Dialogue Summary
5th Dialogue on Tobacco and Nicotine Harm Reduction
A National and Global Priority
October 22-23, 2015
National 4-H Youth Conference Center
7100 Connecticut Avenue
Chevy Chase, MD

Sponsored by the
Institute for Environmental Negotiation
University of Virginia
OVERVIEW

The fifth Dialogue on Tobacco Harm Reduction occurred on October 22-23, 2015. The objective for the 2015 sessions was to generate initial strategies for implementing the Core Principles, which had been established in previous Dialogues and revised and re-released in 2015. The following pages contain the principles themselves, along with a summary of the conversations and ideas associated with advancing each Core Principle.

Readers who are interested in supporting the Core Principles may do so through the following link:

www.surveymonkey.com/s/Morven

The format for the 2015 Dialogue differed from the past. An initial welcome was followed by an acknowledgement of the work done in previous dialogues. The remainder of the agenda was structured to provide dedicated time for each Core Principle, following a consistent format. For each session, a small panel of 3 – 4 individuals briefly discussed the current context of that principle. Participants then engaged in small group conversations to develop suggestions and proposals for implementing and realizing the goals embodied in a given Core Principle. Each group reported out on their discussions, generating additional insights from across the entire room.

At the conclusion of the second day, the entire group came together to for an expanded discussion of Core Principle #9: Engagement and Dialogue – which included developing an initial framework for next steps and further advancing the Core Principles.

Please note that as the conversations progressed, the concept of “Tobacco Harm Reduction” was specified to mean “Smoking Harm Reduction.” Similarly, what is referenced in the Core Principles as “Tobacco, Nicotine and Alternative Risk-Reduction Products” (also “Tobacco, Nicotine, and Alternative Products”) came to be referred to as “Smoking Alternatives.” As a result the original language is retained for each of the Core Principles – which are provided in text boxes – whereas the comments and ideas provided by panel members and participants will use the more recently agreed to phrases.
Core Principle 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. Communication of this information to consumers and others is essential. This should include:

  - All tobacco, nicotine, and alternative products including cigarettes, smokeless tobacco, nicotine replacement products, noncombustible products, gums, lozenges, and all Electronic Nicotine Delivery Systems 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.

Lightning Round Recap

Panel members:
Sara Machir
Lou Ritter
Sally Satel

Key Concepts:

- Many terms are not well defined, nor are they understood by users and the public. The types of products which provide alternatives to combustible cigarettes are constantly evolving. Trying to explain the difference between products is confusing to the consumer; it would be better to emphasize the harm reduction dimension.

- It is vital that real knowledge about the continuum of risk be made available to the end user. Consumers need accurate information to make meaningful decisions about their health.

- The conversation about health impacts is especially complex, with implications for regulation, product categories and evaluation. For example: How should the public health benefit be defined? What constitutes harm reduction or a modified risk tobacco product? What about products that don’t contain tobacco or that don’t contain nicotine?

- The challenges associated with cessation or reduced use of combustible cigarettes invokes questions about the definition of addiction. Does it involve dependence, an activity that requires medical treatment to quit? Is it compulsive activity alone, or does the activity need to inflict harm? Is the concern with nicotine itself, or the delivery mechanism?

- Some vaping products are nicotine-free. The end user finds satisfaction from behavioral cues. Where does this fit in terms of product categories and regulation?
Participant Discussions

Key Questions

Across the table-top conversations, several recurring question emerged:

- What can be done to improve definitions?
- Which definitions should be addressed?
- What research exists on definitions?

Product/Role Definition

There was general agreement among the participants that smoke-free products should comprise a separate category. A simplified approach could be used to convey the idea of risk reduction which consumers are increasingly coming to understand. For example, products could be categorized as:

- High-risk (combustible products),
- Low-risk (non-combustible products), or
- No-risk (cessation)

In the U.S., FDA regulation is correlated with an intended use and an intended user. It will be necessary to create categories that consumers can understand, while providing enough flexibility to include future new products. Currently, the concept of Modified Risk Tobacco Products is being defined through the SNUS application to FDA and, abroad, through the introduction of IQOS.

Ideas for Implementation

Suggestions for advancing Core Principle 1 revolved around several desired outcomes:

- Adopt a Collaborative Approach. Strategies for how to work together on definitions covered a range of options including: convening a conference comprised of multiple stakeholders; the CDC working with stakeholder to establish a Center for Harm Reduction; convening a group of policymakers including FDA, European entities and the leading international regulatory bodies to craft and adopt consistent definitions of products; and using a “wiki” approach. A specific suggestion was made to involve communication specialists such as those working with trade journals, news stations and mainstream media.

