FDLI'S FOOD *and* DRUG
POLICY FORUM

How Should FDA Implement a More Rational and Workable Approach to Regulating Tobacco, Nicotine, and Alternative Harm Reduction Products?

Frank Dukes, PhD
Director
Institute for Environmental Negotiation
University of Virginia

Tanya Denckla Cobb
Associate Director
Institute for Environmental Negotiation
University of Virginia

Scott D. Ballin, JD
Health Policy Consultant
Advisor/Consultant to the Institute for Environmental Negotiation
University of Virginia

VOLUME 3, ISSUE 18 // OCTOBER 23, 2013

THE FOOD AND DRUG LAW INSTITUTE
1155 15TH STREET NW. SUITE 800 // WASHINGTON, DC 20005
www.fdli.org

FDLI

FOOD // DRUGS // ANIMAL DRUGS // BIOLOGICS // COSMETICS // DIAGNOSTICS // DIETARY SUPPLEMENTS // MEDICAL DEVICES // TOBACCO

INFORMATION FOR SUBSCRIBERS AND PURCHASERS

License Agreement (the "Agreement") and Terms of Use for End Users of FDLI Digital Publication Product Services (the "Services")

THIS IS AN AGREEMENT BETWEEN YOU, (THE "END USER"), AND THE FOOD AND DRUG LAW INSTITUTE ("FDLI"). FDLI IS THE PROVIDER OF THE SERVICES THAT PERMIT END USERS, (LIMITED TO FDLI MEMBERS OR NONMEMBER SUBSCRIBERS OR PURCHASERS OR OTHERS AS DETERMINED BY FDLI) TO LICENSE DIGITAL PUBLICATION PRODUCTS (THE "DIGITAL PUBLICATION PRODUCTS") FOR END USER USE ONLY UNDER THE TERMS AND CONDITIONS SET FORTH IN THIS AGREEMENT. PLEASE READ THIS LICENSE AGREEMENT AND TERMS OF USE, AND ALL RULES AND POLICIES FOR THE SERVICES (INCLUDING, BUT NOT LIMITED TO, ANY RULES OR USAGE PROVISIONS SPECIFIED ON THE FDLI WEBSITE) BEFORE USING THE PRODUCTS. BY USING THE PRODUCTS, YOU AGREE TO BE BOUND BY THE TERMS OF THIS AGREEMENT.

Digital Publication Products

FDLI website: The FDLI website enables the End User to download this Digital Publication Product to a personal computer or personal handheld device solely for personal use.
Use of Digital Publication Products: Upon your payment of the applicable fees, FDLI grants you the non-exclusive right to retain a permanent copy of the applicable Digital Publication Product and to view, print and use such Digital Publication Product an unlimited number of times, solely for your personal, non-commercial use.
Restrictions: The End User agrees that Digital Publication Products contain proprietary material that is owned by FDLI, and is protected by United States copyright laws. For reprint permissions or distribution inquiries, contact FDLI at (202) 371-1420.

For subscription or purchasing information, visit **www.fdli.org.**

Disclaimer

The Food and Drug Law Institute, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications and member interaction.
The views, opinions and statements expressed in this article are those of the author(s). The Food and Drug Law Institute neither contributes to nor endorses Forum articles. *As a not-for-profit 501(c)(3) organization, FDLI does not engage in advocacy activities.*

FDLI

1155 15th Street NW, Ste. 800, Washington, D.C. 20005
Tel: (202) 371-1420; Fax: (202) 371-0649
email: comments@fdli.org
website: www.fdli.org
www.fdli.org

FDLI' S FOOD AND DRUG POLICY FORUM

FDLI'S FOOD AND DRUG POLICY FORUM

TABLE OF CONTENTS

How Should FDA Implement a More Rational and Workable Approach to Regulating Tobacco, Nicotine, and Alternative Harm Reduction Products?

I. INTRODUCTION

The central questions of this article are: What are some of the essential elements and processes that are needed for implementing a more rational and workable approach to the regulation of tobacco, nicotine, and alternative product—designed to reduce disease and death from tobacco use? And, can these elements and processes be used not only in the United States, but globally as well?

For decades, the issue of tobacco (primarily smoking) and its effects on public health had been dealt with in a mostly unregulated environment in which the public health and tobacco control organizations waged a two sided 'war' with tobacco companies (often referred to as Big Tobacco). With the advent of the Food and Drug Administration's (FDA) regulatory oversight over tobacco, with FDA's existing oversight of 'nicotine' in the form of nicotine replacement therapies (NRT), and with the development of new innovative science-based products, there is an opportunity today to fundamentally change the way in which we approach the regulation of these products that did not exist even three or four years ago. While relatively new, these issues were first touched on in 1998 at a conference jointly sponsored by Georgetown University and the Food and Drug Law Institute entitled "The Conference on Tobacco Dependence: Innovating Regulatory Approaches to Reduce Disease and Death"—the proceedings of which were published in a Special Supplement to the *Food and Drug Law Journal*.[1] This article will address what kind of issues, elements, and processes will be needed to move the discussions forward, as well as specifically recommend a set of interrelated Core Principles that will need to be considered.

