

FDA Tobacco Regulatory Science Fellowship



Program Overview

Launched in 2012, this regulatory science fellowship is a collaborative program between the FDA Center for Tobacco Products (CTP) and the Institute of Medicine (IOM). It is designed for mid-career professionals to gain experience and expertise to further define and develop the field of regulatory science as it relates to the regulation of tobacco products and FDA's new authorities under the Family Smoking Prevention and Tobacco Control Act. This is an excellent opportunity for exceptional professionals to actively participate in the development of science-based public health strategies, serve as the lead for defined projects, meet with policy leaders, and develop new competencies, including new knowledge, skills, and experiences related to tobacco products and their use, which is the leading cause of preventable death in the United States.

The fellowship is a 12-month, multidisciplinary residential program at CTP in Maryland. The third class of fellows will start in September 2014. Fellows will be placed in one of six offices within the CTP: Compliance and Enforcement; Health Communication and Education; Management; Policy; Regulations; or Science.

Fellows are expected to complete the full 12-month residential fellowship. Each fellow will be awarded up to \$95,000 based on salary history. Fellows may choose to enroll in a health insurance plan through the IOM or get reimbursed for a COBRA plan. Fellows with a sponsoring institution may be compensated for fringe benefits. In addition, each fellow may be eligible to receive a relocation fund (not to exceed \$10,000).

Eligibility

Exceptional professionals with a minimum of five to seven years of experience are encouraged to apply. Some candidates earlier in their career may be considered in special circumstances. Applicants must be U.S. Citizens, non-citizen nationals of the U.S., or have been admitted to the U.S. for permanent residence and have a valid green card number before applying to the program and must have an advanced degree in one of the fields listed below.

- Behavioral Science
- Biomedical Science
- Biomedical Engineering
- Communications
- Consumer Education
- Economics, Political Science, and other Social Sciences such as Sociology, Anthropology, and Psychology
- Law
- Medicine/Nursing
- Physical Science and Toxicology
- Public Health, including Public Health Ethics
- Public Policy/Public Administration

Selection Criteria

Fellows will be selected through a national competition on basis of:

- Professional Achievements
- Quality of Essays
- Expertise in an Area of Relevance to the CTP
- Quality of Letters of Recommendation

Application Materials

The online application will become available on January 6, 2014. Visit the fellowship website at <http://www.tobaccoregulatorysciencefellowship.org> and submit all application materials via the electronic application system. The complete application package includes:

- Curriculum Vitae (C.V.)
- A One-Page Biography
- Three (3) Letters of Recommendation
- Two (2) Short Essays

The deadline to submit all application materials is **March 3, 2014**.

Important Dates

| | |
|--------------------------|---|
| January 6–March 3 | Online Applications Accepted |
| March 31–April 3 | Selection of Finalists for In-Person Interviews |
| April 4 | Notification of Finalists |
| April 22 | In-Person Interviews in Washington, DC |
| April 23 | Notification of Awardees |
| September 8 | Start of Fellowship |

Inquiries

The FDA Tobacco Regulatory Science Fellowship is administered by the IOM and sponsored by the FDA/CTP. All inquiries should be directed to:

FDA Tobacco Regulatory Science Fellowship
 IOM/HPEPF | 500 Fifth Street, NW | Keck WS 838 | Washington, D.C. 20001
 202. 334. 1506 | info@tobaccoregulatorysciencefellowship.org



FDA Mission

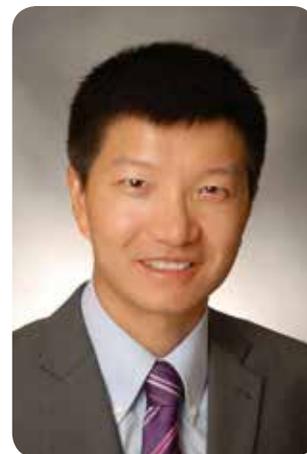
The Food and Drug Administration (FDA) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective, that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe, and for regulating tobacco products to protect the public health.

FDA Center for Tobacco Products (CTP)

The CTP was established by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which was signed into law by President Barack Obama on June 22, 2009. Its mission is to protect Americans from tobacco-related death and disease by regulating the manufacture, marketing, and distribution of tobacco products, and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

Program Overview

The FDA Center for Tobacco Products (CTP), in collaboration with the **Institute of Medicine (IOM)**, offers a regulatory science fellowship program designed for mid-career professionals to gain experience and expertise to further define and develop the field of regulatory science as it relates to the regulation of tobacco products and FDA's new authorities under the Family Smoking Prevention and Tobacco Control Act. This is an excellent opportunity for exceptional professionals to actively participate in the development of science-based public health strategies, serve as the lead for defined projects, meet with policy leaders, and develop new competencies, including new knowledge, skills, and experiences related to tobacco products and their use, which is the leading cause of preventable death in the United States.