- Leverage Existing Resources, such as the specific engagement opportunity provided by the submittal of Deeming Regulations to OMB/OIRA, and the work done by CORESTA on definitions relating to testing methods and validation for e-cigarettes.

- Clarify Misperceptions. Address the issue of whether vaping leads to smoking by adjusting for the phenomenon of risky use. Similarly, state that while nicotine is not harmless it is not harmful if used appropriately. (Pregnant women and those with vascular problems should not use nicotine.) Other suggestions encouraged letters to editors when misinformation is presented, asking that a transparent and credible scientific analysis be provided.

- Address Product Risk. This can be advanced by clarifying the differences between products and what they contain, and explaining comparative risk. It was noted that associated risks need to be discussed as well, such as fires and second-hand exposure. It is likely that comparable risk between categories of products can be scientifically established, while research at finer levels may be impractical.

- Good Practices. To promote clear cross-communications, definitions should be consistent with those found in regulations (or describe how and where they differ – for example, tobacco “ingredients” mean different things for FCTC, TPD, etc.). Ensure that terms accurately make distinctions and are understandable to the general public. Phrases such as “tobacco harm reduction” perpetuate the association of tobacco with combustible cigarettes – the conversation should be around “smoking harm reduction.” Equal care must be given to non-judgmental language regarding the active choices to be made by consumers, rather than choices based on dependency.
Core Principle 2
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 is to regulate these products in a more consistent manner. This should include:

- 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.

Lightning Round Recap
Panel members:
- Azim Chowdhury
- David Graham
- Jim Solyst

Key Concepts:
- The Tobacco Control Act of 2009 governs regulatory policy of nicotine products. Where there is a claim of therapeutic benefit, the product is regulated as a drug. Otherwise, it is classified as a tobacco product. This leaves no middle ground for vapor products, which are an alternative to cigarette smoking.
- Manufacturers applying for MRTP status are responsible for indicating the level of risk and developing language for the warning label. The FDA does not provide instructions for the application, and it is not clear what benefit accrues with a reduced risk benefit order. Would this be linked to a continuum of risk, next to NRT?
- There are no regulations currently in place for nicotine products. Instead, advocacy organization are seeking to exert influence. While the present situation allows for innovation, a comprehensive and science-based regulatory approach would benefit reduced harm products.
- There is cautious optimism that regulation will support innovation and preserve user choices.
Participant Discussions

Key Questions

Dialogue among participants generated three overarching questions:

• What policies, procedures, and regulations would best protect the American public by reducing risk?
• What should the regulatory framework look like?
• How could the framework be used globally?

Overall Framework

It was generally agreed that risk-based regulation should address the following:

  Marketing restrictions,
  Labeling,
  Formulation, and
  Taxation (which is currently missing).

It was noted that, with each country having different regulatory objectives, there will be more than one solution set.

Ideas for Implementation

Suggestions for advancing Core Principle 2 revolved around several desired outcomes:

• Establish Collaboration Among All Stakeholders. Development of a regulatory framework must involve engagement of the right people, at the right level. This includes a seat at the table for consumers. Other organizations, such as ISO and CORESTA must also be part of the process. At a global level, a forum could be held on the U.S. deeming regulations and the equivalent U.K. regulations. This would bring together international stakeholders from industry, public health, academia, and consumer interests.

• Expand and Enhance Understanding of Harm Reduction. There is a responsibility to help global communities better understand harm reduction. Several strategies were suggested including: briefings at the FCTC meeting; YouTube presentations (e.g., a clip of Mitch Zeller’s remarks at the Robert Wood Johnson event would be powerful); and establishing resources for speakers who are involved with informing decisions at the level of local jurisdictions. Other individuals who have contributed to the discussion on a continuum of risk include Michael Fellerbaum, FDA; Deborah Arnott, Action on Smoking and Health; and Robert Blest, The Smoker’s Club. Ultimately, the goal to reduce risk must guide product regulation.

• Promote Communication. Conversations regarding nicotine product regulations should leverage key FDA themes, such as: incentives for innovation, responsiveness to stakeholders, support for small manufacturers and voluntary compliance standards. Discussions with FDA should occur through multiple venues including docket submissions, lawsuits, and listening sessions. Also the scientific community can engage CTP scientists.

• Bi-partisan political outreach should focus on information sharing. At the congressional level, this might entail presentations at oversight hearings. Use of personal stories and thoughtful public comments are effective strategies for reaching multiple audiences.