POLICY RECOMMENDATIONS

- Refine and define the terminologies that are currently being used (including developing new ones) which are better suited to the rapidly changing tobacco, nicotine and alternative products environment;
- Develop a more rational and coherent regulatory approach (by statute and/or through regulation) that regulates all tobacco, nicotine and alternative products based on risks, relative risks and intended uses (continuum of risk);
- Ensure that regulatory oversight includes the monitoring and surveillance of how all tobacco, nicotine, and alternative products are being sold,

marketed, and used to ensure that there are no significant adverse public health ramifications;

- Develop an integrated science and research agenda that includes a broad spectrum of stakeholders to help guide product development and policy decision making;

- Encourage and promote innovation and technology to develop new science-based lower risk tobacco, nicotine and alternative products;

- Encourage the participation of a spectrum of stakeholders in policy decision making that includes researchers and scientists, manufacturers of tobacco, nicotine and alternative products, public health advocates, consumers, health care professionals, producers, entrepreneurs and others;

- Encourage ongoing civil dialogue and engagement of a broad spectrum of stakeholders and experts in both the public and private sectors on issues related to tobacco, nicotine, and alternative products harm reduction.

II. BACKGROUND

A. A National and Global Priority to Reduce Disease and Death

The use of tobacco products particularly in the form of the combustible cigarette remains the single most preventable cause of disease and death in both the United States (over 400,00 deaths annually),[2] and the world (5.3 million premature deaths).[3] In 2014, it will be 50 years since the first Surgeon General's Report on smoking was released.[4] This epidemic, that has continued for more than five decades, is expected to continue, particularly at the global level unless new strategies and approaches are implemented to compliment strategies currently being used.

As is noted in the Preamble to the set of Core Principles that will be highlighted in this article:

> The global epidemic in smoking is alarming in both its magnitude and its escalating prevalence. Despite considerable public health effort, the reduction in the incidence has been slow, and rates of cessation success, even with nicotine replacement therapy (NRT) assistance, tends 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.[5]

Recognizing that nicotine, though addictive, is not itself a significant factor in the causation of disease, addicted smokers urgently need access to significantly lower risk tobacco, nicotine and alternative products.[6] In order to achieve this goal, it is necessary to inform the general public, consumers, policy makers, health care providers and other stakeholders about the benefits that can be obtained by switching from a combustible tobacco product to a significantly lower risk noncombustible product.

Today's products include not only the more traditional tobacco and nicotine products, but newer innovations including gums, lozenges, e-cigarette and inhalers. This expansion presents new challenges, but also creates new opportunities for reducing the devastating disease and death caused by the use of tobacco both on 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 leaf; to 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.

B. The University of Virginia 'Morven' Dialogues - The Search for New Approaches in a 'New Era'

The set of "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" were developed under the auspices of the Institute for Environmental Negotiation (IEN) at the University of Virginia, which is a part of the Institute's ongoing initiative "The Changing Environment of Tobacco, Nicotine and Alternative Products Regulation: Developing a More Coherent and Rational Approach."[7] They are the product of review and accumulation of information related tobacco, nicotine and alternative harm reduction over more than a decade. This includes a review of numerous reports such as the Institutes of Medicine's "Clearing the Smoke-Assessing the Science Base for Tobacco Harm Reduction, National Academy of Sciences, 2001 " , and "Ending the Tobacco Problem, National Academy of Sciences, June 2007; the Royal College of Physicians' "Harm Reduction in Nicotine Addiction- Helping People Who Can't Quit", a report by the Tobacco Advisory Group of the Royal College of Physicians. It includes numerous papers published in scientific journals, presentations at numerous meetings, various white papers, surveys, as well of a series of dialogues that have taken place over the last ten years.[8]

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

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

Moving forward is going to require new thinking and new leadership on the part of many stakeholders, and a better understanding of what is a rapidly changing environment.

III. RECOMMENDATIONS

The Core Principles were developed as part of an effort to focus on what a successful tobacco, nicotine and alternative harm reduction effort, designed to reduce a national and global burden of disease and premature death from tobacco products, might encompass. The 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 complimentary to other existing tobacco control efforts.

