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

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THE MORVEN DIALOGUES

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 harm reduction strategies. The first dialogue was held in March 2011 outside of Charlottesville, Virginia at Morven. 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 and Europe but globally as well.

In late October 2014, a diverse group of 41 stakeholders met at the National 4-H Youth Conference Center in Bethesda, Maryland, for a fourth dialogue of the Forum for Civil Dialogue. This dialogue focused on "Building on the Core Principles: Next Steps for the Implementation of a Rational Approach to the Regulation of all Tobacco, Nicotine, and Alternative Products." The discussion affirmed the value and content of the Core Principles, and also surfaced the need for a few important refinements that reflect the continuing evolution of tobacco, nicotine, and alternative products. These updated and revised Core Principles include the refinements contributed by the fourth dialogue.

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EXECUTIVE SUMMARY

There are an estimated **one billion smokers** worldwide, many living in low and middle-income countries.
Over **5.3 million of those 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 on the market that could have a significant 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 nicotine delivery systems (ENDS).The Core Principles were originally produced and published in October 2013, amended in November 2014, and amended again in October 2015.

The following are a summary of the Core Principles.
A full copy can be found at: http://ien.virginia.edu/sites/ien.virginia.edu/files/MorvenCore-Principles2016.pdf

1. 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 and relative risks and intended uses.

2. 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 close collaboration between authorities). Legislative and regulatory policies should be "consumer friendly" and based on sound science.

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. 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.

4. 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.

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 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.

6. 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 in the development of policy and regulations.

7. 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 for the production of tobacco. A more concerted and cooperative effort should be undertaken to help transition growers out of the production of tobacco and/or assist 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

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.

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[1], though addictive and habit-forming for some, is not itself a significant factor in the causation of disease, and that 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, Electronic Nicotine Delivery Systems (ENDS) including 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 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.

[1]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 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.
- Preventing the purchase, sale, initiation, use and possession of all tobacco, nicotine and alternative products by children and adolescents under legal age 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 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 and, most importantly, should prevent youth access, initiation and use of all tobacco and nicotine products.

Individuals or representatives of organizations and businesses, consumers, academic institutions and other entities who believe that they can embrace them are encouraged to support them and to use them in helping move the tobacco, nicotine, and alternative products harm reduction agenda forward. To add your name (individual or organizational) of support for the Core Principles go to: www.surveymonkey.com/s/Morven

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. Electronic Nicotine Delivery Systems (ENDS)
9. 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, policy makers 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 all Electronic Nicotine Delivery Systems (ENDS) such as e-cigarettes, inhalers, and heat not burn products, 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 comprehensive, inclusive, coherent, proportional, and 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 data sharing and 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;

- In the case of corporate research funding to researchers, scientists and academic institutions there should be appropriate and necessary safeguards in place to ensure that the research and the results of such research are conducted with and 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.

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 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;

- 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 A COMMUNICATION AND REGULATORY FRAMEWORK

It is clear that consumers and users of tobacco, nicotine, and alternative products should always be 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 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;

- 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 A 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.

- Tobacco grown for harm reduction products should be grown using Good Agricultural Practices (GAP)[2] that are designed to ensure environmentally sustainable growing practices while respecting farm workers rights. These practices should also be consistent with national and international laws governing the use of child labor.

[2]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 wile protecting, sustaining or enhancing the environment with regard to 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

8. ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS), E-CIGARETTES

The spectrum of differing types of ENDS (Electronic Nicotine Delivery Systems) and components and accessories associated with them continues to grow. These products have the potential for reducing the devastating disease and death caused by the use of other tobacco products and specifically the combustible cigarette. The Core Principles statement applies to all tobacco, nicotine and alternative products including ENDS. But as a relatively new phenomenon, it may be useful to reiterate and reemphasize some of the parameters under which these products should be manufactured, sold, labeled and marketed. This includes that:

- ENDS (as broadly defined) should be regulated along with other tobacco, nicotine and alternative products based on their risks, relative risks, and intended uses;

- The development of fair but enforceable product standards should be given a high priority by all stakeholders, and should include standards such as those pertaining to, but not limited to, ingredients, safety, and child packaging;

- Advertising and marketing should not target those under the age of 21 and should be truthful and non-misleading. Sales of ENDS to anyone under a minimum of age of sale should be strictly prohibited and enforced. Sale and distribution of ENDS through the internet should be monitored and regulated.

