Applying Regulatory Science Concepts to Risk-Based Decisions Under the New U.S. Tobacco Control Act

JIM SOLYST

The Family Smoking Prevention and Tobacco Control Act (Tobacco Act)\textsuperscript{1} is a new science- and risk-based law that poses significant challenges and opportunities for the U.S. Food and Drug Administration (FDA). The Tobacco Act provides FDA with the authority to undertake a wide range of regulatory activities within specified timeframes. Many of the provisions of the Act relate to the marketing, labeling, and manufacturing of products, but the Act also requires the submission of information and research to be used by FDA scientists in making risk-based decisions. The key science provisions relate to the submission of health information, development of tobacco product standards, modified risk tobacco products, and the formation of a Tobacco Products Scientific Advisory Committee (TPSAC). The Tobacco Act also requires FDA to establish a Center for Tobacco Products (CTP) that is responsible for implementing the bulk of the Act’s provisions.

The most prominent risk-related provision of the Act is Section 911, Modified Risk Tobacco Products, which requires FDA to establish a process for determining whether a product will significantly reduce harm and the risk of tobacco-related disease. The Act charges FDA with considering reduced risk to individual users; for example, the risk reduction potential of a user switching from cigarettes to a...

\textbf{FDA’s task of reducing tobacco-related harm requires unprecedented cooperation with the tobacco industry and a science-based approach to regulatory decision-making.}
smokeless product. More difficult is the charge to also
counter whether such a switch benefits the health
of the population as a whole, taking into account
both users of tobacco products and persons who do
not currently use tobacco products. In making these
determinations, FDA is to rely on scientific evidence
and develop guidance on the scientific evidence re-
quired for assessment and ongoing review of modified
risk tobacco products.

A science-based approach to
regulatory decision-making can be
controversial, primarily because
the science is often not conclusive
and requires policy judgments.

To help develop this risk decision process, FDA has
entered into a contract with the Institute of Medicine
(IOM) to establish a committee charged with recom-
manding to FDA the scientific evidence required
for assessment and ongoing review of modified risk
tobacco products. FDA will use the IOM committee
input to develop guidance that will, among other
things, establish minimum standards for scientific
studies needed for decision-making.

The modified risk process will be a test of how
FDA is implementing its commitment to “regulatory
science.” Regulatory science is a term that has been
used repeatedly by FDA senior officials, including
FDA Commissioner Dr. Margaret Hamburg and CTP
Director Dr. Lawrence Deyton. FDA defines the term
as the science of developing new tools, standards, and
approaches to assess the safety, efficacy, quality, and
performance of FDA-regulated products.

A science-based approach to regulatory decision-
making can be controversial, primarily because the
science is often not conclusive and requires policy
judgments. In addition, research may provide con-
flicting results, and scientists may differ in their
interpretations of the research. The application of a
regulatory science approach in addressing the risks
posed by tobacco products will be particularly chal-
lenging. Researchers and commentators generally
accept that tobacco products are addictive and pose a
health risk, and the U.S. tobacco industry has a repu-
tation for being resistant to government action.

However, there also is an emerging point of view
that there is a wide disparity in the risk posed by to-
brobacco products. There is a “risk continuum,” where
cigarettes pose the greatest risk and the risk to an
individual consumer using smokeless products is
90 percent less. For example, the Royal College of
Physicians of London issued a report in 2007 titled:
“Harm Reduction in Nicotine Addiction: Helping
People Who Can’t Quit.” One of its key conclusions
and recommendations is that: “Low nitrosamine
smokeless tobacco products may have a positive role
to play in a coordinated and regulated harm reduc-
tion strategy that maximizes public health benefit
and protects against market exploitation.” Although
not all public health institutions support the Royal
College of Physicians report, the recommendations
should not be ignored, regardless of the ill feelings
toward the U.S. tobacco industry. FDA is of course
a public health agency, but it also is committed to
considering all available, credible science in making
decisions, even if the decisions may not meet with
approval by all in the public health community.