• Promote Appropriate Harm Reduction Standards. There was general agreement that product standards for reduced-risk claims are most appropriate and achievable at the level of covering product categories. It was noted that randomized trials do not demonstrate reduced risk and that other research designs are needed to inform standards. Related to this, better definition is needed from CTP guidance as to what is “appropriate to the public health.” Some level of federal guidance on basic quality control would be helpful to consumers. For example: What do products contain? How strong is the dose? Also, while the responsibility of developing a regulatory frameworks falls to greater regulatory agencies, industry can start to apply the Core Principles to its marketing and manufacturing activities.
Core Principle 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;
- 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 the utmost independence and integrity, including transparency in the financing, researching, and reporting process.

Lightning Round Recap
Panel members:
  - Ray Niaura
  - Chris Proctor
  - Lars-Erik Rutqvist

Key Concepts:

- A paradox exists in the area of funding for nicotine products. While there is a lack of public funding for research, tobacco-backed research is not accepted.
- There are multiple challenges for tobacco research in terms of: collaborating with other researchers, journal publication and acceptance of research results. Regaining credibility for industry research requires aggressive transparency. The MRTP process has the potential to serve as a game-changer. If the FDA gives an approval to snus, a post-market program will need to be implemented. If there is an order and a desire for collaboration, it will be easier to work with independent scientists.
- Toxicology and clinical studies serve as examples where non-competitive and collaborative areas exist for science. Industry must find a way to pool resources and conduct more research on harm reduction. A credible, arm’s-length funding approach is needed with any accompanying review process.
- While there have been good conversations on standardization, the process has been slow without generating specific conclusions.
- In the area of public funding, CTP guidance on research activities could be better focused to more effectively answer important questions.
Participant Discussions

Key Questions

High-level issues for this Core Principle raised the following questions:

- How can collaboration on research be promoted?
- How can research results be more broadly distributed?
- What options are there for a collaborative research funding mechanism with a critical review process?

Conduct Research on Cessation or Reduced-Risk Benefits

There was discussion about conducting a year-long study on e-cigarettes to assess reduced risk benefits. The approach would randomly allow smokers to choose from among 10 different products. However, the methodology would be incredibly difficult to identify the clinical biological markers for those who quit. One concern is that the results would be specific to the products, not the larger category.

Other comments pertaining to new research suggested the following:

- Research on user benefits should include risk reduction and other potential beneficial applications, such as treating schizophrenia and bipolar disorders.
- Develop trial designs to streamline testing of potential reduced-risk products.
- Determine the threshold of acceptable demonstration ahead of time, so that results can be integrated to support preferred outcomes.
- Look at the role of genetics in terms of the capacity to quit smoking.
- Both quantitative and qualitative research studies are needed on the behavioral aspects of use, cessation, product selection, and changes in use.

Ideas for Implementation

Suggestions for advancing Core Principle 3 revolved around several desired goals:

- Share Research and Results. Forums should be sought for sharing research that has not been peer-reviewed, making it available to all for their analysis and information. As an example, industry can provide unpublished data and research through the comment portal on the FDA docket. The data is available to the public. When comments are submitted on the docket, researchers should be encouraged to access the data submitted and use it in articles submitted for publication.

- Encourage Rigorous Review. Establish an independent scrutiny mechanism for all research conducted on nicotine and alternative products. There was a suggestion for a “meta-review” process to review and compare the science from universities and industry.

- Adopt a Collaborative Approach. There is a need to encourage and establish third-party coalitions to generate unbiased research that can be peer-reviewed and published. Industry can support transparency by inviting members of the scientific community into labs, to promote understanding of companies, priorities, and research agendas.

- Leverage Existing Studies. Pull or re-examine data from other studies and research such as those conducted by NIH (PATH Study) or Swedish Match.

- Establish Independent Funding Mechanisms for Research. IOM’s good governance guidelines provide a path forward for this. CTP could provide IOM with the charge and funding to take this on. While industry and other stakeholders could assist with funding and offer suggestions, decisions would be made independently by IOM. Another model is that of the E-research Foundation.
Core Principle 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, and manufacturers of tobacco, nicotine and alternative risk-reduction products be encouraged to commit increasing amounts of financial resources to developing innovative lower-risk products and that those manufacturers of 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.

Lightning Round Recap

Panel members:
- Gal Cohen
- Bonnie Herzog
- Jed Rose
- David Sweanor

Key Concepts:

- Innovation and transition are apparent in all aspects of life, with new ideas and disruptive innovations emerging at a rapid pace. It was noted that incentives for innovation are not necessarily legislative, demand often increases as people become aware of alternatives.

