE

According to the World Health Organization, there are more than one billion smokers in the world, with an increasing number of these smokers living in low and middle income countries. This year alone, a staggering 5.3 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 has 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 of 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.

Recognizing that nicotine, though addictive, 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 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, e-cigarettes, and inhalers. This expansion presents new challenges, but it also creates new opportunities for reducing the devastating disease and death caused by the use of 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; to the manner in which the products are labeled, sold, marketed, and used.

The development and implementation of effective 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.

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 combustible tobacco products.
- The spectrum of harm is not a continuous curve, but rather a "cliff," reflecting the level of toxicity of specific combustible smoking products.
- Existing efforts to reduce the toll of tobacco are not succeeding at anywhere near the rate needed to meaningfully change the projections of expected early death.
- With the advent of long-sought 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 such as gums, lozenges, e-cigarettes, and other devices.
- Nicotine although addictive is not carcinogenic and at relevant exposures presents minimal health risks.
- All tobacco, nicotine, and alternative products should be evaluated on the basis of both individual risk and relative risk.
- 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 as a means 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.

In an effort to focus on 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. These Core Principles are owned by none, yet belong to and can be embraced by everyone. They serve as guiding principles for the on-going efforts to reduce the harm associated with smoking. They represent a framework for moving forward and should be considered as being complementary to other existing tobacco control efforts.

Individuals or representatives of organizations and businesses, consumers, academic institutions and other entities who believe that they can embrace them are encouraged to endorse them and to use them in helping move the tobacco, nicotine, and alternative products harm reduction agenda forward.

Therefore Be It Resolved that in order to address the global burden of disease and death caused by the use of 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 core principles fall within eight categories:

1. Definitions and Terminologies: Adapting to a Changing Environment
2. Regulatory Oversight
3. Research and Science
4. Innovation and Technology
5. Monitoring and Surveillance
6. Consumers and the General Public
7. Tobacco Agriculture
8. Engagement and Dialogue

1. CLEAR COMMUNICATION TO ADAPT TO A CHANGING ENVIRONMENT: DEVELOP CLEAR AND USEFUL DEFINITIONS AND TERMINOLOGIES

Today's marketplace has 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 where instead there are multiple shades of gray. The inability to communicate about the risk-benefits of different products constitutes an urgent health communication issue. The communication of this information to consumers and others is essential. This should include that:

- All tobacco, nicotine, and alternative products including cigarettes, smokeless tobacco, nicotine replacement products, noncombustible products, e-cigarettes, gums, lozenges, and inhalers are more clearly defined for purposes of public understanding, statutory definition and regulatory consistency and relevance;

- Such terms as cessation, innovative products, tobacco industry, therapeutic products, alternative products, smoking/vaping, harm reduction, addiction, smoking replacement products, modified risk tobacco products 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 and to transmit and communicate that information in a more consistent manner to consumers, the general public, patients and other stakeholders.

2. REGULATORY OVERSIGHT: DEVELOP CONSISTENT, SCIENCE-BASED, CONSUMER FRIENDLY, AND INCENTIVE-BASED REGULATORY FRAMEWORK

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

- A governmental regulatory body (bodies) should regulate the manufacturing, labeling, distribution, sale, and marketing of all tobacco, nicotine, and alternative products based on risks, relative risks, and intended uses (continuum of risk) with a key goal of benefiting public health;
- Sound science, transparently developed and communicated, provides the basis for those regulations and standards, including the regulations and standards governing harm reduction and alternative products;
- Those regulations and standards take into consideration the interests and needs of the consumer and users of products;
- 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 is used as the 'reference product' for evaluating the risks and relative risks of other tobacco, nicotine, and alternative products;
- Legislative and regulatory bodies develop consumer/user-friendly policies and regulations for all tobacco, nicotine, and alternative products that ensures 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 are given a high priority for approval as viable alternatives to the use of combustible cigarettes. This could include the fast tracking approval of 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 as a means to reduce the incidence of smoking.
- The broad scientific community should be encouraged to participate in the development of policies and regulations for all tobacco, nicotine, and alternative products.

3. 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 and in particular to 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 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;
- 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 collaborations (consortia) 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;
- Scientific journals should be encouraged to publish research originating from any source so long as the highest standards of research, transparency and peer review are applied;

4. INNOVATION AND TECHNOLOGY: ENCOURAGE AND INCENTIVIZE LOWER RISK PRODUCTS

As is happening in other areas, the development of other products, new technology and innovation should be encouraged in both the private and public health sectors. Historically, established industries have been transformed or eliminated only when innovation flourishes. Innovation, in the form of novel nicotine delivery devices and in the application of technology to mitigate the problem of tobacco use and nicotine dependence, should be actively encouraged in both the private and public health sectors. This includes that:

- Governmental research bodies, manufacturers of tobacco and nicotine and alternative risk-reduction be encouraged to commit increasing amounts of financial resources to developing innovative lower-risk products and that those manufacturing combustible products such as cigarettes be incentivized to reprioritize their corporate goals and objectives away from combustible cigarettes.

- There should be concrete incentives (e.g., tax credits, patent extensions, regulatory priority) provided to tobacco growers, manufacturers of nicotine, alternative product manufacturers, entrepreneurs, and research institutions to develop products (through advances in technology and innovation) that are significantly lower in risk than combustible products.

