UNITED STATES OFFICE OF
GOVERNMENT ETHICS

Ethics Program Review

U.S. Food and Drug Administration

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The United States Office of Government Ethics (OGE) conducted a review of the U.S. Food and Drug Administration (FDA) ethics program during August and September 2016. The following summarizes the results of that review.

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Objectives, Scope and Methodology

Objectives: OGE provides overall leadership and oversight of the executive branch ethics program designed to prevent and resolve conflicts of interest. The Ethics in Government Act gives OGE the authority to evaluate the effectiveness of executive agency ethics programs.[1] OGE uses this evaluation authority largely to conduct reviews of agency ethics programs. The purpose of a review is to identify and report on the strengths and weaknesses of an ethics program by evaluating (1) agency compliance with ethics requirements as set forth in relevant laws, regulations, and policies and (2) ethics-related systems, processes, and procedures for administering the program.

Scope: OGE's review focused on the administration of FDA's ethics program by the Division of Ethics and Integrity (DEI) located in FDA's Office of Operations. Because FDA is a component of the Department of Health and Human Services (HHS), DEI receives guidance and support from ethics officials within the Office of the General Counsel (OGC) Ethics Division at HHS headquarters in Washington, D.C. OGE recently reviewed the ethics program at HHS headquarters and the results of that review have been issued in a separate report.

Methodology: OGE conducted the review of FDA's ethics program in August and September 2016. OGE reviewed the various elements of the ethics program within FDA including: program administration, financial disclosure, education and training, ethics advice and counseling, and agency-specific ethics rules on outside activities and prohibited financial interests.[2] As part of its review, OGE examined a variety of documents provided by FDA ethics officials, including the 2015 Annual Agency Ethics Program Questionnaire (Questionnaire), public and confidential financial disclosure reports filed in 2016, ethics training materials, and

[1] *See* title IV of the Ethics in Government Act, 5 U.S.C. app. § 402 and 5 C.F.R. part 2638.
[2] HHS has a supplemental standards of conduct regulation at 5 C.F.R. part 5501 and a supplemental financial disclosure regulation at part 5502. Provisions of both regulations apply to FDA employees.

advice and counseling provided to FDA employees. In addition, OGE met with ethics officials from DEI and the HHS OGC-Ethics Division, as well as with officials from the Advisory Committee Oversight and Management Staff (ACOMS) who provide ethics services for the SGEs serving on 33 advisory committees in FDA's Office of the Commissioner.

Agency Background

HHS is the principal Cabinet-level department of the federal executive branch whose mission is to enhance the health and well-being of all Americans. FDA is the agency within HHS responsible for protecting and promoting the public health by ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of food and feed, cosmetics, and radiation-emitting products; and regulating tobacco products.

FDA is led by a Commissioner who is a presidentially appointed, Senate-confirmed (PAS) official. FDA has more than 17,000 employees in centers located on campuses and offices in the Washington, D.C. area, New York, Chicago, Atlanta, Dallas, Oakland and international locations in China, India, Europe, the Middle East, and Latin America. FDA consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods and Veterinary Medicine, Global Regulatory Operations and Policy, and Operations.[3]

Program Administration

DEI manages and oversees FDA's ethics program agency-wide, except for the ethics service provided to SGEs serving on the FDA's advisory committees, which are administered by ACOMS. DEI has 17 staff members and is organizationally situated under FDA's Office of Operations. The Acting Deputy Commissioner for Operations and Chief Operating Officer serves as FDA's Deputy Ethics Counselor (DEC). The DEC has been given delegated authority to manage FDA's ethics program by HHS' Designated Agency Ethics Official (DAEO).[4] In 2016, FDA elevated the Director position to the Senior Executive Service (SES) level and Deputy Director position to the GS-15 level. DEI hired a new Director, a new Deputy Director, two additional Supervisory Ethics Specialists for a total of three Supervisory Ethics Specialists and a Management Analyst to manage FDA's ethics records system. The DEI staff also includes 11 full-time Ethics Specialists. Assisting DEI are management and/or personnel specialists who

[3] Within the directorates are the following centers and offices: Center for Tobacco Products (CTP), Center for Biologics Evaluation & Research (CBER), Center for Drug Evaluation & Research (CDER), Center for Devices & Radiological Health (CDRH), Center for Food Safety & Nutrition (CFSN), Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR), Office of Regulatory Affairs (ORA), and the Office of Operations (OO).