- Trends indicate that there will be a huge shift from combustion to non-combustion products, providing opportunities both commercially and for public health. Due to differences in regulatory frameworks, innovation may initially occur in Europe and transfer to the U.S. If product registration shows vapor composition, consumers will understand the value proposition.

- Current levels of misinformation about products is causing uncertainty among investors. Similarly, retailers are concerned that products might be banned and are hesitant to accumulate inventory that may not move. The release of information, such as that by PMI, can help reassure investors.

- A barrier to the allocation of NIH grants occurs during the peer-review process. While the NIH institutes emphasize innovation, there is rarely all the backup documentation necessary to assure success. As a result, the peer reviews may dismiss the application as not feasible. A proposal may not receiving funding because it’s never been done before. This is a structural issue at NIH, where concept level innovation is encouraged but then faces difficulties for securing funding.
Participant Discussions

Key Questions

Underscoring the role of consumer demand in determining innovative successes, participants asked the following questions:

• What are the changes in consumer demand and what is the rational for changing behaviors and products?
• How can the private sector be proactive in supporting future innovation?
• How can alternative products best be described and discussed?

Ideas for Implementation

Suggestions for advancing Core Principle 4 encompassed the following:

• Provide Incentives. A transformative innovation would be to provide incentives for cigarette makers to transition to alternative products. The incentive would help maintain profitability to offset the significant research and development needed to produce liquid (for an open system) at a level of quality and price that compensates for the loss in cigarette sales.

A different approach would extend the incentives that employers provide for smoking cessation or NRT, to include smoking alternatives products.

• Promote Innovation. Regulation itself, as with content emissions and product standards, will drive innovation. Conversely some regulations will discourage new technologies. Changing expectation around connectivity and monitoring will also affect innovation. It will be important to secure a particular category, then ensure that good products are available.

• Identify Strategies for Determining Risk. Options are needed to complement or substitute for lifetime risk studies. The FDA has experience with incentives and innovations for opioid alternatives, and with setting aspirational and achievable standards for product development.

One option is to approach large health insurers and suggest a study to test the hypothesis that switching from cigarettes to smoking alternatives will improve lung function and reduce health care visits for cardio-respiratory conditions.

• Fast-track Innovation. Link research to a number of parameters to create allowable standards set by the FDA. If an innovation meets the standards, it would be approved.

• Level the Playing Field. Analogous to the pharmaceutical industry, innovation comes from patenting – which smaller companies may not be well-positioned for. Mechanisms could be established to support innovation by smaller companies who lack the financial resources to fund research. It was noted that precedent exists for FDA assisting smaller companies, notably in the areas of food regulation and labeling.

It may be that most of the heavy lifting would be done by industry-related organizations that are more independent and objective than industry. Universities are developing their own spinoffs to promote innovation.

• Develop a Strong Consumer Research Program. This would provide feedback quickly and systematically. For example, vaping stores could gather information on why consumers try other products or step down in nicotine levels. Understanding user goals would inform product development.

• Establish a Tax and Pricing Structure. Many state budgets depend substantially on tobacco sales. A tax structure is needed to offset the loss of state revenues as sales of tobacco products diminish.
Core Principle 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;
• A 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.

Lightning Round Recap
Panel members:
   Jack Henningfield
   Ray Niaura
   David Sweanor

Key Concepts:
• Fast-tracking is achievable. The objective would be to establish parameters for safety, rather than proving efficacy. This is the model used for over-the-counter medication.
• Precedent exists for fast-tracking. Early regulation of products often sets a high bar. Reasonable safety standards are needed for products looking to reduce health risks. That was the approach taken for reviewing and approving AIDS medications. Consider which aspects might be most important for FDA – chemical composition, engineering?
• Monitoring is key for accountability. Many in the tobacco industry have advocated targeted and rapid research for safety and patterns of use. Proposals would need to be established for fast-track standards. This might involve establishing a limited market or safety outcomes (proximal and distal). Over time, the monitoring plan may become less frequent. Safety signals would need to be selected. These are especially important for the public health standard and would need to determine which thresholds make a difference in outcomes.
• The only practical approach, for oversight of monitoring field trials and post-market surveillance, would be under the control of the federal government. Federal agencies have the ability to establish standardized and technically-sufficient methodologies. This also removes the burden of designing a monitoring process, which might not receive FDA approval.
Participant Discussions

Key Questions

The following questions raise the main issues that need to be addressed:

- What does monitoring entail?
- What kinds of safety signals are needed; what constitutes the public health standard?
- What options or examples exist for this type of effort?

Range of Issues

Conversations on this Core Principle covered a wide range of topics: fast-tracking applications, threshold criteria, and a broad discussion on data collection. It was suggested that the different aspects of this Core Principle be broken out, to better determine what is needed to advance each aspect.

