



Support for the FDA's Regulation of Tobacco

Ensuring that the law giving the FDA regulatory authority over tobacco products is effectively implemented

SUMMARY

The Family Smoking Prevention and Tobacco Control Act of 2009 gave the Food and Drug Administration (FDA) new authority to regulate tobacco. Between December 2009 and May 2011, the [Campaign for Tobacco-Free Kids](#) supported the FDA's efforts to regulate tobacco products by monitoring the tobacco industry's practices, assessing and translating scientific findings, examining issues, and anticipating and defending against legal challenges.

Key Results

- The efforts of the Campaign for Tobacco Free Kids helped the FDA to implement several actions, including:
 - New cigarette warning labels
 - A ban on flavored tobacco
 - A ban on use of the terms light, low or mild to describe cigarettes
 - The addition of labeling on smokeless products
 - The issuing of premarket application guidelines for new tobacco products

Funding

The Robert Wood Johnson Foundation (RWJF) provided \$250,000 to support this project.

CONTEXT

As a result of the Family Smoking Prevention and Tobacco Control Act of 2009 the FDA gained new authority to regulate tobacco. It can now restrict tobacco marketing to youth, enhance efforts to limit youth access to tobacco, require changes in tobacco products to protect public health, regulate claims about tobacco safety and require more effective warnings on cigarette packs.

Tobacco use is the leading preventable cause of death in the United States, claiming more than 400,000 lives annually. The Congressional Budget Office estimated that the new law will reduce youth smoking by 11 percent over 10 years, which could prevent more than 2 million young people who are alive today from beginning to smoke.

The FDA created a Center for Tobacco Products to implement its new powers. While the center was acquiring staff and organizational capacity, it relied on external organizations to provide research and other support.

RWJF's Interest in This Area

There is consensus in the public health world that tobacco prevention programs and regulation of the manufacturing, marketing and sale of tobacco products help to reduce tobacco use.

RWJF has supported more than 1,350 grants related to tobacco use. See *The Tobacco Campaigns of RWJF*, part of the Foundation's Retrospective Series for an assessment of the Foundation's work over 25 years. As part of this work, RWJF established the National Center for Tobacco-Free Kids in 1995, renaming it the Campaign for Tobacco-Free Kids in 1996. See [Program Results Report](#) on the campaign's work.

The campaign's mission is to prevent children and youth from smoking, help smokers quit, and protect everyone from secondhand smoke. It conducts media campaigns and research and engages advocates to press for change in policies regulating tobacco sales and use. The campaign was also instrumental in getting the tobacco-control legislation signed into law.

Two of RWJF's grants to the campaign between May 2007 and June 2009, totaling \$1,093,464, supported a national effort to educate policy-makers, the media, opinion leaders and the public about why the FDA should have authority over tobacco products. (See [Program Results Report](#).) In 2009, RWJF joined more than 1,000 public health organizations in supporting the FDA's authority to regulate tobacco products.

THE PROJECT

From December 2009 through May 2011, this project enabled the Campaign for Tobacco-Free Kids to support the FDA by monitoring the tobacco industry's practices, assessing and translating scientific findings, examining issues, and anticipating and defending against legal challenges.

Matthew L. Myers, J.D., president of the Campaign for Tobacco-Free Kids, directed the project, which involved:

- Filing some 23 submissions to the FDA to help the agency take action, set direction and establish a legal record. Topics included:
 - Tobacco industry marketing to youth and in racial/ethnic minority communities
 - Experimental study of graphic cigarette warning labels
 - Retailer training
 - Descriptors, such as light, mild or low
- Providing legal support to the FDA against lawsuits by the tobacco industry. The campaign filed amicus briefs:
 - Urging the federal court to reject tobacco companies' claims against the FDA's new authority
 - Supporting the FDA's position on e-cigarettes
 - Urging dismissal of RJ Reynolds' claim of conflicts of interest among members of the Tobacco Products Scientific Advisory Committee
- Keeping the FDA and public health community informed about important issues. For example, the campaign:
 - Engaged more than 340 members of the public health community in a webinar in June 2010 on tobacco regulation issues and the FDA's implementation of its new authority. A second webinar, in May 2011, for national partners in the tobacco-control field provided updates on the FDA's Center for Tobacco Products.
 - Submitted a report on the tobacco industry's use of color-coded packaging in order to avoid a ban on using the terms light and low tar
 - Briefed federal legislators on the implications of research on the use of menthol in cigarettes
- Working closely with the scientific community to reach agreement on complex scientific issues related to product regulation and to build a strong evidence base for the campaign's recommendations to the FDA. For example, campaign staff convened 15 leading tobacco-control scientists in December 2010 to address topics such as:
 - Priorities for regulating the content of tobacco products
 - Standards for the introduction of new tobacco products
 - Criteria for determining whether a new product is substantially equivalent to an older product

Challenges

This project originally included plans to conduct research studies needed to inform and support FDA policies and positions. In working with other public health organizations, however, the project team determined that the campaign's expertise and resources would best be spent on nonresearch activities, while recommending research studies to be conducted by others. With permission from RWJF, the campaign reallocated its research funding to advance the project's other activities.

