Legal Update

Note: This special edition of the Legal Update is dedicated to issues related to the federal regulation of tobacco products. The Tobacco Control Legal Consortium’s FDA Tobacco Project works to mobilize members of the public health community to support the Food and Drug Administration’s regulation of tobacco products.

FDA to Hold Hearing on Nicotine Replacement Therapies

The U.S. Food and Drug Administration (FDA) is holding a one-day public hearing on December 17 in Silver Spring, Maryland to obtain input on issues related to the approval of nicotine replacement therapies (NRT). The FDA is also seeking comments from the public, as well as recognized scientific, medical and public health experts, on the best way to regulate, promote and encourage the development of innovative products and treatments for tobacco dependence. The FDA is required to report to Congress on innovative products and treatments for tobacco dependence, including

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Opportunity to Comment on R.J. Reynolds Citizen Petition

The U.S. Food and Drug Administration (FDA) is accepting public comments on a recent citizen petition filed by R.J. Reynolds Tobacco Company urging the FDA to issue a new regulation altering the text of the smokeless tobacco product warning. The petition asks that the label be changed from “WARNING: This product is not a safe alternative to cigarettes,” to “WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes.”

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Over the last year, the Consortium has released a series of resources to help inform the public health community about ways to engage in the federal regulatory process and support the Food and Drug Administration’s regulation of tobacco by providing input and the best evidence available. Below are our latest publications on issues related to the federal regulation of tobacco. All of these resources are available on our website at www.publichealthlawcenter.org, under Publications and Resources, and at our FDA Tobacco Action Center site.

**Backgraders**

- **Telling the Public Health Story to the FDA: How the FDA Regulates Tobacco through the Rulemaking Process**  
  An overview of how the public health community can participate in the federal tobacco regulatory process.

- **Getting Scientific Data to the FDA**  
  A resource for the scientific and academic community outlining how to participate in the federal tobacco regulatory process.

- **Freedom of Information Act and the FDA**  
  An overview of the Freedom of Information Act and how it can be used to request documents from the FDA Center for Tobacco Products.

- **Citizen Petitions: An Underutilized Tool in Tobacco Regulation**  
  An overview of citizen petitions and how they can be used to urge the FDA to adopt strong tobacco control policies.

- **Federal Regulation of Tobacco and its Impact on the Retail Environment**  
  An overview of how the Tobacco Control Act has affected the sale of tobacco products in the retail setting.

- **Family Smoking Prevention and Tobacco Control Act Litigation Update**  
  A summary of three challenges to the Tobacco Control Act and regulations promulgated by the FDA and three other lawsuits in which the tobacco industry attempted to use the Tobacco Control Act to attack local tobacco control policies and to avoid remedies imposed by a federal court.

**Talking Points**

- **Encourage the FDA to Keep the Existing Warning Labels for Smokeless Tobacco**  
  Talking points for those who wish to comment on R.J. Reynolds’ citizen petition requesting that the FDA change the warning on smokeless tobacco products, converting them to Modified Risk Tobacco Products without following the procedures outlined in the Tobacco Control Act.

**Public Health Law Policy Change Webinar Series**

The Public Health Law Center offers monthly webinars on significant and timely topics in public health topics, such as tobacco control strategies and regulation. Below are links to a few archived recordings of webinars on ways the public health community can support the FDA in regulating tobacco products. For slides of these webinars, and to view other archived webinar recordings, visit our website here.

- **Telling the Public Health Story to the FDA’s Center for Tobacco Products**  
  This webinar provides an overview of federal regulation of tobacco and explains how to interact directly with the FDA’s Center for Tobacco Products, including how to submit comments to the FDA on tobacco regulation, to promote public health objectives.

- **Pressing the FDA on Menthol**  
  The Family Smoking Prevention and Tobacco Control Act of 2009 granted the FDA the authority to address the crushing public health burden of menthol in tobacco products, especially on youth, African-Americans, and the LGBTQ community. Unfortunately, in the three years since the law was enacted, the FDA has studied the issue but failed to act on this authority. This webinar describes what the public health community can do to press the FDA to take bold action on menthol.
Consortium attorneys are engaged in a special project to encourage members of the public health community to support the Food and Drug Administration’s regulation of tobacco products. The tobacco industry has opposed nearly every action the agency has taken in this area and has filed lawsuits in efforts to block various provisions of the law and regulations passed after the law took effect. To ensure that the FDA enacts regulations to protect public health adequately, the public health community needs to provide a strong counterbalance to the tobacco industry’s immense resources.