This article examines FDA’s commitment to
regulatory science and how it may be applied in
implementing the risk provisions of the Tobacco Con-
trol Act. The article describes the Tobacco Control
Act in general, with particular focus on the key risk
section, Modified Risk Tobacco Products, and also
the concept of harm reduction. The article addresses
the challenges and opportunities in establishing a
new federal science-based office, particularly one
that must regulate risky and controversial products
and deal with an industry with a troubled past. The
article also addresses the role of independent scien-
tific bodies in assisting regulatory agencies that make
risk-based decisions.

Commitment to Regulatory Science

Regulatory science is referred to frequently by
FDA senior officials; Dr. Hamburg in particular has
made regulatory science a focus of her vision for the
agency. Shortly after being confirmed, she and FDA
Principal Deputy Commissioner Josh Sharfstein wrote
an article, “The FDA as a Public Health Agency,”
stating their intentions to place renewed emphasis
on science integrity and public health. The article
dresses the challenge of “modernizing scientific
and legal regulatory approaches to a host of complex matters.” Most importantly, the article cites the fundamental role of science in decision-making and the importance of a “culture that encourages scientific exchange and represents alternative viewpoints along the path of decision making.”

Dr. Deyton has also publicly promoted the concept of regulatory science. In a February 2010 keynote address at the Society for Nicotine and Tobacco Research, he embraced the new Tobacco Control Act as a “victory for science and public health,” and added that FDA’s implementation will be “driven by regulatory science, not political science.” He noted that he personally has “spent more than 30 years transferring science into public health policy,” and that just the day before, he participated in a panel with Commissioner Hamburg and others addressing “regulatory science.”

In addition, Dr. Deyton co-authored, with Dr. Hamburg and Deputy Commissioner Sharfstein, an article, “Tobacco Product Regulation — A Public Health Approach,” wherein he states that FDA’s “public health approach” to tobacco regulation has four key elements, including “applying regulatory science to the control of tobacco products ….”

FDA use of the term regulatory science is consistent with the intentions of the Obama administration to move away from the perception that the George W. Bush administration allowed science to be politicized. The Obama administration has been vocal about its commitment to science and its departure from the policies of the previous administration. In his inaugural address, the President promised to “restore science to its rightful place.” The President’s Office of Science and Technology Policy (OSTP) has taken a lead in promoting the importance of science, technology, and innovation. In an Executive Memorandum issued on March 9, 2009, the president asked OSTP “to ensure that public policy is informed by the best possible science, and that political officials should not suppress or alter scientific or technological findings and conclusions.”

Focusing on science and regulation is not a new strategy; almost every administration has its own take on the proper role of science in regulation. Certainly the George W. Bush administration used the application of science as a way to achieve desired results. This administration was focused on “regulatory reform” and it instructed the Office of Management and Budget to develop guidelines for agencies to follow in conducting risk assessments, cost-benefit analyses, and the quality of the information used to make regulatory decisions. Critics claimed that the regulatory reform effort was overly pro-industry and was designed to limit regulations by controlling how science was used in the regulatory process. Proponents believe the Bush reforms have provided a foundation for effective science-based decision-making.

The discipline of regulatory science must be developed through support from partnerships and external research and collaboration.

Regulatory Science for Public Health

On October 6, 2010, FDA issued the report “Advancing Regulatory Science for Public Health,” which defined the term and put forth a strategy to strengthen the field of regulatory science and to unleash its potential to improve public health. The report presents FDA’s priorities for regulatory science, which include “Meeting the Challenges for Regulating Tobacco.”

The report cites recent breakthroughs in science and technology that have the potential to transform FDA’s ability to prevent, diagnose, and treat disease. To fully realize this ability, FDA understands it must participate more actively in the scientific research enterprise and play an increasingly integral role in developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of products. The report presents a broad vision for how FDA can accomplish the mission of advancing regulatory science and unleashing its potential to improve public health.