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

> **"Therefore Be It Resolved** that in order to address the global burden of disease and death caused by the use of cigarettes and other dangerous combustible tobacco products and in the furtherance of promoting public health through product modification and the development and availability of significantly lower-risk tobacco, nicotine, and alternative products, the following *interrelated principles* be embraced and implemented. These core principles fall within eight categories:
>
> 1. Definitions and Terminologies: Adapting to a Changing Environment

2. Regulatory Oversight

3. Research and Science

4. Innovation and Technology

5. Monitoring and Surveillance

6. Consumers and the General Public

7. Tobacco Agriculture

8. Engagement and Dialogue

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

Today's marketplace has a rapidly growing number of products and manufacturers. It is no longer a marketplace where new products are or can be evaluated only in terms of black and white, but where instead there are multiple shades of gray. The inability to communicate about the risk-benefits of different products constitutes an urgent health communication issue. The communication of this information to consumers and others is essential. This should include that:

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

2. 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;

3. Governmental agencies, policy makers, non-governmental organizations, health care providers, manufacturers and consumer organizations need to work cooperatively and transparently to develop more useful definitions and terminologies and to transmit and communicate that information in a more consistent manner to consumers, the general public, patients and other stakeholders.

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

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

1. 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;

2. Sound science, transparently developed and communicated, provides the basis for those regulations and standards, including the regulations and standards governing harm reduction alternative products;

3. Those regulations and standards take into consideration the interests and needs of the consumer and users of products;

4. 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;

5. The combustible cigarette is used as the 'reference product' for evaluating the risks and relative risks of other tobacco, nicotine, and alternative products;

6. 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;

7. 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;

8. 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.

9. 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:

1. 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;

2. Manufacturers of tobacco, nicotine, and alternative products should make non-proprietary research readily available to regulators, academia and the public;

3. 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;

4. There should be greater interaction, including collaborations (consortia) between all researchers and scientists, regardless of institutional affiliation;

5. 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;

6. 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;

7. 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;

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:

1. Governmental research bodies, manufacturers of tobacco and nicotine and alternative risk-reduction products should 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.

2. 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.

3. 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:

1. 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;

2. 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;

3. 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.

4. 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.

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

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

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

1. 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;

2. 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;

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

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

Agriculture is often left out of consideration when discussing harm reduction but it has an important role to play in how low risk products are developed and manufactured. This should include that:

1. 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);

2. 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;

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

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

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

1. 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;

2. 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.

3. 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.

IV. IMPACT OF POLICY RECOMMENDATIONS

The ramifications of the implementation of the recommendations contained in the Core Principles could have significant positive public health consequences both in the United States but equally important, globally as well. By changing the regulatory environment and establishing a more consistent and rational regulatory framework (at the FDA as well as in regulatory agencies at the global level) in which all tobacco, nicotine and alternative products are subject to regulation based up the *risks, relative risks and intended uses* of the product (continuum of risk) we cannot only reduce the disease and death caused by the use of tobacco products (particularly in the form of combustible cigarettes) but also oversee the corporate behaviors of those in tobacco, nicotine, and alternative products businesses who might otherwise attempt to circumvent fair and appropriate regulatory oversight. By giving or advocating incentives for all companies to innovate and conduct science based research and instilling competition into a regulated market place we can change and level the playing field even further. Those who choose to ignore the regulatory requirements or fail to play by a fair set of 'rules' within a regulated system will find themselves on the outside and forced to no longer continue to market their hazardous products. By monitoring and conducting ongoing surveillance on the manufacture, sale, distribution and marketing of all tobacco, nicotine, and alternative products we can quickly and more effectively evaluate the effects of a product (or a class of products) on the health of an individual and on the broader population. And by encouraging civil dialogue and engagement in both the public and private sectors we can better ensure the transparency and participation of all stakeholders seeking to find meaningful and workable solutions to the tobacco epidemic.

V. CONCLUSION

Accomplishing the objectives of these interrelated policy recommendations, which are designed to advance public health goals, is going to require leadership on the part of a spectrum of stakeholders who are willing to recognize that we are in a 'New Era' — one which is changing dramatically and which presents both challenges but more importantly new opportunities. By addressing the various topics in a more civil, rational, and transparent manner and by using the recommendations contained in the Core Principles as part of an effort to develop more workable, effective and complimentary statutory and regulatory policies, in both the United States as well as abroad, we can collectively address what remains a global public health crisis.

ENDNOTES

1. *See* Supplement, 53 Food & Drug L.J. (1998).

2. *See* Centers for Disease Control and Prevention, Department of HHS, Smoking and Tobacco, 2013, www.cdc.gov/TOBACCO.

3. *See* World Health Organization, Tobacco Free Initiative, Tobacco F acts, www.who.int/tobacco/mpower/tobacco_facts.

4. Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service. Washington DC: Public Health Service, DHEW publication no.(PHS) 64-1103.

5. *See* World Health Organization, Tobacco Free Initiative, Tobacco Facts, www.who.int/tobacco/mpower/tobacco_facts.