One of the recommended research studies was undertaken by the University of Buffalo, and funded by the American Legacy Foundation. It provided evidence that menthol cigarettes are disproportionately used by young people and explored ways that the tobacco industry misused data to state that menthol does not initiate youth into smoking.

RESULTS

Project staff reported the following results to RWJF:

- **The Campaign for Tobacco Free Kids assisted the FDA to implement several actions, including:**
 - New cigarette warning labels that add the 1-800-QUIT-NOW number, which automatically reroutes callers to a quitline in their home state
 - A ban on flavored tobacco
 - A ban on use of the terms light, low or mild to describe cigarettes
 - The addition of labeling on smokeless products
 - The issuing of premarket application guidelines for new tobacco products

According to Project Director Myers: “What has already been adopted indicates that we have helped FDA implement regulatory and policy decisions that reflect the positions of the public health community, rather than the tobacco industry.”

Communications Results

- **Staff of the Campaign for Tobacco Free Kids discussed the FDA's role in implementing the law in presentations to 11 national organizations**, including the American Association for Cancer Research, the American Bar Association, the National Association of Attorneys General and the National Council of State Legislators.
- **Campaign staff presented or provided comments at 16 public meetings of the FDA, the Institute of Medicine and regional tobacco-control conferences.**

- **Campaign staff attended 13 meetings of the Tobacco Products Scientific Advisory Committee.**
- **The campaign issued 14 FDA-related press releases and statements.**
- **The campaign’s activities attracted news coverage in 58 articles published by national media, such as the *Washington Post*, *Dow Jones News Service*, the *New York Times* and NPR.**

SIGNIFICANCE OF THE PROJECT

This project contributed to the FDA’s ability to make decisions and take regulatory action based on scientific evidence provided by the public health community. “For the FDA legislation to achieve its true public health goals, there needs to be continued and substantial civil-society involvement in providing critical information to the FDA and in involving the public health community in the entire FDA [oversight] process,” observes Myers.

AFTERWARD

As of June 2011, the Campaign for Tobacco Free Kids planned to continue supporting the FDA on issues it will face over the next six months. Among other activities, Myers expected to:

- Continue providing legal support as the tobacco companies’ case against the FDA advances through the courts
- Prepare media materials on the new warning labels for cigarette packages
- File comments on proposed guidelines for new tobacco product regulation and brief the tobacco-control community
- Develop a strategic plan for implementing a ban or restrictions on menthol cigarettes

Myers expects that the FDA’s tasks going forward will become even more complex and pose even more challenging policy and scientific questions. For example:

- The FDA must make a series of determinations related to its power to regulate tobacco products and product-related claims.
- The FDA must figure out how to balance First Amendment issues with the need to evaluate and potentially limit tobacco advertising and marketing to prevent the tobacco industry from marketing to youth or deceiving the public.

Consequently, in Myer’s view, it will be necessary for anti-tobacco advocates to become more sophisticated and involve the scientific community to an even greater degree.

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BIBLIOGRAPHY

(Current as of date of the report; as provided by the grantee organization; not verified by RWJF; items not available from RWJF.)

Reports

Fact Sheets

FDA Authority Over Tobacco: Effective Dates. Washington: Campaign for Tobacco-Free Kids, June 9, 2010. Available [online](#).

New FDA Tobacco Law's Restrictions Going Into Effect. Washington: Campaign for Tobacco-Free Kids, June 22, 2010.

State and Local Tobacco Prevention Options. Washington: Campaign for Tobacco-Free Kids, June 22, 2010.

The Impact of the New FDA Tobacco Law on State Tobacco Control Efforts. Washington: Campaign for Tobacco-Free Kids, July 21, 2010. Available [online](#).

Tobacco Warning Labels: Evidence of Effectiveness. (Update). Washington: Campaign for Tobacco-Free Kids, June 14, 2011. Available [online](#).