FDA plans to expand ongoing efforts within the agency and build additional partnerships with academia, industry, and government around the country. The report repeatedly emphasizes that the discipline of regulatory science must be developed through support from partnerships and external research and collaboration. A number of projects are already
underway, including the creation and support of academic Centers of Excellence to carry out applied science research both independently and in collaboration with FDA. The centers will be integrated with expanded intramural FDA research and with other clinical research networks. FDA will build on the existing Critical Path Initiative to catalyze and enable partnerships and consortia that advance regulatory science and public health through innovation and modernization of the medical product development and evaluation process.

The report includes sections on the role of regulatory science in addressing important and pressing public health challenges, including new medical treatments, improving pediatric practices and child health, protecting against emerging infectious disease and terrorism, enhancing safety and health through informatics, protecting the food supply, and modernizing safety testing. Also included in the list of pressing concerns is meeting the challenges for regulating tobacco.

The sections on these pressing concerns consist of descriptions of what FDA has done to date and what FDA can do with increased investment in regulatory science. With the exception of the tobacco section, there are examples regarding how FDA and the regulated industry can work together in a collaborative manner. For example, the I-SPY 2 Trial was developed under the Biomarkers Consortium, a unique public-private partnership that includes FDA, the National Institutes of Health, and major pharmaceutical companies. The report also cites a “successful public-private partnership” during the 2009 H1N1 influenza pandemic that brought about the development and approval of safe and effective vaccines in record time.

The section of the report on regulating tobacco provides an overview of the Tobacco Control Act and highlights the fact that the Act requires the CTP to:

- require industry reporting of tobacco product ingredients and constituent data, including a description of the nicotine content and delivery mechanisms;
- establish tobacco product standards; and
- require good manufacturing practice standards for tobacco product manufacturing facilities.

Implementation of these provisions will require FDA to work closely with the tobacco manufacturing industry. All indications are that FDA is willing to do so. However, unlike FDA’s relationship with the other industries it regulates, there is no history of working together and, more importantly, there is a lack of an infrastructure to facilitate the exchange of ideas and approaches.

Elements of an Industry Regulatory Science Infrastructure

Most large U.S. industries regulated by FDA or other science-based agencies, such as the Environmental Protection Agency, have a “regulatory infrastructure” that enables them to effectively engage in and contribute to the regulatory science process. Large companies often have corporate science and policy programs that seek to interact with the scientific community and regulatory agencies by participating in scientific societies and submitting technical comments. In addition, companies may also have established relationships with think tanks, academic institutions, and non-governmental organizations (NGOs). These companies are also likely to belong to a trade association that is also engaged in the regulatory science process. Many smaller companies with limited resources totally depend on a trade association to represent their regulatory science interests.

Most industries regulated by FDA — drugs, food, medical devices, veterinary medicine, radiological — belong to one or more trade associations that provide a variety of services to members and interact with regulatory agencies. The primary purpose of trade associations is to provide services to members, but they also benefit regulatory agencies by facilitating information exchange. It is often efficient for an agency or FDA center to work through a trade association to reach the regulated community.

Many trade associations engage in advocacy activities designed to present information and a point of view to Congress, agencies, and the general public. But typically advocacy is just one of several services provided. They also offer educational services designed to ensure understanding of and compliance with regulations. Trade associations also provide technical and scientific comments to agencies, either during special sessions or through the formal review and comment process. Often a third party, such an academic institution, will work with a trade association to sponsor
seminars to promote the exchange of information and views between industry and government. Many trade associations have established independent external advisory bodies that offer advice, and often criticism, to the industry.

A particularly significant service offered by many trade associations is the establishment of an industry code of conduct and voluntary operating standard. Often, members are obligated to comply with such standards as terms of the membership to the association. Industry voluntary standards vary considerably, from an agreement to merely comply with regulations to a commitment to going well beyond what is required by law. Voluntary standards do not take the place of regulation, but they can offer a laboratory for innovative approaches and an opportunity for participants to share information and improve performance.

State of the Tobacco Industry Regulatory Science

The larger tobacco companies all have scientific affairs programs and significant research capabilities. In general, the larger tobacco companies have the resources and inclination to interact in the regulatory science arena, but their overall involvement is limited due to the unwillingness of many academic institutions, scientific societies, and NGOs to engage in dialogue and partnership with the tobacco industry.