The Consortium’s FDA Tobacco Project is committed to helping members of the public health community become informed participants in the federal regulatory process. The Project’s main goals are to:

1. Provide strong, evidence-based information to help the FDA enact strong tobacco regulations to promote public health;
2. Help the FDA defend its decisions against the tobacco industry’s legal challenges; and
3. Proactively engage with the FDA to shape its agenda for the benefit of public health.

The FDA Tobacco Action Center on the Public Health Law Center’s website provides information about the FDA tobacco regulatory process and how to get involved. We also send out electronic Action Alerts with regulatory news and opportunities to submit comments to the FDA and help strengthen regulations and guidance documents.

Key Consortium attorneys engaged in the FDA Tobacco Project include:

Desmond Jenson, J.D.  A recent graduate of William Mitchell College of Law, Desmond worked during law school as a research assistant at the Public Health Law Center where he helped draft publications and provide legal technical assistance to the public health community. Desmond received his B.A. from Augsburg College, cum laude. While at William Mitchell, Desmond received an award for earning the highest grade in his Public Health Law class.

Joelle Lester, J.D.  Joelle previously worked as an associate at the firm of McGrann Shea Carnival Straughn & Lamb; a grassroots organizer and executive director of the Oregon Student Association, a non-profit higher education advocacy group; and a lobbyist for the Wisconsin Association of School Boards. She received her B.A. from the University of Wisconsin — Madison and her J.D. from the University of Minnesota Law School, cum laude.

Mike Freiberg, J.D.  An adjunct law professor at William Mitchell College of Law, Mike has worked for a member of Congress as a legislative assistant specializing in health care and as a committee administrator in the Minnesota Senate; has served two terms as a Golden Valley City Councilmember; and was recently elected State Representative. He received his B.A. from Georgetown University and his J.D. from William Mitchell College of Law, where he was salutatorian of his class. (Although no longer engaged in this project, Mike was instrumental in its startup and will soon begin a new study of regulatory issues related to menthol tobacco products.)

» For more information about the Consortium’s FDA Tobacco Project, visit our FDA website.
FDA to Hold Hearing on Nicotine Replacement Therapies

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the way the FDA will coordinate the exchange of information on NRT among the relevant offices and centers with the FDA, the Centers for Disease Control and Prevention, the National Institutes of Health and the Department of Health and Human Services.

Anyone wishing to present at the hearing must register by December 6. A live webcast and recording will also be available on the FDA website. Those who cannot attend the hearing can still submit comments to the docket for the FDA to consider in formulating its opinion on NRT.

» Read more about the FDA hearing.
» Submit comments to the docket.

Opportunity to Comment on R.J. Reynolds Citizen Petition

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As more than twenty leading public health organizations, including the Consortium, pointed out in comments submitted to the FDA on November 9, 2012:

Though presented as merely a request to FDA to modify one of the statutory product warnings on smokeless tobacco, in reality the RIR Petition is a transparent attempt to secure FDA’s support for their marketing of ST [smokeless tobacco] as a safer product than cigarettes, while evading the evidentiary requirements that Congress carefully constructed to ensure that such claims of reduced harm do not serve to increase tobacco use, cause more people to become addicted to tobacco, and die from tobacco-related disease. The Petition thus represents an attack on the integrity of the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”), the statute FDA is charged with enforcing, and should be treated as such.

The FDA will stop accepting public comments as soon as it takes action on this petition. For that reason, those with views and information to share on this issue, and who are not bound by organizational or funding restrictions that would limit their ability to comment, should submit comments as soon as possible.

» For more information about this petition and how to submit comments to the FDA, visit the FDA Tobacco Action Center on our website.
» To comment on the R.J. Reynolds petition, and for guidance, compliance and regulatory news on federal tobacco regulation, visit the FDA website.
This Legal Update feature showcases individuals and organizations with distinguished records of accomplishments in public health law. Today we spotlight two exceptional public health lawyers: William B. Schultz and Mitch Zeller.

William B. Schultz: A National Leader in Public Health Law

President Barack Obama faces many difficult decisions every day. It’s unlikely, though, that appointing William P. Schultz General Counsel of the U.S. Department of Health and Human Services was one of those decisions. In fact, for anyone aware of his wealth of experience in the legislative, regulatory, academic and public health arenas, as well as his impressive litigation background, the appointment of William Schultz may have been a fairly easy decision to make.

The Office of General Counsel is the legal team for the Department of Health and Human Services, consisting of over 400 attorneys and a large staff that supports the development and implementation of the Department’s programs by providing the highest quality legal services to the Secretary of Health and Human Services and the organization’s various agencies and divisions. In addition to being heavily involved in administrative and Federal court litigation, and collaborating with the Department of Justice in complex district court and appellate litigation, the Office also reviews proposed regulations and legislation affecting significant issues of health and human services.