[4] DECs at HHS components are generally senior-level management officials chosen by the DAEO in consultation with the head of each operating or staff division. The DAEO delegates to each DEC the responsibility and authority to administer the public and confidential financial disclosure systems, manage the prior approval to engage in outside activity requirement and subsequent annual reporting processes, resolve conflicts of interest, conduct education and training, provide advice and counseling, and assist the DAEO and Office of Inspector General in enforcing ethics laws.

serve the ethics program as Ethics Coordinators or DEC Points of Contact (DEC POCs) and three HHS ethics attorneys and one ethics specialist.

Agency Leadership Support

FDA's senior leadership has demonstrated support for the agency's ethics program. For example, the Commissioner established a Steering Committee tasked with providing policy direction and identifying resources to improve FDA's ethics program. The Commissioner leads the weekly Steering committee meetings whose members include the FDA Chief of Staff, the Director of the Office of Human Resources, FDA Center Directors, the DEC, and the Chief Operating Officer.

Financial Disclosure

Title I of the Ethics in Government Act requires that agencies administer public and confidential financial disclosure systems. Financial disclosure serves to prevent, identify, and resolve conflicts of interest by providing for a systematic review of the financial interests of officers and employees. The financial disclosure process also offers an opportunity for ethics officials to provide ethics-related counseling to report filers.

To evaluate FDA's financial disclosure systems, OGE evaluated the required written procedures for administering the systems and a sample of public and confidential financial disclosure reports that were required to be filed by FDA employees.

Financial Disclosure Written Procedures

Each executive branch agency must establish written procedures for collecting, reviewing, evaluating, and where applicable, making publicly available financial disclosure reports filed by the agency's officers and employees.[5] FDA's written procedures were developed by the HHS OGC-Ethics Division and are implemented by DEI. OGE's evaluation of these procedures found them to be in compliance with applicable requirements.

Public Financial Disclosure System

Beginning in 2016, FDA's public financial disclosure report filers submit their reports through OGE's electronic filing system, *Integrity*. DEI reviews and certifies the public reports filed by career FDA employees. The HHS OGC-Ethics Division reviews and certifies the reports for PAS officials, non-career members of the SES, and Schedule C employees.

DEI is responsible for notifying career officials of the requirement to file public financial disclosure reports. Notification is generally made via email and includes guidance explaining how to submit reports through *Integrity*. Once a filer submits a report, a DEI Ethics Specialist conducts an intermediate review. Once the intermediate review is completed, the report is forwarded to the Director of DEI for a second review. The Director then forwards the report to the DEC for certification. Certified reports that are reviewed and certified by the DEC are

[5] *See* Section 402(d)(1) of the Ethics in Government Act.

forwarded to the HHS OGC-Ethics Division. As part of its oversight responsibilities, the OGC-Ethics Division conducts an additional review of the reports to help ensure that all potential conflicts of interest have been promptly identified and resolved.

OGE's Examination of Public Financial Disclosure Reports

To evaluate DEI's administration of the public financial disclosure system for career FDA employees, OGE examined a sample consisting of 15 new entrant, 121 annual and 3 termination reports that were required to be filed by career employees in 2016. OGE initially found significant deficiencies in the number of annual reports certified timely. FDA subsequently provided additional documentation substantiating that reports were generally reviewed and certified timely. OGE reminds FDA to document the review and certification for all reports. Table 1 below presents the results of OGE's review.

Table 1. OGE's Examination of Public Financial Disclosure Reports

	New Entrant	Annual	Termination	Total
Reports Examined	15	121	3	139
Filed Timely	10 (67%)	117 (97%)	3 (100%)	130 (94%)
Certified Timely	12 (80%)	98 (81%)	2 (67%)	112 (81%)

Of all the reports OGE examined, 94% were filed timely; however, only 67% of new entrant reports were filed timely. DEI discovered a communication gap between DEI and the Office of Human Resources with respect to employees entering public financial disclosure positions, including those serving on an acting basis. As a result, DEI had been unable, in some cases, to timely notify employees entering into public financial disclosure positions of the process to file their public financial disclosure report in Integrity. Recognizing this vulnerability, the DEI Director instituted a new practice of weekly meetings with FDA's Office of Human Resources and HHS OGC-Ethics Division to discuss new employees who are required to file financial disclosure reports. In addition, the Office of Human Resources advises DEI when position titles change, new positions are identified, or positions are reclassified. Despite these procedures, the timely collection of new entrant reports requires improvement.