Ideas for Implementation

Suggestions for advancing Core Principle 5 revolved around several desired outcomes:

- Explore Options for Expediting Product Applications. FDA offers four approaches for expediting applications. The fast-track option establishes clear safety signals and parameters for a given product. A key element would involve setting the “public health standard,” which would be a complex process.

- Monitor Field Trials and Conduct Post-Market Surveillance. The federal government is best suited for providing oversight of these tasks. They can establish technically sophisticated and standardized methods to ensure that they have the data they need.

- Seek to Partner with FDA on Studies. If the FDA were to partner with industry and provide guidance on application studies, the overall process – and associated data outcomes – would be improved. FDA input would be especially valuable in the areas of study design, pre-market field trials, and post-market surveillance. The parts that are most difficult for industry to do are the ones that are easiest for the FDA to take on.

Pre-marketing data could be incorporated into models. If information could be standardized, then studies could be standardized.

- Judgment Criteria are Needed from FDA. These criteria will establish thresholds for defining a “public health standard.” Monitoring systems can then be established to track these signals – an example of this is the RADARS system designed for oxycotin. Market research companies could also play a key role, especially those (such as L & E Research) who have conducted research with smokers and already have population-based databases.

Establishing some type of self-regulating body could help identify and manage any potential issues within industry before reaching a level where regulatory agencies would need to step in.

- Encourage FDA to Establish Standardized Guidelines for Modified-Risk Tobacco Products. Regulators do not want to release products that create chaos in the market. As a result, a mechanism is needed to reign in products that do not perform as expected. Clear FDA guidelines, conditions and equivalents would provide industry with a better understanding of what is required for product approval.

- Improve Information. Currently, the FDA relies on calls to poison control centers for data on accidental ingestion of nicotine. Monitoring and surveillance programs need to include mechanisms to catch these types of unforeseen outcomes. Studies also need to clearly define key data objectives, such as: use of smoking alternatives compared to cigarettes, levels of adult and youth users, product toxicity and safety.
Core Principle 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 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 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.

Lightning Round Recap

Panel members:
Cynthia Cabrera
David Sweanor
Julie Woessner

Key Concepts:

- Consumers are poorly informed as a result of: regulatory constraints on information that vaping shops are allowed to provide to consumers; misinformation; and advocacy groups that vigorously promote cessation for reducing risks associated with smoking. It would be enlightening to conduct a survey to see how access to different information affects perceptions and behavioral choices.
- Multiple venues exist for raising awareness on harm reduction and alternative products. Examples include: high profile op-eds, webinars, YouTube videos, brochures, social media, and strategic interviews. Legal challenges also draw attention to issues. These strategies reflect much of what was done 30 years ago in the campaign to stop smoking.
- A large disconnect exists between regulators and consumers. One panelist could only find four surveys on smoking cessation using vapor products and the results were inconclusive. Alternatively, anecdotal reports of numerous vapers speak to the role of alternative products in reducing or ceasing cigarette smoking. Consumers and other stakeholders need to be engaged in the regulatory process, to provide input about their experiences and concerns.
- Independent research is needed on the role of alternative products in reducing or ceasing cigarette smoking and the associated harm.
Participant Discussions

Key Questions

The small-group discussions generated several overarching questions:

- How can better information be provided to consumers?
- What options exist for creating media coverage?
- What issues will surface within the next year?

Ideas for Implementation

Suggestions for advancing Core Principle 6 addressed the following themes:

- Engage Consumers and Other Stakeholders in the Regulatory Process. Encourage the FDA and CTP to engage in negotiated rule-making for tobacco, nicotine and alternative products and on the issue of smoking harm reduction. Concurrently, speak with legislators and emphasize the need for input from consumers and the public on smoking alternatives regulation. Enlist journalists who write about flavors to focus on consumer protection issues.

- Share Information and Stories. Issues resonate with the larger public when people understand who benefits from a particular situation. One thought is to collect 10,000 vignettes from vapor users to describe the road they took in switching from cigarette smoking to vaping.

Similarly, it would be helpful to describe how consumers get information about smoking alternatives products. An IOM committee could be convened to analyze and report on the situation, with recommendations for improving access to – and the accuracy of – such information.

- Understand Consumer Needs. Work with consumer organizations to conduct market research on consumer needs – especially on smokers who do not try smoking alternatives products.

- Describe Relative Risk in User-Friendly Terms. Consider using a red-yellow-green dashboard to convey relative risks for different categories of products, or a hub-and-spoke image as used in the United Kingdom. Consumers also need to know that use behavior (“puffs”) affects the amount of nicotine uptake.