Bill Schultz has a long history of legislative leadership and litigation experience. Before serving as Principal Deputy General Counsel and Acting General Counsel of the U.S. Department of Health and Human Services, Bill was a partner at Zuckerman Spaeder LLP for ten years. From 1999 to 2000, Bill was Deputy Assistant Attorney General for the Civil Division at the U.S. Department of Justice. He served as Deputy Commissioner for Policy at the U.S. Food and Drug Administration from 1994 to 1999, where he oversaw the Agency’s policy development activities and the processing of all FDA regulations. He not only was the principal advisor to the Commissioner on policy matters before the Agency and bore primary responsibility for coordinating FDA’s policies with other government agencies and countries, but he also oversaw implementation of the President’s Tobacco Initiative.

From 1990 to 1994, Bill served as Counsel for the Energy and Commerce Committee’s Subcommittee on Health and the Environment in the U.S. House of Representatives under Chairman Henry A. Waxman. He led in drafting and negotiating landmark laws...
Interview with William Schultz

William Schultz, Acting General Counsel, Department of Health and Human Services, recently took time out of his busy schedule to answer a few of our questions about his views on federal tobacco regulation and legislation.

Q: What are some of the most effective ways the public health community can share data with the FDA to help in its consideration and drafting of tobacco regulations?

Schultz: There are many different ways to share data or opinions with the FDA. This can be done formally by commenting on regulations and guidances or by submitting citizen petitions, or informally through articles and speeches at conferences attended by FDA officials.

Q: What do you see as the most challenging emerging issue in federal tobacco regulation? In global tobacco regulation?

Schultz: The constant challenge is to identify effective measures that prevent children from using tobacco products and to assist addicted tobacco users who would like to quit. This will require staying ahead of a very innovative and aggressive industry, which is never easy.

Q: Over your years of work in tobacco regulation and litigation, what event or events stand out as pivotal, and why?

Schultz: Certainly FDA Commissioner David Kessler’s decision to launch an investigation of the tobacco industry in the spring of 1994, followed by his testimony before Congress, where he made a compelling case that nicotine in tobacco is a drug and reported on FDA’s vigorous investigation into the marketing to children. I think the FDA’s investigation and the Congressional hearings that spring and summer played an important role in educating the public about the marketing tactics of the tobacco industry and about the addictive nature of the product. The testimony of the tobacco company CEOs in April 1994 further undercut the credibility of the industry. Finally the enactment of the Family Smoking Prevention and Tobacco Control Act in 2009 gave the FDA the authority to regulate tobacco and guaranteed funds that are larger than the budget of many federal agencies.

Q: You were at the Department of Justice in 1999 when the Department filed its historic civil lawsuit against major tobacco companies under the RICO statute (U.S. v. Philip Morris). Were you at all surprised with the way the litigation played out? What are your thoughts about Judge Gladys Kessler’s final ruling in 2006?

Schultz: I wouldn’t say I was surprised only because I didn’t know how it would play out. We always thought it was a strong case legally and that judgment was generally supported by Judge Kessler and the D.C. Circuit. On the other hand, tobacco litigation often divides the court as it did the Supreme Court (5-4) in the challenge to FDA’s initial tobacco rule and the D.C. Circuit (2-1) in one of the early appeals to an aspect of the DOJ case. Recent district court and D.C. Circuit rulings have been favorable to DOJ.

Judge Kessler’s 2006 decision was a tour de force. Some of her evidentiary conclusions were adopted by Congress in the findings enacted as part of the FDA legislation, and I suspect that courts, legislators and academics will cite Judge Kessler’s careful opinion for many years in the future.

Q: Given your wide range of experience in federal regulation, what in your view distinguishes tobacco regulation from other areas of regulation?

Schultz: Of course, we haven’t had much tobacco regulation yet, but one challenge is that the industry is not accustomed to regulation and has a long track record of litigation. Also since the industry’s principal tool for marketing to children has been advertising, First Amendment considerations must be taken into account more frequently than in other areas of regulation. On the other hand, the opportunities for saving lives here are larger than in any other regulatory field.

“On the other hand, the opportunities for saving lives [in tobacco regulation] are larger than in any other regulatory field.” — Bill Schultz
Mitch Zeller: A National Expert in Public Health Law

Mitch Zeller has more than 25 years of regulatory, legislative and communications experience working with federal health agencies on public health policy issues. As Senior Vice President at Pinney Associates, he currently leads domestic and global efforts around strategic communications and health policy on the regulation of pharmaceuticals and tobacco products and the treatment of tobacco dependence. He has also served as executive vice president of the American Legacy Foundation, where he created the Foundation’s first Office of Policy and Government Relations and oversaw the $100 million multi-media “truth® campaign,” Legacy’s award-winning youth tobacco prevention counter-marketing program.