Since the passage of the Tobacco Control Act, the tobacco industry has actively participated in the FDA regulatory science process in two ways: submitting technical comments in response to Federal Register (FR) notices and attending and testifying at FDA TPSAC meetings. The CTP and other FDA programs have issued a number of FR notices specific to tobacco and broader regulatory science initiatives. CTP Director Deyton has strongly encouraged industry and other stakeholders to respond to the FR notices, and the industry has seemingly followed his advice.

The TPSAC has met on several occasions since its inaugural meeting in March 2010, and the tobacco industry has participated in meetings, often providing useful information. The TPSAC is charged with reviewing and evaluating the safety, dependence, and health issues relating to tobacco products and to provide appropriate advice, information, and recommendations to the FDA. Specifically, the committee will submit reports or recommendations on tobacco-related topics, including:

- the impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics, and other racial and ethnic minorities;
- the nature and impact of the use of dissolvable tobacco products on the public health, including such use on children;
- the effects of the alteration of nicotine yields from tobacco products and whether there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved; and
- any application submitted by a manufacturer for a modified risk tobacco product.

Voluntary standards do not take the place of regulation, but they can offer a laboratory for innovative approaches and an opportunity for participants to share information and improve performance.

The TPSAC consists of 12 members knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. In addition to the voting members, the committee includes three nonvoting members who are identified with industry interests. These members include one representative of the tobacco manufacturing industry, one representative of the interests of tobacco growers, and one representative of the interests of the small business tobacco manufacturing industry. The representative from the tobacco manufacturing industry, Dr. Daniel Hecht, has seemingly been particularly useful in providing information to the committee. Many of the TPSAC meetings have provided opportunities for stakeholders, including the industry, to offer comments. In addition, manufacturers of menthol cigarettes presented information to the TPSAC over the course of a two-day meeting in July 2010.

The industry's involvement with the TPSAC
and response to FR notices is certainly important to establishing a trusting, long-term relationship with FDA and the tobacco science community. However, the tobacco industry is not as equipped to engage in the regulatory science process as are other industries regulated by FDA. For example, the U.S. tobacco industry does not have a trade association, and it is unlikely one will be formed in the near future. The 1998 Tobacco Master Settlement Agreement (MSA) between the industry and the attorneys general of 46 states disbanded existing organizations and imposed restrictions regarding the formation and operation of a new tobacco industry trade association.

There is also limited involvement between the tobacco industry and academia, and most academic institutions have bans or severe limitations regarding the acceptance of tobacco industry funds. Industry, academia, and NGO scientists attend the same scientific society conferences, but the environment is tense and not conducive to open and free exchange. This challenging environment results in little or no collaboration. For example, it is extremely difficult for a tobacco company to have academics serve on an independent scientific advisory body.

Critics of the tobacco industry may be comforted by the lack of a trade association or collaboration with academic institutions; however, for a regulatory science approach to tobacco control to be most effective, it will be necessary to change the current environment.

**FDAs Role in Changing the Current Environment**

The current chilling and polarizing environment in tobacco science is unlikely to change without significant leadership from FDA or a highly credible scientific body. The agency must determine if and how it wants to engage with the tobacco industry to strengthen tobacco regulatory science. To date, FDA has communicated two very different messages to the tobacco industry: (1) the industry should engage in the regulatory science process and (2) FDA is well aware of the challenges it faces in working with industry. What is perhaps more important is what FDA has not communicated: it has not put forth a strategy for overcoming the current obstacles and ultimately benefiting from the contributions the tobacco industry — like other industries — can conceivably make to regulatory science.

FDA certainly faces a significant challenge in bringing the tobacco industry into the fold and establishing a relationship that will strengthen the regulatory science needed to effectively regulate tobacco products. The most obvious obstacles are the products manufactured by, and the history of, the U.S. tobacco industry. It is generally accepted that although there is a continuum of risk, with cigarettes being much more hazardous than smokeless products, all tobacco products contain nicotine and are therefore addictive and have health implications. Obviously, the cost-benefit equation for tobacco products is different than for any other industry sector regulated by FDA. The tobacco industry is different as well: not only is it newly regulated, it is also noted for its historic lack of transparency.