- Encourage Independent Assessments of Smoking Cessation and Harm Reduction. Reach out to Consumer Reports, NIH, NIDA, or health insurers to conduct and report on their own studies of health consequences associated with use of alternative products compared to cigarette smoking. Researchers themselves should be talking to legislators about vapor and harm reduction, including environmental tobacco smoke exposure.

- Challenge Misinformation. Contact journals and organizations who provide flawed, incomplete, or inaccurate reports. If they are not responsive to the concerns raised, document the exchange to build a case to take to legislators. Contact local and state jurisdictions who incorporate existing misinformation into ordinances. Consider filing actions (e.g. that misinformation violates consumer protection laws).

- Mobilize the Vaping Community. A large, grassroots effort is needed to connect consumers, vapor shops, manufacturers, and Chambers of Commerce. There is the possibility of consumer outrage, if smokers have foregone using alternative products because of information that there is no difference in risk. Also, constraints on sharing of accurate information trigger concerns relating to consumer protection, social justice, and freedom of speech. A “Million Vaper March” was proposed.

- Anticipate Consumer Issues. Within the next year, emerging consumer issues will likely encompass labeling regulations, relative risk, and the role of alternative products in smoking cessation.
Core Principle 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) 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.

Lightning Round Recap
Panel members:
- Hoppy Henton
- Lars-Erik Lutqvist
- Sara Machir

Key Concepts:
- Agricultural interests have been advocating for FDA oversight for the past twelve years. Growers in the U.S. often project a bunker mentality, as production has gone overseas and there is a reduction in profitability. While cigarette and nicotine companies are making money, growers are not.
- In moving to non-combustible products, U.S. growers are shut out of the market as e-liquids are being made from tobacco scraps from China and India.
- There was a program to incent tobacco that was flue-cured according to specific standards, with a premium paid for leaf which contained reduced nitrosomine levels. Applying flue-cured standards to non-combustion products could play a factor in harm reduction.
- The voluntary reduced-risk standard by Swedish Match, for snus, provides an example for reducing nitrosomine levels. The company worked closely with growers, and contracted for flue-cured tobacco which met conditions relating to curing, planting, and pesticide application.
- From a public affairs perspective, it is important to maintain good relations with growers. Communities and growers alike want to support local jobs and the cultural heritage associated with tobacco.
- Currently, the U.S. has no consistent standards for imported tobacco leaf. The question is whether there is an interest in creating that type of standard.
Participant Discussions

Key Questions

During small group discussions, several key questions surfaced:

- Is there a niche market for country-specific tobacco-based nicotine for ENDS?
- What can be done to better engage agricultural interests?
- How can good growing practices be promoted for agriculture?

Discussion on Tobacco Types

A question was raised as to why tobacco grown in the U.S. does not work for non-combustible products. It was explained that the tobacco currently grown in the U.S. is traditionally grown for combustible cigarettes. There are darker varieties that can be used for snus. Much of this relates to the extraction process for e-liquids, where significantly less tobacco is needed. With the accompanying reduction in acreage, the question is whether the market would still be profitable.

Discussion on Production Practices

The FDA has indicated that it will look at processes for producing e-liquid very closely. This will involve looking at the solvents used for extraction, as well as ingredient analysis.

In the production process for e-liquids, tobacco is boiled whereby the impurities are removed. Consequently, the value of good agricultural practices is diminished. There is little benefit to the buyer with reduced pesticide use. Subsequently, the idea of tracing a liquid back to its source largely becomes a non-issue.

Ideas for Implementation

Suggestions for advancing Core Principle 7 revolved around several concepts:

- Find a Niche. There may be opportunities for “designer tobacco” which is grown to buyer specifications. This would be associated with tobacco or liquid properties that buyers are seeking for a specific product.

Other opportunities may exist in terms of consumer interest in “locally grown” or non-GMO crops. Many people are apprehensive about material from China. The argument for where tobacco is grown could potentially be a strong one.

- Recognize the Implications of a Global Market. U.S. tobacco can be expensive. It would be contrary to public health interests if costs for nicotine increased, thereby increasing consumer costs and perhaps discouraging smokers from switching to alternative products. Manufacturers of e-liquids are looking for competitive pricing and production of nicotine, especially at the pharmaceutical level.

- Explore Options for New Markets. This would entail looking at what is needed to transition growers from traditional tobacco to that needed for e-liquids. It could also include support for tobacco growers to move to production of other crops.

- Create Incentives for Better Growing Practices. Political leadership and long-term contracting agreements can both support better growing practices, by establishing parameters for factors such as child labor conditions and application of fertilizers and pesticides.