OGE's examination revealed that 81% of the sampled reports were certified timely. The DEI Director explained that ethics officials were still in the process of reviewing the approximately 12,000 confidential financial disclosure reports filed in 2016 when the 2016 annual public filing cycle began in May, which contributed to a delay in certifying the public reports. Based on this experience, the DEI Director determined that to improve efficiency, beginning with the 2017 annual public filing cycle, public financial disclosure reports will be assigned to a select group of Ethics Specialists that will focus solely on these reports. The Director has also hired additional staff to implement this new approach to public financial disclosure report review.

OGE's examination of the sample of public reports found evidence, in the form of reviewer's notes, that reports received a detailed review. Moreover, DEI officials' review of reports was thorough enough in many cases to prompt them to counsel filers and provide advice aimed at preventing conflicts of interest and other ethics-related violations.

Model Practice

OGE identifies model practices and shares them when it appears they may benefit other executive agency ethics programs. OGE considers the following to be a model practice implemented at FDA:

- As part of its oversight responsibilities, the OGC-Ethics Division conducts an additional review of public financial disclosure reports to help ensure that all potential conflicts of interest have been promptly identified and resolved.

Recommendation

1. Ensure that new entrant public financial disclosure reports are filed timely.

Confidential Financial Disclosure System

DEI relies on the DEC POCs to identify confidential filers, notify the filers regarding their responsibility to file reports, and track the completion of the reports in FDA's confidential Electronic Financial Disclosure System. Once a confidential report is completed by the filer, the center DEC POC conducts an initial review and contacts the filer directly to correct reporting omissions and errors as necessary. Then, DEI Ethics Specialists perform the final review and certification, examining the reports for financial conflicts of interest, including whether the reports list interests in significantly regulated organizations in contravention of FDA's supplemental standards of conduct regulation. If a potential conflict of interest is found, a DEI Ethics Specialist contacts the filer for more information and resolves any potential conflicts.

FDA's Electronic Financial Disclosure System

In 2015, FDA began using the HHS' Electronic Financial Disclosure System (EFDS) for its confidential filers. The EFDS application is used HHS-wide, with the exception of certain agencies.

OGE's Examination of Confidential Financial Disclosure Reports

Approximately 70% of FDA's 17,000 employees filed confidential financial disclosure reports in 2016. To evaluate FDA's confidential financial disclosure system, OGE reviewed a sample of 182 new entrant and 374 annual reports that were required to be filed in 2016 at 7 of the 13 FDA centers. Table 2 below presents the overall results of OGE's examination. Tables 3 through 9 present the results of OGE's examination of reports at each of the centers sampled.

Table 2. OGE's Examination of Confidential Financial Disclosure Reports Overall

	New Entrant	Annual	Total
Reports Examined	182	374	556
Filed Timely	63 (35%)	347 (93%)	410 (74%)
Certified Timely	114 (63%)	118 (32%)	232 (42%)

Table 3. OGE's Examination of Confidential Financial Disclosure Reports at the Center for Tobacco Products (CTP)

	New Entrant	Annual	Total
Reports Examined	28	51	79
Filed Timely	7 (25%)	46 (90%)	53 (67%)
Certified Timely	27 (96%)	30 (59%)	57 (72%)

Table 4. OGE's Examination of Confidential Financial Disclosure Reports at the Office of Regulatory Affairs (ORA)

	New Entrant	Annual	Total
Reports Examined	46	95	141
Filed Timely	14 (30%)	91 (96%)	105 (74%)
Certified Timely	24 (52%)	28 (29%)	52 (37%)

Table 5. OGE's Examination of Confidential Financial Disclosure Reports at the Center for Devices & Radiological Health (CDRH)

	New Entrant	Annual	Total
Reports Examined	26	53	79
Filed Timely	13 (50%)	49 (92%)	62 (78%)
Certified Timely	16 (62%)	4 (8%)	20 (25%)