FDA CTP is well aware of the challenges it faces in regulating an industry with a history of not cooperating with authorities. In a May 2010 speech at the Tobacco Merchants Association annual conference, Dr. Deyton very directly expressed his concerns: “We at FDA understand that it is never easy for an industry to submit to new regulation. The tobacco industry poses special challenges, and speaking frankly, the industry has a long history of resistance to government action.”

The tobacco industry itself is undoubtedly aware of the need to prove that it has changed and is now willing to constructively engage in the regulatory science process. However, it will not be easy. Not only does the industry have to overcome years of “resistance to government action,” it must do so without all the venues and infrastructure that support industry-government interaction. Further, few in the public health community are advocating for greater involvement by the tobacco industry in regulatory science.
It may be unfair to expect a new FDA center to go against current sentiment and encourage the public health and academic communities to welcome opportunities to interact and collaborate with the tobacco industry. Although such an initiative might be a sound long-term strategy, it is not likely to be high on the CTP priority list, given the many statutory imposed deadlines that must be met. However, CTP may have paved the way for the future when it entered into a contract with the Institute of Medicine to establish a committee to address the scientific standards for studies on modified risk tobacco products.

The idea of relying upon the Institute of Medicine is cited in Section 911 of the Tobacco Control Act, which states: “regulations or guidance issued under paragraph (1) shall be developed in consultation with the Institute of Medicine, and with the input of other appropriate scientific and medical experts, on the design and conduct of such studies and surveillance.”

Independent Science Advisory Bodies

The IOM is one of four organizations that comprise the National Academies. The others are the National Academy of Sciences, the National Academy of Engineering, and the National Research Council. In the past decade, IOM has established several committees addressing tobacco. Most notably, with funding from FDA, IOM established the Committee to Assess the Science Base for Tobacco Harm Reduction, which issued the 2001 report “Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction.” The committee recommendations clearly had an impact on the Tobacco Control Act, particularly Section 911 Modified Risk Tobacco Products. In addition to the “Clearing the Smoke” report, IOM also established the Committee on Reducing Tobacco Use, which issued a report in 2007 titled “Ending the Tobacco Problem: A Blueprint for the Nation.”

Independent advisory bodies such as IOM have become increasingly instrumental in the regulatory science process. One type of advisory body provides short- and long-term advice to a specific agency or program within an agency, such as the FDA Risk Communication Advisory Committee (RCAC) and the TPSAC. These bodies can be established by the agency (FDA established the RCAC) or mandated by a statute (the Tobacco Control Act mandated the establishment of TPSAC). The bodies are typically in place for a long period of time and members and chairs serve set terms.

Another approach is to have the National Academies establish a committee to address a specific issue within a set timeframe. The National Academies enlist the nation’s foremost scientists, engineers, health professionals, and other experts to address the scientific and technical aspects of some of society’s most pressing problems. Each year, more than 6,000 of these experts are selected to serve on hundreds of study committees that are convened to answer specific sets of questions. All serve without pay.

**Obviously, the cost-benefit equation for tobacco products is different than for any other industry sector regulated by FDA.**

Federal agencies are the primary financial sponsors of the Academies’ work. State agencies, foundations, other private sponsors, and the National Academies endowment fund additional studies. The Academies provide independent advice; the external sponsors have no control over the conduct of a study once the statement of task and budget are finalized. Study committees gather information from many sources in public meetings, but they deliberate in private in order to avoid political, special interest, and sponsor influence.

Through this careful study process, the National Academies produce 200–300 authoritative reports each year. Recent reports cover such topics as the obesity epidemic, the use of forensics in the courtroom, invasive plants, underage drinking, the Hubble Telescope, vaccine safety, the hydrogen economy, transportation safety, climate change, and homeland security. Many reports influence policy decisions, some are instrumental in enabling new research programs, and others provide program reviews.