- Increase Communication with Growers. Greater dialogue is needed between growers and health advocates on the issue of reduced harm and lower carcinogen levels. Similarly, buyers need to provide growers with information from test results on tobacco quality and share forecasts on consumer trends and changing markets.
Core Principle 8
Electronic Nicotine Delivery Systems/E-Cigarettes: Specifying a role for ENDS/e-cigarettes in reducing disease and death caused by tobacco

• 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 the legal 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.
• 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, trade associations 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.

**NOTE:** It was agreed that the stricken words be removed to reduce subjectivity.

Lightning Round Recap
Panel members:
  - Cynthia Cabrera
  - David Graham
  - Jack Henningfield
  - Lou Ritter

Key Concepts:
• The magnitude of public health benefits that could be gained by switching from cigarettes to smoking alternatives is not widely understood. Gun control is widely debated while thousands more are suffering and dying from smoking-related diseases. Much of this is due to the fact that researchers and scientists have not engaged politically on the issue.

Another challenge is posed by the diversity of products. The industry is not monolithic. The products found in convenience stores are different from those sold in vaping stores. There are legitimate concerns that need to be addressed. Some are related to hardware, such as charge control reliability, where safety features are needed.

• Other concerns are related to enticement of youth, in terms of marketing and flavorings. Here, outcome-based studies are needed. While any flavor “could” potentially entice youth, the impact should be evaluated for different populations. For example, do flavors increase user satisfaction? Is this a factor in smokers switching to non-smoking products?

• Paradoxically, the prohibitions against making harm reduction and cessation statements results in marketing strategies that focus on appeal factors.

• Taxation could be an important policy driver. Many states rely on cigarette taxes for revenue. A reasonable tax structure could increase support for non-smoking products.
Participant Discussions

Key Questions

Across the table-top conversations, several recurring questions emerged:

• How do we incorporate smoking harm reduction and smoking alternatives products into a tobacco control policy?
• What options exist for developing a regulatory standard that provides both aspirational goals (that can be achieved) and protection (through product standards)?
• How can the debate about smoking alternatives be changed and brought to the public?

Discussion on Overall Health Effects

There are questions as to whether smoking alternatives are a gateway to using nicotine and, if so, to what extent. Instead, the focus should be on differentiating the health effects between cigarettes and smoking alternatives. Cigarettes kill and ENDS do not. This message needs a credible messenger.

A survey of public views could be one way to raise the issue. For example, ask a generic question as to whether it is acceptable for people to use addictive products, if the use doesn’t harm the users or the people around them. Then ask them about specific products such as caffeine, marijuana and nicotine.

Ideas for Implementation

Proposals for advancing Core Principle 8 centered on the following themes:

• Conduct Research on Motivational Aspects of Switching to Smoking Alternatives. There are behavioral rewards associated with vaping, independent of nicotine. (Some products are even nicotine-free.) This is a critical aspect for switching from cigarettes, or dual-use, and needs to be understood.
• Evaluation of Smoking Alternatives Need a Matching Control Against Cigarettes. The risk comparison should be simplified to reflect high risk (combustion), moderate risk (non-combustion), and no-risk (cessation). Conversely, risks vary among different products in the non-combustion category.
• Frame the Need for Education. Consumers and the public should not be left in the dark. Current studies are emphasizing nicotine uptake, rather than the uptake of physiologically damaging substances. Information on innovations, harm reduction, and cessation benefits of smoking alternatives should be presented to the AAAS, as well as the FDA. The impacts of smoking alternatives should be evaluated using evidence-based protocols.
• Integrate Smoking Alternatives into a Comprehensive Package for Tobacco Control. It is essential to show that non-smoking products work with tobacco control, and not against it.
• Promote Good Practices. Industry has a responsibility to ensure that products are not being marketed or sold to youth, and that products are developed to encourage smokers away from cigarettes to less harmful alternatives.
• Candidly Discuss Marketing Objectives. Should people who have never smoked be encouraged to try smoking alternatives? What’s the marketing strategy regarding people who don’t smoke? As long as cigarettes exist, is the smoking public enough of a consumer base?
• Encourage a Regulatory Framework that addresses: ingredient review, product and safety standards, and taxation. Oversight is needed, with appropriate sanctions for those who violate regulations.
Core Principle 9  
Engagement and Dialogue: Encourage civil dialogues with broad stakeholder engagement

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 U.S. Food and Drug Administration, academic institutions, public health and scientific conferences, and trade association meetings.