Table 6. OGE's Examination of Confidential Financial Disclosure Reports at the Center for Drugs Evaluation & Research (CDER)

	New Entrant	Annual	Total
Reports Examined	32	74	106
Filed Timely	13 (41%)	70 (95%)	83 (78%)
Certified Timely	23 (72%)	9 (12%)	32 (30%)

Table 7. OGE's Examination of Confidential Financial Disclosure Reports at the National Center for Toxicological Research (NCTR)

	New Entrant	Annual	Total
Reports Examined	3	21	24
Filed Timely	0 (0%)	20 (95%)	20 (83%)
Certified Timely	2 (67%)	20 (95%)	22 (92%)

Table 8. OGE's Examination of Confidential Financial Disclosure Reports at the Center for Veterinary Medicine (CVM)

	New Entrant	Annual	Total
Reports Examined	24	55	79
Filed Timely	5 (21%)	50 (91%)	55 (70%)
Certified Timely	7 (29%)	13 (24%)	20 (25%)

Table 9. OGE's Examination of Confidential Financial Disclosure Reports at the Center for Biologics Evaluation & Research (CBER)

	New Entrant	Annual	Total
Reports Examined	23	25	48
Filed Timely	11 (48%)	23 (92%)	34 (71%)
Certified Timely	15 (65%)	16 (64%)	31 (65%)

Filing Timeliness

A new entrant confidential report must be submitted no later than 30 days after a filer enters a position or office that requires the filing of a report.[6] Newly hired FDA employees attend a two-day New Employee Orientation sponsored by the Office of Human Resources. During the orientation, the DEI Ethics Specialist provides new employees with an initial ethics orientation. The orientation includes an explanation that an employee may be required to file a confidential report. DEC POCs review new employees' job duties in consultation with supervisors to identify which employees should file new entrant reports. Once new entrants are identified, DEC POCs notify new employees to file using the EFDS system.

As noted above in Table 2, OGE examined samples of new entrant confidential reports from 7 of the 13 FDA centers and found that, of the 182 new entrant reports examined, 119 (65%) appeared to have been filed late or the timeliness of filing could not be determined. According to the Director of DEI, this late filing partially stems from the fact that employees are not designated as filers upon their appointment date. Rather, as also noted above, FDA reviews the job duties of each new employee and then determines whether the position the employee is entering is a covered filing position. Because the employee is notified of their filing status after the ethics officials' review of their position, rather than upon entry into the position, filing can be delayed beyond the 30-day deadline. Additionally, according to two DEI Supervisory Ethics Specialists, the EFDS system allows only the new employee to enter whether they are a new entrant or annual filer. New employees sometimes do not enter appointment dates or filing status causing EFDS to default to recognizing the filer as an annual filer when, in fact, they are new entrant filers. Because of this weakness in the system, tracking new entrant filers is a challenge for DEC POCS and DEI Ethics Specialists. DEI is working with the Office of Human Resources to establish a process to help ensure that new entrant confidential financial disclosure filers are notified to file a report as soon as they begin working at FDA.

OGE acknowledges that some of the reports examined may have been mistakenly annotated as new entrant reports, making it appear that they were filed late when in fact they were filed timely. However, whether the reports were correctly annotated as new entrant reports and filed late or filed timely but incorrectly annotated as new entrant reports, FDA must continue its efforts to ensure that reports are both correctly annotated and filed timely.

Because annual filers are already identified and entered into the EFDS system, the timeliness of filing for annual filers is noticeably better. OGE's examination of a sample of FDA's annual confidential reports from 7 of the 13 centers found that 347 (93%) of the 374 reports examined were filed timely.

Certification Timeliness

As indicated in Table 2 above, 37% of new entrant reports and 68% of annual reports were certified late. DEI officials indicated that the late certification of reports was caused by a combination of staffing limitations and the large number of confidential financial disclosure filers at FDA. DEI experienced significant staff turnover during the confidential and public

[6] *See* 5 C.F.R. § 2634.903(b).

financial disclosure certification seasons. Only 14 DEI Ethics Specialists were available to review and certify over 12,000 public and confidential financial disclosure reports in 2016.[7]

During the OGE on-site fieldwork in August 2016, DEI noted that DEI Ethics Specialists were still reviewing and certifying reports filed in 2015. During a follow-up conversation in November 2016, DEI noted that they were still completing review and certification of 2015 and 2016 confidential reports and in March 2017, FDA confirmed all reports submitted in 2015 had been certified.[8] For reports submitted in 2016, all annual reports have been certified and all but seven new entrant reports have been certified.