**IOM Committee on Scientific Standards for Studies on Modified Risk Tobacco Products**

In September 2010, FDA entered into a contract with the IOM to establish a committee to provide...
consensus recommendations to FDA regarding its statutory requirement to develop guidance on the scientific evidence needed to support a modified risk tobacco product claim. The contract calls for IOM to establish a committee and issue a report within 15 months (November 30, 2011) that addresses the Scientific Evidence subsection of Section 911. The contract directly cites language from the statute in asking the IOM committee to undertake the following:

(A) to the extent that adequate scientific evidence exists, establish minimum standards for scientific studies needed prior to issuing an order under subsection (g) to show that a substantial reduction in morbidity or mortality among individual tobacco users occurs for

Exhibit A

Harm Reduction

Harm reduction is an attempt to reduce adverse impacts for smokers who will not or cannot abstain from using tobacco. It is based on the recognition that the health hazards of cigarette smoking are primarily due to the burning of tobacco and its additives and that smoking-related health hazards could be reduced by switching to “cleaner” sources of nicotine. A tobacco product is considered harm reducing if it lowers total tobacco-related mortality and morbidity, even though use of that product may involve continued exposure to tobacco-related toxicants. Products that could be considered as harm reducing include nicotine-replacement products, such as the patch or gum, and smokeless tobacco products, such as Swedish snus.

There are contrasting views within the scientific and public health communities regarding the benefits of harm reduction. Some view harm reduction products as a component of a comprehensive tobacco control program, which includes abstinence-oriented prevention and treatment. Others believe there are unintended negative consequences associated with harm reduction and the only safe solution is to quit smoking without any aid or by using an approved nicotine replacement product.

There is a considerable amount of research and analysis devoted to harm reduction, and highly credible research institutions have issued reports and articles containing conclusions and recommendations. For example, in 2007, a report from the Royal College of Physicians concluded that harm reduction in smoking can be achieved by providing smokers with safer sources of nicotine that are acceptable and effective cigarette substitutes. In 2001, the IOM Committee to Assess the Science Base for Tobacco Harm Reduction wrote the report “Clearing the Smoke,” which recommended that harm reduction be a component of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment.

Governmental public health agencies have been very cautious in communicating about harm reduction. Agencies have acknowledged the concept and potential role of harm reduction but have not advised smokers to switch to harm-reducing products. For example, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) was charged by the European Commission to evaluate the health effects of smokeless tobacco products, with particular attention to snus. SCENIHR issued a final report in 2008 titled “Health Effects of Smokeless Tobacco Products,” which contains a subchapter on harm reduction. The SCENIHR report presents information regarding use of snus in Sweden and concludes that it is appropriate to consider the potential benefits, as well as risks, to public health if snus were to be made available elsewhere in Europe.

Harm reduction research will continue and public health agencies globally will likely increase efforts to define and communicate the proper role for tobacco harm reduction products in a comprehensive tobacco control program. The standard for assessing potential harm reduction products will likely come from the United States, closely following the precedent set by FDA, based on input from the IOM Committee on Scientific Standards for Studies on Modified Risk Tobacco Products.
products described in subsection (g)(1) or is reasonably likely for products described in subsection (g)(2);
(B) include validated biomarkers, intermediate clinical endpoints, and other feasible outcome measures, as appropriate;
(C) establish minimum standards for post-market studies, that shall include regular and long-term assessments of health outcomes and mortality, intermediate clinical endpoints, consumer perception of harm reduction, and the impact on quitting behavior and new use of tobacco products, as appropriate ....

The committee report will undoubtedly be the single most important resource for FDA to use in developing guidance on the scientific evidence required for the assessment and ongoing review of modified risk tobacco products. Another way of characterizing the IOM committee report is that it will assist FDA in developing guidance that is based in regulatory science.

