The Commissioner's Fellowship Program

Outcomes Evaluation Report

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Photo of Commissioner's Fellows

Introduction

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

Additionally, FDA is responsible for advancing the public health by helping to speed innovations that make medicines and foods more safe, effective and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.

FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Finally, FDA plays a significant role in the Nation's counterterrorism capability, by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats. Underpinning all of FDA's work is a well-trained scientific workforce.

Having a well-trained workforce has been a primary goal of the Federal government as evidenced in the establishment of the Human Capital Assessment and Accountability Framework (HCAAF) and the Chief Human Capital Officers Act, which carries out functions in 5 U.S.C. 1402. Within the HCAAF, succession planning, recruitment, and training are strategies identified to meet an organization's human capital needs. The Food and Drug Cosmetic Act, Section 742, also supports education through fellowships and scientific training.

In 2007, the Subcommittee on Science and Technology in its report to the Science Board noted that the "turnover rate in FDA science staff is twice that of other government agencies."[1] Although the report references a 2002 GAO report and FDA had hiring surges in FY 2008 and FY 2009, the Agency still faces workforce challenges. For example, the number of FDA staff eligible for retirement is expected to increase from 1,483 in FY 09 to 2,849 by the end of FY14—more than a quarter of FDA's workforce during this period.[2]

In 2007, the Science Board's Subcommittee on Science and Technology also reported that "the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities."[3] The Subcommittee identified an "excellent staff with

[1] *FDA Science and Mission at Risk*, pg. 4, November 2007.

[2] *FDA 2010 Workforce Analysis*, *2011-2012 Workforce Plan*.

[3] *FDA Science and Mission at Risk*, pg. 2, November 2007.

cutting-edge scientific expertise appropriate to the mission"[4] as crucial for a strong scientific foundation at FDA, yet found FDA's recruitment and retention, professional development, and external collaborations to be deficient.

Summary

To meet the scientific workforce challenges, in 2008, FDA launched the Commissioner's Fellowship Program (CFP) to achieve three goals:

1) Attract top-tier scientists to FDA to address regulatory science issues through mentored projects of high priority to the Agency

2) Provide regulatory science training

3) Serve as a potential recruiting tool.

The first CFP Class of 2008 graduated in September 2010. To date, the CFP classes starting in 2008, 2009, 2010, 2011, 2012, and 2013 classes have graduated.

Attracting Scientists to FDA

Every year, hundreds of applicants have applied to FDA's CFP, vastly in excess of available positions. There have been 973, 725, 642, 513, 294, and 204 applicants for the 2008, 2009, 2010 2011, 2012, and 2013 classes, respectively.

Number of Applications and Fellows Selected

	2008	2009	2010	2011	2012	2013
Applications	**973**	**725**	**642**	**513**	**294**	**204**
Fellows Selected	50	50	45	32	22	13

Completing Regulatory Science Training

To graduate, Fellows must complete three requirements:

1) 11 required courses that emphasize core disciplinary needs to provide a solid base for regulatory science.

[4] *FDA Science and Mission at Risk*, pg. 2, November 2007.

2) A regulatory science project addressing a high-priority need under the mentorship of an established FDA scientist.

3) Substantive engagement in regulatory/review work.

Since 2008, **192 Fellows** have completed the required training and graduated from the program.

Contributing to FDA's Regulatory Science Activities

The 2008, 2009, 2010 2011, 2012, and 2013 CFP graduates have addressed 48, 50, 36, 30, 18, and 13 regulatory science projects respectively.

Center Regulatory Science Projects

Center Projects	2008	2009	2010	2011	2012	2013	Total
Center for Biologics Evaluation and Research (CBER)	9	6	5	5	3	3	27
Center for Drug Evaluation and Research (CDER)	7	6	7	3	3	1	26
Center for Devices and Radiologic Health (CDRH)	6	11	4	8	2	2	31
Center for Tobacco Products (CTP)				1	1		2
Center for Food Safety and Applies Nutrition (CFSAN)	7	6	4	2	3	1	22
Center for Veterinary Medicine (CVM)	7	7	4	2			20
National Center for Toxicologic Research (NCTR)	7	7	7	3	4	3	28
Office of Regulatory Affairs		2	3	4	2	3	11
Office of the Commissioner	5	5	2	2			14
Total Regulatory Science Projects	**48**	**50**	**36**	**30**	**18**	**13**	**195**

Since the publication of the FDA Regulatory Science Strategic Plan in August 2011, there have been 30 Regulatory Science projects addressed by the 2011 CFP Graduates, 18 Regulatory

Science projects addressed by the 2012 CFP Graduates, and 13 Regulatory Science projects addressed by the 2013 CFP Graduates.

CFP Fellows Regulatory Science Priority Area Projects

Regulatory Science Priority Areas	Number of CFP Class of 2011 Fellows Projects	Number of CFP Class of 2012 Fellows Projects	Number of CFP Class of 2013 Fellows Projects
Transform Toxicology to Enhance Product Safety	2	4	3
Stimulate Innovation in Clinical Trials and Personalized Medicine	3	2	
Support New Ways to Improve Product Manufacturing and Quality	3	0	1
Ensure FDA Readiness to Evaluate Innovative Emerging Technologies	12	4	2
Harness Data through Information Sciences to Improve Health Outcomes	2	2	1
Implement a New Prevention-Based Food Safety System	6	4	3
Support Medical Countermeasures Development to Protect National Health and Security	2	2	3
Total	30	18	13

The CFP Graduates have represented FDA with 245 regulatory science presentations and 184 publications. Their work earned 26 of them Center or FDA Honor Awards.

Fellows Retained at FDA

Of the 192 CFP graduates to date, FDA has retained 76% (n=146), with CDRH hiring 32% of the graduates. Academia and industry have also hired graduates.

CFP Fellows' Employment at Graduation

	2008	2009	2010	2011	2012	2013	Total
Fellows Hired	50	50	45	32	22	13	212
Fellows Graduated	48	50	36	30	18	10	192
Retained at FDA	39	38	28	19	14	8	146
Academia	4	4	3	3	1		15
Industry	3	1	3	2			9
Other	2	7	2	6	3	2	22

FDA Product Centers Hiring Commissioner's Fellows at Graduation

Fellows FDA Retained	CBER	CDER	CDRH	CTP	CFSAN	CVM	ORA	NCTR	OC
2008 (39)	4	5	9	2	5	7	0	4	3
2009 (38)	2	4	14	1	4	5	1	4	3
2010 (28)	1	9	8	0	4	1	1	3	1
2011 (19)	0	5	8	2	0	1	0	2	1
2012 (14)	2	4	4	0	1	0	2	1	0
2013 (8)	2	1	4	1	0	0	0	0	0
Total	**9**	**27**	**43**	**5**	**14**	**14**	**4**	**14**	**8**

The 192 graduates of 84 men and 108 women represent different ethnic groups.

Ethnicity of Graduates

Ethnicity	2008 Graduates	2009 Graduates	2010 Graduates	2011 Graduates	2012 Graduates	2013 Graduates
White	19	23	16	12	7	6

Asian	22	19	13	16	10	2
Hispanic/Latino	2	3	2	0	0	0
African American	5	5	5	2	1	2