6. *See* Royal College of Physicians. Harm Reduction in Nicotine Addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians (London:RCP 2007); and *see also* Human, Delon, Wise Nicotine (2010).

7. *See* Institute for Environmental Negotiation, University of Virginia, www.virginia.edu/ien/tobacco.

8. *See e.g.*, Ballin, S., "Smokefree' Tobacco and Nicotine Products - Reducing the Risks of Tobacco Related Disease, A Constructive and Practical "Road Map" Towards a Civil Dialogue to Influence Public and Private Sector Policy Decisions", November 2007, www.tobaccoatacrossroads.com.

ABOUT THE AUTHORS

Frank Dukes, Ph.D., author of *Reaching for Higher Ground in Conflict Resolution* and *Resolving Public Conflict,* is an experienced facilitator, trainer and mediator, and is a senior practitioner on the national Roster of Environmental Dispute Resolution and Consensus Building Professionals. He brings a strong understanding of local state, federal, and community involvement, and has worked with numerous communities and individuals on a wide range of issues including, water supply, school districting, facility siting and tobacco. In the area of tobacco he and the Institute were instrumental in bringing the public health community and tobacco growers together to discuss such issues as FDA regulation and a tobacco buyout. More recently he has been involved in a series of dialogues related to tobacco, nicotine, and alternative products harm reduction. He teaches courses in collaborative planning and other topics at UVa. Contact Information: ed7k@virginia.edu.

Tanya Denckla Cobb is an author and seasoned mediator and facilitator. Through her career she has worked for the federal government, state government, local and state nonprofit organizations, and as an independent consultant and writer. She is a senior practitioner on the national Roster of Environmental Dispute Resolution and Consensus Building Professionals. Her work at IEN has included a broad range of environmental, agricultural and community issues, including work on the public health and tobacco grower dialogues in the 1990s (The Southern Tobacco Communities Project) and, more recently, the Morven Dialogues on tobacco, nicotine, and alternative products harm reduction. She teaches group facilitation and other topics at UVa. Contact Information: td6n@virginia.edu.

Scott D. Ballin, JD has worked in the public health policy arena for more than 40 years, which has included a significant focus on the issue of tobacco. He served as the Vice President and Legislative Counsel of the American Heart Association and was instrumental in advocating that tobacco be

brought under the regulatory jurisdiction of the US Food and Drug Administration. He served on the Steering Committee and was a two time Chairman of the Coalition on Smoking OR Health, the first tobacco control coalition formed in the United States. He has consulted with a number of organizations including the Campaign for Tobacco Free Kids, the American Lung Association, and the Institute for Environmental Negotiation at the University of Virginia. He has presented at numerous meetings and conferences and written a number of 'white papers' on tobacco, nicotine and alternative products harm reduction. He is a strong advocate for constructive, transparent dialogue and bringing stakeholders and other experts together in 'safe havens' to discuss sensitive and controversial issues. Contact Infomation: ScDBa@aol.com.

ABOUT THE FOOD AND DRUG POLICY FORUM

FDLI's Food and Drug Policy Forum provides a marketplace for the exchange of policy ideas regarding food and drug law issues. The Forum welcomes articles on cutting-edge state, national and international policy issues related to food and drug law.

FDLI's Food and Drug Policy Forum is designed to provide a venue for the presentation of information, analysis and policy recommendations in these areas food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices and tobacco.

Each issue of the Forum presents an important policy topic in the form of a question, provides background information and detailed discussion of the issues involved in the policy question, relevant research, pertinent sources and policy recommendations. This publication is digital-only, peer-reviewed and smartphone enabled.

The Forum is published biweekly (24 times a year) and is provided as a complimentary benefit to FDLI members, and by subscription to members of associations on the Forum Editorial Advisory Board and non-members. Individual issues of the Forum are also available for separate purchase.

The 24-member Food and Drug Policy Forum Editorial Advisory Board, comprised of eight representatives of leading associations interested in food and drug law issues and 16 food and drug and healthcare professionals, provides peer review and guidance on articles considered for publication in the Forum.

ABOUT FDLI

The Food and Drug Law Institute, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications and member interaction. FDLIs' scope includes food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices and tobacco. As a not-for-profit 50l(c)(3) organization, FDLI does not engage in advocacy activities.

FDLI's Mission is to provide education, training, and publications on food and drug law; act as a liaison to promote networking as a means to develop professional relationships and idea generation; and ensure an open, balanced marketplace of ideas to inform innovative public policy, law, and regulation.

In addition to the Forum, FDLI publishes the quarterly, peer-reviewed Food and Drug Law Journal presenting in-depth scholarly analysis of food and drug law developments; Update magazine, which provides members with concise analytical articles on cutting-edge food and drug issues; the FDLI Monograph Series, an annual six-publication set of practical guides on contemporary food and drug law topics, and numerous comprehensive new books each year.