In addition to having an immediate impact on FDAs implementation of the Tobacco Control Act, the IOM committee may also be the first step in normalizing the tobacco regulatory science environment. “Normal” is defined as being similar to the regulatory science environment that is typical to the other industries regulated by FDA; for example, having the opportunity to collaborate with academic institutions and participate in open and fruitful discussions with stakeholders. Many of the experts that serve on IOM

---

**Exhibit B**

**GothiaTek**

GothiaTek is a voluntary, comprehensive quality standard developed by the smokeless tobacco company Swedish Match in 2000. The standard came about through collaboration between toxicologists at the Swedish Food Authority and Swedish Match who were seeking quality assurance and quality control in the production process of Swedish snus, which has been a part of the culture for generations.

The use of snus in Sweden has historical and cultural significance, and the relationship between snus manufacturers and the Swedish government is also interesting and relevant to tobacco regulation. Until the early 1940s, snus was the predominant form of tobacco used in Sweden, and even now smoking is considerably less widespread among Swedish adults than in most other European Union (EU) countries. In 2007, 14 percent of adult Swedes smoked, while smoking in the remaining EU countries varied between 21 percent and 44 percent, according to the World Health Organization in 2008 and Swedish national authorities. The Swedish government has historically been actively involved in the manufacturing of snus. In fact, for much of the 20th century there was a Swedish state-owned tobacco monopoly that controlled the production of snus.

The unprecedented involvement of the government in snus manufacturing facilitated a collaborative effort with industry. In the later part of the 20th century, government and industry engaged in scientific and public debates about the health effects of tobacco products in general and, more specifically, the role of potential toxicants and agrochemical residues in smokeless tobacco products. As a result, the routine monitoring of the chemical properties of snus was greatly expanded, assays of tobacco-specific nitrosamines (TSNAs) were introduced in 1984, and an extensive, annual chemical testing of all snus brands started in 1988.

Today, GothiaTek is a comprehensive program consisting of a series for standards addressing constituents, the manufacturing standard, and required consumer information. GothiaTek reflects the latest in toxicological science and production techniques, which has resulted in lower than ever toxicant levels. The information derived through the collaborative effort of the government and Swedish Match, combined with an improved tobacco scientific base in general, improves the opportunity for science-based decision-making.
committees come from academia; for example, several of the members of the "Clearing the Smoke" committee are academics, and several academics now serve on the new IOM Committee on Scientific Standards for Studies on Modified Risk Tobacco Products. Conceivably, the experience of serving on the modified risk committee will increase their willingness — and the willingness of their academic institutions — to interact with tobacco industry scientists.

In addition to having an immediate impact on FDA's implementation of the Tobacco Control Act, the IOM committee may also be the first step in normalizing the tobacco regulatory science environment.

The IOM committee deliberations will be the first time since the passage of the Tobacco Control Act that an independent science advisory body, external to FDA, has addressed health issues associated with tobacco products. Specifically, the IOM committee will be addressing harm reduction, which can be a lightning rod for controversy in the public health and tobacco control communities. Equally significant, harm reduction or modified risk — the terms are essentially equivalent — is an excellent example of the importance of making decisions within a regulatory science framework (Exhibit A).

Tobacco Industry Efforts to Engage in Regulatory Science

There are a number of steps that must be taken to improve the tobacco regulatory science environment. Certainly the establishment of an IOM committee by FDA — and ideally, a continuous FDA-IOM relationship — will do much to facilitate dialogue and collaboration. In addition, FDA must be willing to more actively engage with industry scientists and promote industry-government-academia collaboration. For example, in December 2010, CTP sponsored a stakeholder discussion with tobacco manufacturers and growers that provided an opportunity for meaningful engagement and dialogue. But ultimately, it is up to the tobacco industry to demonstrate that it is committed to regulatory science and that its potential contribution to regulatory science is significant enough to overcome years of strained relationships.

There is evidence that the U.S. and global tobacco industry has taken strides toward becoming a responsible and dependable contributor to the regulatory science discussion that has developed with the passage of the Tobacco Act. The large companies are conducting research and presenting findings at conferences sponsored by highly credible toxicology and risk-based scientific societies, such as the Society for Toxicology and the Society for Risk Analysis. In addition, industry presence continues to be evident at tobacco-oriented conferences, including those sponsored by the Society for Research on Nicotine and Tobacco and the Cooperation Centre for Scientific Research Relative to Tobacco. It can be assumed that with the passage and implementation of the Tobacco Control Act, the level of participation at such conferences will increase.