While OGE recognizes staffing limitations can affect the timely review and certification of reports, it is imperative that these reports receive prompt conflict-of-interest reviews to identify where remedial action may be necessary. OGE suggests that FDA conduct a review of its confidential filers to ensure that only those employees who meet the filing criteria are being required to file reports.[9] Ensuring that filers are properly designated could potentially reduce the volume of filers. Prioritizing reports by complexity and risk may also help to prevent the backlog of reports required to be reviewed and certified.

Recommendation

2. Ensure that all confidential reports filed in 2017 are reviewed and certified timely.

Education and Training

An ethics training program is essential to raising awareness among employees about the ethics laws and rules that apply to them and the availability of agency ethics officials to provide ethics counseling. Each agency's ethics training program is required to include at least an initial ethics orientation for all new employees and annual ethics training for covered employees.[10] During the period covered by OGE's review, each agency's ethics training program was required to include at least an initial ethics orientation for new employees and annual ethics training for covered employees.[11]

[7] At the time of OGE's onsite fieldwork in August 2016, DEI had 12 Ethics Specialists and 2 Ethics Specialist Supervisors available to review the 139 public financial disclosure reports and 11,935 confidential financial disclosure reports required to be filed in 2016.

[8] In 2015, 10,893 confidential reports were filed at FDA. Of those, 10,839 reports had been certified by the end of calendar year 2016. The review of the remaining 54 reports has been given priority over the reports required to be filed in 2017. The review and certification of some of the 54 reports was delayed by remedial action being taken by ethics officials. In 2016, 10,925 confidential reports were required to be filed at FDA. Ethics officials determined that it was impracticable to collect 97 of these reports due to extended medical leave or other reasonable cause. As of January 6, 2017, FDA had reviewed and certified 10,600 reports. The remaining reports have been initially reviewed by DEI and the DEC POCs and require additional follow-up information or remedial action before certification.

[9] *See* 5 C.F.R. § 2634.903.

[10] *See* 5 C.F.R. §§ 2638.704 and 705 for definition of covered employees.

[11] Effective January 1, 2017, the regulation governing executive branch agency ethics training at 5 C.F.R. part 2638 was amended. Because this review covers ethics activities for calendar year 2016, OGE evaluated FDA's training program against the requirements in place at that time.

Initial Ethics Orientation

To meet initial ethics orientation (IEO) requirements, all new agency employees must receive ethics official contact information along with the following material within 90 days of beginning work: (1) the Standards of Conduct for Employees of the Executive Branch (Standards of Conduct) and any agency supplemental standards of conduct to keep or review; or (2) summaries of the Standards of Conduct, any agency supplemental standards of conduct, and the Principles of Ethical Conduct (Principles) to keep. Employees must receive one hour of official duty time to review the material.[12]

To meet the initial ethics orientation requirement, all new FDA employees are required to receive an ethics presentation and handout from DEI on the first day of the New Employee Orientation session administered by the Office of Human Resources. The ethics presentation and handout cover the Principles, the Standards of Conduct, the HHS supplemental standards of conduct, ethics contact information, and the criminal conflict of interest statutes. OGE reviewed the initial ethics orientation materials and determined the materials meet the applicable content requirements.

Annual Ethics Training

To meet the annual ethics training requirements, covered employees must receive annual training consisting of a review of: (1) the Principles; (2) the Standards of Conduct; (3) any agency supplemental standards of conduct; (4) the criminal conflict of interest statutes; and (5) ethics official contact information. Training length and delivery method may vary by an employee's financial disclosure filing status.[13]

DEI offers annual ethics training to all FDA employees through an online computer-based training program accessed through FDA's Compliance Training System. FDA's objective for 2016 annual ethics training was to increase awareness of ethics rules, laws, and responsibilities for each FDA employee by covering several topics such as the Principles, the Standards of Conduct, the HHS supplemental standards of conduct, and the criminal conflict of interest statutes. OGE examined FDA's annual ethics training and determined the training provided by DEI to covered employees meets the content requirements. DEI tracks completion of annual ethics training electronically for all FDA employees who complete online computer-based training.