Mitch Zeller’s deep-seated commitment to tobacco control and public health is reflected in his decades of legislative and regulatory experience and accomplishments.

Mitch has held several key positions at the Food and Drug Administration directly related to tobacco regulation. From 1993 until June 2000, Zeller served as associate commissioner and director of the FDA Office of Tobacco Programs, where he built the first-ever nationwide enforcement program to reduce youth access to tobacco. Before then, he served as the FDA’s representative on tobacco issues in all dealings with the Congress, federal and state agencies, public health groups and foreign governments.

Mitch also served as an official U.S. delegate to the World Health Organization (WHO) Working Group for the Framework Convention on Tobacco Control. From 1988 to 1993, Mitch was counsel to the Human Resources and Intergovernmental Relations Subcommittee of the House Government Operations Committee where he conducted oversight of federal health and safety agencies. From 1982 to 1988, he served as assistant director for Legal Affairs with the Center for Science in the Public Interest, a consumer organization in Washington, D.C.

Mitch has published papers in several leading medical and public health journals and has won many awards for his work on tobacco, including the Secretary’s Award for Distinguished Service and the National Public Affairs Special Recognition Award from the
**Ask A Lawyer**

**Q** “What can the public health community do to encourage the FDA to take action on tobacco regulation? Since the Tobacco Control Act was passed it seems like all we do is wait for the FDA to do something.”

**A** In 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act into law, granting authority to the U.S. Food and Drug Administration (FDA) to regulate tobacco products. In the three years since, many public health professionals and advocates have been frustrated by the pace and seemingly reactive nature of the federal regulatory process. Many are also unsure of how to engage with the FDA in the absence of proposed rules or guidance documents. The Tobacco Control Legal Consortium’s FDA Tobacco Project is designed to educate and mobilize the public health community to improve and support federal regulation of tobacco products.

Typically, the public becomes involved in federal tobacco regulation when the FDA provides notice of a proposed regulation or guidance and opens a docket on the proposal. The notice states the period of time during which public comments will be allowed. The docket on each proposed regulation is a collection of documents that stores information related to a rulemaking or other action. When the docket is open, members of the public have the opportunity to submit comments on the proposed regulation or guidance. The FDA may then revise a rule in light of the comments submitted and adopt the revised rule or publish the revised rule for additional public comment. The Consortium’s *Telling the Public Health Story to the FDA* provides more information on submitting comments to the FDA on proposed regulations.

Responding to the FDA’s actions is not the only way for the public to engage in federal regulation of tobacco, however. Public health advocates can take the initiative to press the FDA to take a particular action by filing a citizen petition. A citizen petition is a tool created by federal regulation that allows members of the public to directly petition the agency to issue, change or cancel a regulation, or to take other action. A citizen petition enables advocates to help shape the agenda and urge the FDA Center for Tobacco Products to do more with its authority under the Act. More details are provided in our publication, *Citizen Petition: An Underutilized Tool in Tobacco Regulation*. Because a citizen petition is initiated by the public, it changes public participation in the regulatory process from reactive to proactive.

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William Schultz’s broad legislative, regulatory and public interest background, his litigation expertise, and his natural leadership abilities make his latest prestigious appointment an unsurprising step in a remarkable career.

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providing comprehensive standards for nutrition labels on food, revising medical device legislation and authorizing the FDA to charge user fees for drug and biologics reviews. He also spearheaded legislative efforts on animal drugs, pesticides, orphan drugs and dietary supplements.

Prior to this, Bill was a Senior Attorney at Public Citizen Litigation Group, representing public interest and public health organizations in courts, agencies and Congress. He argued dozens of appellate cases, including several in the U.S. Supreme Court.

Bill received a bachelor’s degree in economics from Yale University and his J.D. from the University of Virginia School of Law. After law school, he clerked for Judge William B. Bryant of the U.S. District Court for the District of Columbia. For close to ten years, he was an adjunct professor at Georgetown University Law Center, where he taught civil litigation and food and drug law. He has written numerous articles in professional law journals and other media.

William Schultz’s broad legislative, regulatory and public interest background, his litigation expertise, and his natural leadership abilities make his latest prestigious appointment an unsurprising step in a remarkable career. The Tobacco Control Legal Consortium is proud to salute this national leader in public health law.