- New investment capital should be sought that can be applied to the development of new technologies and innovations intended to help reduce the devastating toll caused by smoking.

5. 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 monitored and evaluated, and results acted on appropriately to provide assurance of efficacy and reduced risk. Rigorous monitoring, evaluation and enforcement can provide an effective bridge to address concerns with fast-tracking reduced-risk products. This 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 body (bodies) should provide leadership for developing a monitoring and surveilance 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;

- 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 demonstrates that the sale and marketing of a product is having unintended consequences such as increasing underage use, or serving as a gateway to increased harm, appropriate steps will be taken to expeditiously correct such unintended consequences, including the removal of the product if necessary.

- Where it is determined that a manufacturer has intentionally not met their obligations under a statute or regulation, enforcement measures should be quickly implemented and appropriate penalties assessed.

6. CONSUMERS AND THE GENERAL PUBLIC: INVOLVE THOSE IMPACTED BY DECISIONS IN DEVELOPING COMMUNICATION AND REGULATORY FRAMEWORK

It is clear that consumers and users of tobacco, nicotine, and alternative products should always been provided with the science-based information necessary information 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 cigarettes and other combustible tobacco products continue to smoke, and many consumers believe that other forms of tobacco and/or nicotine are equally hazardous. Those consumers who are at the greatest risk for disease and death need alternatives that are affordable, accessible and acceptable, and that are also demonstrated to be significantly lower in risk. To correct this void it is important that:

- The general public, health care providers, and consumers and users of tobacco, nicotine, and alternative products have accurate, science-based, and understandable information about the risks, relative risks, intended uses and effectiveness of all tobacco, nicotine, and alternative products;

- 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. Efforts to reach the consumers must include enabling and actively facilitating their participation to ensure their perspectives are heard;

- Governmental agencies should have a role in ensuring that the information provided to the consumer, health care providers, the general public and other stakeholders is scientifically accurate, and is provided in a manner appropriate to the target audience.

7. TOBACCO AGRICULTURE: INVOLVE AGRICULTURE STAKEHOLDERS IN DEVELOPING COMMUNICATION AND REGULATORY FRAMEWORK

Agriculture is often left out of consideration when discussing harm reduction but it has an important role to play in how low risk products are developed and manufactured. 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 for the production of tobacco (growing, curing, and processing);

- Grower organizations, producers, agronomists and academic research institutions both in the United States and internationally should 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 better products;

- Concerted efforts are undertaken to assist growers in transitioning out of the production of tobacco and/or in assisting growers in transitioning to a new system of production that makes risk-reduction a priority.

8. ENGAGEMENT AND DIALOGUE: ENCOURAGE CIVIL DIALOGUES WITH BROAD STAKEHOLDER INVOLVEMENT

Reducing disease and deaths (mortality and morbidity) will depend on developing new relationships among all of the relevant stakeholders. In this 'New Era' and rapidly changing environment there is an ongoing need to engage in more dialogues with broad representation of stakeholders at multiple levels and in multiple venues both in the public and private sectors. This will require that:

- Stakeholders and other experts (including, but not limited to, governmental agencies; public health organizations; tobacco, nicotine, and alternative product manufacturers; researchers; scientists; consumers; laboratory testing facilities; and tobacco agricultural interests) should be encouraged to engage in civil dialogues on a spectrum of tobacco, nicotine and alternative products harm reduction topics;

- Where adversarial situations exist, such engagement 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 independent facilitators.

- These venues may include both the public and private sectors, including regulatory agencies such as the US Food and Drug Administration, academic institutions, public health and scientific conferences, and trade association meetings.

These Core Principles are the product of a review and accumulation of information related to tobacco, nicotine, and alternative product harm reduction over more than a decade. This includes a review of numerous reports such as the Institute of Medicine's "Clearing the Smoke" and "Ending the Tobacco Problem"; the Royal College of Physicians' "Harm Reduction in Nicotine Addiction- Helping People Who Can't Quit"; and the FDLI/Georgetown University "Conference on Tobacco Dependence: Innovating Regulatory Approaches to Reduce Disease and Death." It includes numerous papers published in scientific journals, presentations at numerous meetings, various white papers, surveys, as well as a series of dialogues that have taken place over the last ten years.

On June 13-14, 2013 approximately 20 people interested in harm reduction and with very diverse backgrounds met at 'Morven', a retreat site at the University of Virginia, in Charlottesville, Virginia. This was the third of a series of on-going dialogues conducted by the Institute for Environmental Negotiation (IEN) at the University of Virginia, and a continuation of earlier dialogues conducted in the 1990's between the public health community and tobacco producers. These efforts compliment other dialogues and engagements that have been conducted and facilitated by the Food and Drug Administration and the Food Drug and Law Institute.

These Core Principles are not intended to be all encompassing but they do represent a significant and historic effort to provide the foundation for meaningful solutions for dealing with the increasingly important but complex area of tobacco, nicotine, and alternative products harm reduction. They are intended to give stakeholders some guidance on what some of the important and challenging issues are but to also suggest that there are many opportunities to be taken.

For more information about these on-going dialogues, please go to:
www.virginia.edu/ien/tobacco.