The fellowship is a 12-month, multidisciplinary residential program at CTP in Maryland, starting September 2014. Fellows will be placed in one of six offices within the CTP: Compliance and Enforcement; Health Communication and Education; Management; Policy; Regulations; or Science ([see pages 5–7](#)).

Fellows are expected to complete the full 12-month residential fellowship. Each fellow will be awarded up to \$95,000 based on salary history. Fellows may choose to enroll in a health insurance plan through the IOM or get reimbursed for a COBRA plan. Fellows with a sponsoring institution may be compensated for fringe benefits. In addition, each fellow may be eligible to receive a relocation fund (not to exceed \$10,000).

Who Is Eligible To Apply?

Exceptional mid-career professionals are encouraged to apply and must fulfill the following requirements:

- be U.S. Citizens, non-citizen nationals of the U.S., or have been admitted to the U.S. for permanent residence and have a valid green card number before applying to the program.
- have a minimum of five to seven years of experience.
- have an advanced degree in one of the fields listed below.
 - Behavioral Science
 - Biomedical Science
 - Biomedical Engineering
 - Communications
 - Consumer Education
 - Economics, Political Science, and other Social Sciences such as Sociology, Anthropology, and Psychology
 - Law
 - Medicine/Nursing
 - Physical Science and Toxicology
 - Public Health, including Public Health Ethics
 - Public Policy/Public Administration

Note: All degree requirements (including thesis or dissertation defense) must be complete before the program start date of September 8, 2014.



How Do I Apply?

The online application will become available on January 6, 2014. Visit the fellowship website at www.tobaccoregulatorysciencefellowship.org and submit all application materials via the electronic application system. The complete application package includes:

- Curriculum Vitae (C.V.)
- A One-Page Biography (limited to 300 words)
- Three (3) Letters of Recommendation
- Two (2) Short Essays (each limited to 300 words)
 - Explain how this fellowship would contribute to your career development.
 - Describe an instance or an issue related to your discipline which challenged you to come up with an innovative and collaborative problem-solving solution.

The deadline to submit all application materials is **March 3, 2014**.

How Are Applicants Selected?

Fellows will be selected through a national competition on the basis of:

- Professional Achievements
- Quality of Essays
- Expertise in an Area of Relevance to the CTP
- Quality of Letters of Recommendation

If you are selected as a finalist, you must participate in an in-person interview at the IOM in Washington, DC. Below are important dates for selection, notification, and interviews.

| | |
|--------------------------|---|
| January 6–March 3 | Online Applications Accepted |
| March 31–April 3 | Selection of Finalists for In-Person Interviews |
| April 4 | Notification of Finalists |
| April 22 | In-Person Interviews in Washington, DC |
| April 23 | Notification of Awardees |
| September 8 | Start of Fellowship |

What Stipend and Benefits Can I Expect?

Fellows are expected to complete the full 12-month residential fellowship at CTP in Maryland. Each fellow will be awarded up to \$95,000 based on salary history. Fellows may choose to enroll in a health insurance plan through the IOM or get reimbursed for a COBRA plan. Fellows with a sponsoring institution may be compensated for fringe benefits. In addition, each fellow may be eligible to receive a relocation fund (not to exceed \$10,000) and may receive a monthly reimbursement of up to \$50 to compensate for travel expenses related to fellowship meetings held offsite.



Fellowship Core Curriculum

Fellows will participate in structured orientation and professional development activities, including opportunities to meet with FDA, CTP, and U.S. Department of Health and Human Services leadership, attend congressional hearings, and develop a set of core competencies.

Each fellow will be given a specific project assignment to work on over the course of the fellowship year. The fellowship culminates with formal presentations by each fellow to the CTP leadership and others describing the outcome of that project and lessons learned while participating in the fellowship program.

The orientation and professional development program will provide the fellows with an initial introduction to CTP and FDA, and with ongoing programs and activities that provide engagement with key Federal policy makers and training in the following areas:

- The history of the Federal Government's role in reducing the toll of disease, disability, and death caused by tobacco use in the U.S.;
- The provisions, mandates, and expectations of H.R. 1256 (Public Law 111-31), the 2009 Family Smoking Prevention and Tobacco Control Act;
- The vision, mission, and core values of CTP, and the roles and responsibilities of each CTP Office in fulfilling CTP's strategic vision and statutory mandates;
- The role of Congress and the relevant FDA/CTP Oversight, Authorizing, and Appropriations Committees;
- Writing for policy makers: talking points, briefings, and decision memos;
- Translating research and analysis into meaningful and effective policy and regulatory proposals;
- Media training;
- Public speaking;
- Collaboration and consensus building; and
- Project management and leadership training.

Finally, every effort will be made to identify opportunities for the fellows to participate in DC-based fellowship activities and gatherings sponsored by other fellowship programs, such as the Robert Wood Johnson Foundation (RWJF) Health Policy Fellows, American Association for the Advancement of Science (AAAS) Science & Technology Policy Fellows, White House Fellows, and others.