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American Heart Association. He received his B.A. from Dartmouth College in Hanover, New Hampshire and his J.D. from the American University Washington College of Law in Washington, D.C. He has a non-compensated appointment as Visiting Scientist at the Harvard School of Public Health and Professorial Lecturer at the Washington College of Law at American University.

Mitch Zeller’s deep-seated commitment to tobacco control and public health is reflected in his decades of legislative and regulatory experience and accomplishments. The Tobacco Control Legal Consortium congratulates Mitch Zeller on his successful career and leadership in public health law.

Ask A Lawyer

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One of the strengths of the citizen petition is that it opens a docket on an important public health issue, which creates a platform for public health professionals and advocates to speak publicly about critical issues in tobacco regulation. An open docket allows public health advocates to submit comments supporting or opposing a petition; it can also serve as a way to submit relevant data without taking a position, to inform the FDA’s consideration of the request. And importantly, the FDA is required to respond to all citizen petitions. This requirement does not ensure a meaningful response from the FDA, but it does mean that the agency is forced to acknowledge the issue presented in the citizen petition. Filing a citizen petition is one more useful tool in the public health toolbox as we work to encourage the FDA to fulfill the promise of the Tobacco Control Act.

For more information about how to engage with the FDA’s regulation of tobacco products, visit our online FDA Tobacco Action Center. If you would like technical assistance with creating a citizen petition or commenting on an existing petition, please contact a staff attorney with the Tobacco Control Legal Consortium at (651) 290-7506. If you have questions about the petition process, contact the FDA Dockets Management Branch at (301) 827-6860.
Australia’s Historic Cigarette Plain Packaging Laws Take Effect

As of December 1, 2012, all cigarettes sold in Australia must be in plain packages, free of colorful logos and promotional text, with the brand and variant name in small font, and large health warnings prominently displayed. In an August 2012 ruling hailed by health officials around the world, Australia’s highest court upheld the government’s tough new plain packaging law. The court rejected a challenge by several tobacco companies, including Philip Morris Limited and British American Tobacco, which claimed the act violated their intellectual property rights and devalued their trademarks.

Australia is the first nation to require plain packaging for tobacco products. The ruling is a victory for the government: tobacco-related illnesses are responsible for the deaths of an estimated 15,000 people in Australia each year and approximately A$31.5 billion ($33 billion) in annual health costs. Other countries, including New Zealand, the United Kingdom, Norway, India, France, and Canada, are considering implementing similar legislation.

Read JT International SA v. Commonwealth of Australia opinion.

Resource Roundup

Latest Global Report on Cigarette Package Health Warnings

The Canadian Cancer Society recently released the third edition of Cigarette Package Health Warnings: International Status Report, a report that ranks 190 countries and jurisdictions based on the size of their health warnings on cigarette packages and lists countries that have finalized requirements for pictorial warnings. The report demonstrates the worldwide trend for large picture warnings; to date, 63 countries/jurisdictions have finalized graphic warnings. Canada was the first country to implement pictorial cigarette package warnings in 2001. Australia (see related article above) has the largest cigarette package graphic health warnings in the world.

Read Cigarette Package Health Warnings: International Status Report.

New Resource on Tobacco Additives

Sixteen European countries recently launched websites that feature fact sheets and detailed reports on the general and tobacco industry use of tobacco additives, such as menthol, as well as their harmful health effects. These publications were prepared by the German Cancer Research Center, Heidelberg, Germany and the National Institute for Public Health and the Environment, Bilthoven, the Netherlands, and translated by partners.

Read Additives in Tobacco Products.
Upcoming Events

Society for Research in Nicotine and Tobacco Annual Meeting
The Society for Research in Nicotine and Tobacco will hold its 19th annual meeting March 13–16, 2013 in Boston, MA.
» Visit the event website for conference and registration information.

U.S. Dept. of Health & Human Services Launches New Tobacco Control Website
On November 15, 2012, the U.S. Department of Health and Human Services launched BeTobaccoFree.gov, a comprehensive website providing one-stop access to tobacco-related information from across its agencies (CDC/OSH, FDA, NIH/NCI, the Office of the Assistant Secretary, and the Office of the Surgeon General). This consolidated resource includes general information on tobacco, as well as federal and state laws and policies, health statistics, and evidence-based methods on how to quit.

Job Opening

Positions — Center for Tobacco Products
The Center for Tobacco Products, located at the Department of Health and Human Services, Food and Drug Administration, has several career opportunities available related to compliance and enforcement, health communication and education, management, and science. The Center is the newest arm of the FDA and is the Federal agency charged with regulating tobacco. These positions are located in Rockville, Maryland.
» Visit the Center for Tobacco Products website for more information.