- Flavors are not inherently bad, but they do increase appeal. Therefore, companies should specifically avoid using any flavor descriptors that ~~could~~ target ~~and entice~~ youth. (** It was agreed that the stricken words be removed to reduce subjectivity.)

- As with all tobacco, nicotine and alternative products, monitoring and surveillance of who is using the product and how it is used should be given a high priority;

- The scientific/regulatory standards for allowing ENDS 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 approach to the scientific study of ENDS should be undertaken involving academic research institutions, public health authorities, regulatory authorities, and manufacturers etc.;

- There must be a concerted and coordinated effort to educate the public, consumers, health care professionals, policy makers, regulators and the media about ENDS and the potential role they could play in reducing disease and death caused by the use of other tobacco products but in particular the combustible cigarette. ENDS should not be actively marketed to recruit new users of nicotine.

9. 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. Words do matter, and if collaboration is to be fostered, then it is important that stakeholders avoid portraying these difficult issues in an "us versus them" manner. 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:

- All 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 October 30-31, 2014 approximately 40 stakeholders met at the National 4-H Youth Conference Center in Bethesda, Maryland for a fourth dialogue of the Forum for Civil Dialogue. This was the fourth 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 complement 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 guidance on some of the important and challenging issues, and 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.

To add your individual or organizational name of support please go to:
www.surveymonkey.com/s/Morven

About the Institute for Environmental Negotiation

IEN is a nationally recognized leader in fostering collaborative change across a broad range of issues through multi-agency and multi-stakeholder processes as well as through community outreach and engagement. Team members are known for their 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 with environmental justice communities and under-served and under-represented interests.

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Tanya Denckla Cobb is a seasoned mediator and facilitator in environmental public policy. Through her career she has worked for the federal government, state government, local and state nonprofit organizations, and as an independent consultant. She was among the first certified in 1993 by the Virginia Supreme Court to mediate court-referred cases and conduct training in mediation. At IEN her work involves designing and facilitating public involvement, consensus building, collaborative problem solving, interest-based negotiation and mediation processes, and strategic planning for a broad range of community situations and needs. She also develops customized training around all of these skills. Her recent work includes projects on transportation and travel management, coastal resiliency, sea level rise, stormwater regulations, agricultural and food issues, tobacco harm reduction, park use conflicts, and urban and community forestry.

Frank Dukes, Distinguished Institute Fellow - ed7k@virginia.edu

Frank Dukes is a nationally recognized practitioner in the field of collaborative planning and environmental conflict resolution. His writing has influenced up-and-coming facilitators, with works such as Reaching for Higher Ground in Conflict Resolution and Community-Based Collaboration. In 2016, Frank Dukes received the University of Virginia's "John T Casteen III Diversity-Equity-Inclusion Leadership Award" for his leadership and deep commitment to achieving a sustainable and quantifiable impact on diversity, equity and inclusion at the University and in the local community. Equal to his work on social justice are his efforts on natural resource issues; the Association of Conflict Resolution presented Dr. Dukes with the 2012 "Sharon M. Pickett Award" for advancing environmental protection through alternative dispute resolution.

Judie Talbot, Senior Associate - jat5yc@virginia.edu

Judie Talbot's experience as a public policy and outreach facilitator encompasses all aspects of collaborative planning, mediation and conflict resolution. Her projects involve working with diverse interests and constituencies on challenging issues which often entail sensitive content. As a facilitator, Judie works with representatives of corporations, non-profit organizations, academic institutions, under-served communities, elected officials, as well as local, State, Tribal and Federal agencies. These projects address issues associated with land use, water resource management, recreation planning, natural resource management and planning, and transportation.

Scott Ballin, Health Policy Advisor and Special Advisor to the Morven Dialogues - scdba@aol.com

Scott D. Ballin's involvement with issues related to tobacco and public health spans more than 40 years. He has worked on issues regarding labeling reforms on cigarettes and smokeless tobacco products, FDA regulation of tobacco, excise taxes, clean indoor air laws, and tobacco agriculture reforms. For more than 10 years he served as the American Heart Association's Vice President and Legislative Counsel, and as a Steering Committee Member and two-time Chairman of the Coalition on Smoking OR Health (AHA,AC,ALA), the first truly active national coalition in the tobacco control movement. He served on the Steering Committee of the Alliance for Health Economic and Agriculture Development, an organization formed to enact the recommendations contained in a Presidential report, Tobacco at a Crossroads. He recently advised the US Food and Drug Law Institute in preparation for an October 2016 Tobacco Conference.