Lightning Round Recap

Panel members:
Farrell Delman
Jack Henningfield
Jenny Kane

Key Concepts:
• Much has transpired during the last 10-12 years in the area of dialogue and engagement. Initial efforts were primarily funded by public health interests, to discuss smoking and health. Now industry representatives are providing funding to address smoking harm reduction.

• During that same time, shifts in the nomenclature have created challenges for harm reduction. Specifically, the focus on smoking cessation has shifted to tobacco cessation and even nicotine cessation. For industry, the goal is simply to provide alternatives to smoking.

• A non-governmental organization (NGO) or center could be quite helpful in serving as a neutral entity for collaborative research, and for meta-analysis of research. Greater attention could be given to studies at the level of product categories, rather than individual products.

• An NGO would also be involved in: disseminating findings, raising political and public awareness of harm reduction, and informing policy priorities. Such a center should encourage involvement and engagement of broad stakeholder interests, including those of consumers.

Careful consideration would be needed on creating the organizational structure and funding mechanisms, to ensure that research and priorities are science-based and not determined by funding partners.

• Existing membership organizations, such as FDLI, should be leveraged to further advance education and discussion.
Overview

Delon Human transitioned the two days of dialogue to a discussion on next steps. He reflected on the abundance of talent and expertise of those in the room and asked participants to consider what actions could be taken, both individually and collectively, to reduce the harm associated with smoking and to better convey the role of smoking alternatives in harm reduction.

Delon identified three key barriers that will need to be addressed in the coming year:

• Cognitive dissonance associated with balancing individual and public health priorities: The potential for individual health benefits from smoking alternatives cannot wait 20 years for population studies to be completed.

• Conflicts of interest that discourage or prohibit health organizations and industry from working together: The reality is that many conflicts of interests occur at multiple levels. The objective is to be aware of those conflicts and to assure that all perspectives are heard and thoughtfully considered in decisions.

• Consumers’ needs and interests are not represented in policy and regulatory discussions: Greater information is needed on why consumers change their habits and what their preferences are.

Key Questions

Dialogue participants were asked to consider and respond to three aspects associated with a plan of action for the coming year:

• Have any opportunities been missed to advance smoking harm reduction?

• From personal and organizational perspectives, what are the priorities for the coming year?

• What individual actions can be taken to realize those priorities?

Ideas for Implementation

• Adopt a Collaborative Approach. Leverage the efforts of NGOs that work with FDA, such as FDLI, to expand the range of represented interests in public health conversations. Other approaches should include: the development of a trade association to improve dialogue with manufacturers, creating partnerships to enhance education and outreach, and strengthening public relation skills and communication strategies.

Engage the right people at the right level. Refer to the Stakeholder Diagram to foster exchanges with a broader group of interests. Look at engaging trade partners, including China which manufactures many e-product components.

• Conduct Outcome-based Studies on the Role of Smoking Alternatives in Smoking Cessation. Conduct a short (one-year), open label cessation study that compares smoking alternatives to NRT in terms of effects on smoking. Challenge personally-held beliefs through science. Two meta-analyses show that products containing nicotine are more effective than placebos in helping people to quit smoking. Results should be pulled from the PATH study to look at how smoking alternatives fit with smoking cessation.

• Engage at International Levels. There are multiple opportunities to engage others on the subject of smoking harm reduction. The U.S. should attend the FCTC negotiations to ensure its voice is heard. U.S. interests should also monitor developments in international standards – recognizing, and being sensitive to, differences between the U.S., Europe, and other countries.

• Adopt Good Practices. Industry can and should voluntarily apply the Core Principles to manufacturing and marketing activities.
• Share Information. Use websites, such as the FDA Docket Comments Portal or e-research foundation, to post materials from both industry and non-industry experts to share information and broaden understanding of smoking harm reduction and smoking alternatives. Collaborative work that does not revolve around proprietary information should be fostered.

• Develop a Strategic Plan. Using a consensus based approach, collectively identify goals and strategies for the next 12 months. Be proactive in providing leadership.

• Further Investigate the Idea of an NGO. Look at options for, and interest in, creating a coalition, forum or Center for common action on a more sustained basis. A non-profit center represents a longer term strategy. Its organization and board should be independent, creating a forum for all perspectives to be represented on a wide variety of issues.

• Create Work Groups to take further action on the ideas discussed in the Dialogue, focusing on:
  – Mission, Vision, Strategic Framework
  – Communication, Consumers, Outreach
  – Definitions and Regulations
  – Science and Research
The Tobacco, Nicotine, and Alternative Products Harm Reduction Roundabout

Reaching Stakeholders and Other Constituencies

Building Capacity for Successful Harm Reduction