FDA CTP Participating Office

Office of Compliance and Enforcement

The Office of Compliance and Enforcement (OCE) activities ensure that regulated industry fully complies with the law. To achieve this end, OCE uses a three pronged approach: 1) developing and providing compliance training and education, 2) monitoring regulated industry's compliance with the law through surveillance, inspections, and investigations, and 3) initiating advisory and enforcement actions such as issuing Warning Letters and Civil Money Penalties against noncompliant industry, as appropriate. Some of the major functions that OCE is responsible for include: contracting with states and territories to conduct compliance check inspections of tobacco product retailers; surveillance of promotional activities of tobacco product manufacturers and distributors; compliance review of tobacco product document submissions; providing small businesses with the technical assistance they need to comply with requirements of the law; and implementing, overseeing, and enforcing the provisions of the Tobacco Control Act that regulate the sale, manufacturing and marketing of tobacco products. OCE seeks individuals with excellent writing, analytical, and communication skills. They should be able to analyze legal and compliance issues and work well as part of a team. A background in law, health care, law enforcement, marketing, science, or public health is recommended.

Office of Health Communication and Education

The Office of Health Communication and Education educates the public about the Tobacco Control Act, FDA's regulatory authorities, and the tobacco products that the FDA regulates. Through this office, FDA conducts multiple, integrated public health campaigns focused on preventing tobacco initiation and promoting cessation among the nation's youth and young adults by educating on the dangers of regulated tobacco products. The Office seeks expertise of behavioral scientists, tobacco and public health experts in risk communications, and other professionals with experience in marketing, advertising, and public relations.

Office of Management

The Office of Management provides objective, valid, accurate information and guidance on human capital, travel, information technology, financial management, training, and logistical services to enhance operations and support the public health goals and objectives of the CTP. The Office empowers the pursuit of public health and regulatory achievement by providing excellence and high-quality services—attracting, retaining, and developing a world-class workforce. The Office seeks individuals with excellent writing, analytical, and communication skills, and a strong desire to work in public service. The Office is interested in individuals with a Master's of Public Administration Degree, a Master's of Public Policy Degree, or a Master's of Business Administration Degree.

Office of Policy

The Office of Policy works closely with the CTP Director and its offices to provide policy, legal, and economic analysis on a wide range of priorities, options, and issues.¹ The Office works to ensure that the CTP's statutory public health goals and policy needs are integrated across all science, regulation, compliance, public education, and management programs. In addition, the Office provides public health and economic analysis and modeling of policy options, and works closely with all CTP offices

¹ The Food and Drug Law Division of the HHS Office of General Counsel serves as the official lawyers for FDA and provides formal legal analysis required for official FDA/HHS decision making and regulation.

on evolving issues in tobacco product regulation and control, such as impact on population health, development of tobacco product standards, modified risk products, and regulation of tobacco product marketing. The Office also engages with external stakeholders to inform and educate them about the policy implications of the Tobacco Control Act and FDA regulations and to gather useful facts and insights. The Office relies on individuals with expertise and backgrounds in the law, economics including cost-benefit analysis, public policy, and public health.

Office of Regulations

The Office of Regulations leads and coordinates the development of regulations, guidelines, and other regulatory documents related to the review and regulation of tobacco products. It also is responsible for responding to citizen petitions, obtaining appropriate delegations of authority, and managing the CTP's information collection activities. The Office serves as the Center's experts on issues involving the interpretation and application of the Administrative Procedure Act and other applicable laws, Executive Orders, and FDA/HHS/OMB policies. The Office works closely with other CTP offices as well as FDA's Office of the Chief Counsel and Office of the Commissioner. The Office of Regulations is currently seeking fellows with the ability to analyze complicated legal, scientific, and policy issues as well as excellent verbal and written communication skills. Candidates with expertise in administrative law issues are particularly desirable.

Office of Science

The Office of Science provides the scientific expertise needed to support regulatory decisions, reviews tobacco product applications, evaluates the knowledge base for regulatory decisions, and carries out research to fill the gaps in scientific knowledge related to tobacco product regulation. To accomplish this, the Office conducts product-related, toxicological, clinical, consumer behavior, epidemiological, and consumer perception research regarding the initiation, use, cessation, and adverse health impact of tobacco products. Currently, the Office seeks candidates who have advanced education (Ph.D., M.D., or equivalent) and experience relevant to methods of reporting and analyzing constituent concentrations in tobacco products; analysis of exposure parameters in diverse tobacco-using populations; the toxicological basis of dose-response relationships between constituents and tobacco-related disease; assessing the risks of tobacco products to users and nonusers; human health risk assessment modeling; qualitative and quantitative research on the impacts of product labeling, advertising, or marketing on consumer perceptions and behaviors; epidemiology in both clinical studies and large surveys evaluating the impact of tobacco product use on biomarkers of exposure and disease.

Comments or Questions?

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