The large tobacco companies present their commitment to research and describe ongoing studies in their corporate Web sites, which typically have a section on tobacco science. The British American Tobacco (BAT) science-based Web site in particular offers considerable information and links. Termed “BAT Science,” it is described as a site “where you will find an overview of our current research and development programmes, research data and recently published papers and posters.” Like most industry-funded science sites, BAT Science is straightforward about the dangers of smoking: “Cigarette smoking is a cause of serious and fatal diseases, so our research and development activities are principally focused on better understanding the mechanisms of harm caused by tobacco use and on developing potentially less harmful products which address this issue.”

Much of the tobacco industry's focus and science funding are devoted to harm reduction. For example, the BAT Science Web site states the following: "The science of tobacco harm reduction is complex, extremely challenging and spans many scientific disciplines. We have significantly expanded our research capabilities and expenditure over the past few years to reflect the importance we place on work in this area.”
Harm reduction is also a primary focus of the Swedish company Swedish Match. The company’s chief product line is Swedish snus, a moist to semi-moist oral tobacco product traditionally produced and used in Sweden and made from finely ground, mainly air-cured tobaccos and other ingredients. Swedish snus have been used in Sweden for generations, and there are several epidemiological and tobacco use studies that contribute to the factual basis for what is termed the “Swedish experience.” The key facts of the Swedish experience are that total tobacco consumption in the country is about the same as in comparable countries, but Swedish men smoke considerably less. The proportion of daily smokers is currently 12 percent among men (the lowest in Europe), whereas 19 percent of Swedish men use snus. Significantly, Sweden also has the lowest lung cancer mortality rate in Europe, the lowest percentage of smoking-related deaths among developed countries, and among the lowest oral cancer rates in Europe.

What is particularly notable about Swedish Match is the company’s voluntary quality standard, termed GothiaTek, which “provides a guarantee assuring the consumer that all Swedish Match products undergo controls and maintain the highest quality throughout all the stages from tobacco plant to consumer.” GothiaTek was established in coordination with the Swedish Food Agency, which regulates snus under the Swedish Food Act (Exhibit B).

Conclusion

Tobacco companies must continue to take available actions to engage in the regulatory science process, including responding to FR notices, contributing to FDA TPSAC meetings when requested, and participating in scientific societies. In general, the industry must take every opportunity to make information and research strategies known to the science and public health communities and to the broader public. For now, the tobacco industry will have to settle for small steps, hoping they will lead to more visible opportunities; for example, displaying posters rather than giving oral presentations at national scientific conferences. The tobacco industry will also have to be upfront about past mistakes and continue to cite the health issues associated with its products.

Most importantly, FDA must recognize it is in the best interests of regulatory science to provide the leadership necessary to change the current environment and contribute to an atmosphere of collaboration and open exchange of science.

Endnotes


Jim Solyst is a principal consultant with ENVIRON International Corp., a global environmental engineering and health sciences firm, where he provides regulatory science and public policy services to industry clients. He specializes in product risk assessment and management relating to chemical manufacturing and works closely with EPA, FDA, and the Office of Management and Budget. He has written extensively on the recently passed Tobacco Control Act and is currently providing services to a smokeless tobacco company. Prior to joining ENVIRON in 2007, Solyst served as senior director for science and risk policy at the American Chemistry Council for 12 years. He also directed environmental health and emergency management programs at the National Governors’ Association for 12 years. Solyst holds a B.A. degree from the University of Maryland and a masters degree from Ohio State University. He is a member of the National Academy of Sciences (NAS) Chemical Sciences Roundtable and served on the NAS Committee on Promoting Safe and Secure Chemical Management in Developing Countries. He is a member of the American Chemical Society’s Committee on Environmental Improvement and an external affiliate, Johns Hopkins School of Public Health, Risk Sciences and Public Policy Institute.