Covered employees – public and confidential disclosure filers – are required to receive annual ethics training each calendar year. OGE selected a sample of 133 public financial disclosure filers and 538 confidential financial disclosure filers to determine FDA's compliance with ethics training requirements for covered employees. Based on FDA's documentation, OGE found 132 (99%) public filers and 538 (100%) confidential filers completed 2016 annual ethics training. OGE also found 27 (20%) public filers and 47 (9%) confidential filers completed annual ethics training in calendar year 2017. Upon further examination of FDA's documentation, OGE discovered DEI's deadline to complete 2016 annual ethics training was in

[12] *See* 5 C.F.R. § 2638.703.
[13] *See* 5 C.F.R. §§ 2638.704 and 705.

2017, which is the following calendar year; therefore, the annual ethics training completed in calendar year 2017, albeit late, is sufficient for meeting the 2016 annual ethics training requirement. DEI is responsible for setting deadlines and ensuring covered employees receive annual ethics training each calendar year.

Advice and Counseling

The DAEO is required to ensure that a counseling program for agency employees concerning ethics and Standards of Conduct matters, including post-employment matters, is developed and conducted.[14] The DAEO may delegate to one or more deputy ethics officials the responsibility for developing and conducting the counseling program.[15]

The HHS DAEO has delegated the authority to provide advice and counseling for most career and non-career FDA employees to DEI.[16] The HHS OGC-Ethics Division provides advice to all PAS officials.

OGE examined a sample of written advice provided by DEI in 2016. The advice addressed gift questions, conflict-of-interest matters, seeking outside employment, and other ethics-related topics. The majority of the advice was provided by email. The advice appeared to be consistent with applicable laws and regulations and rendered timely.

Post-Employment Counseling

DEC POCs provide departing employees with a Certification for Separating Employees (FDA Form 2097), which provides guidance on the post-employment restrictions. Employees are required to sign the form, certifying that they have received the written guidance. DEI also provides departing employees with in-person counseling, upon request.

To enhance the counseling program for departing employees, the Director of DEI stated that, in consultation with the FDA's DEC, he is considering requiring all departing senior FDA employees to obtain in-person ethics counseling regarding the post-employment restrictions. He also plans to strongly encourage in-person counseling regarding seeking and post-employment restrictions for all FDA employees. However, a mandatory requirement for all FDA employees would depend upon the availability of resources in DEI.

Since OGE's on-site review, DEI has restructured its job functions to address post-employment counseling. Ethics Specialists on the new DEI Ethics Advice and Policy team will now be solely responsible for providing seeking and post-employment ethics guidance to FDA employees.[17]

[14] *See* 5 C.F.R. § 2638.203.
[15] *See* 5 C.F.R. § 2638.204.
[16] The DEC POCs are not authorized to provide advice and counseling and therefore forward ethics inquiries to DEI.
[17] The Ethics Advice and Policy Team will also be responsible for providing pre-employment counseling on the applicable ethics restrictions, including FDA-specific prohibited holding rules; reviewing and processing Requests to Engage in Outside Activities (HHS 520); and responding to ethics questions submitted to the FDA Ethics Hotline and Ethics Advice Inbox.

Agency-Specific Ethics Rules

An agency may modify or supplement the Standards of Conduct, with the concurrence of OGE, to meet the particular needs of that agency. A supplemental agency regulation is issued jointly by the agency and OGE and is published in Title 5 of the Code of Federal Regulations.[18]

HHS has jointly issued with OGE a supplemental standards of conduct regulation.[19] These supplemental standards of conduct impose requirements applicable to employees HHS-wide, as well as requirements applicable to only certain HHS components, including FDA.

One provision of the supplemental standards of conduct generally prohibits, with some exceptions, FDA employees, their spouses, and minor children from holding a financial interest (e.g. a stock holding) in a significantly regulated organization (SRO).[20] The list of SROs regularly changes is updated on a monthly basis on FDA's Ethics intranet website. The DEI Director explained that through an interagency agreement with the HHS OGC-Ethics Division. FDA integrated the SRO list with EFDS filing system. Currently, when DEI Ethics Specialists conduct reviews of financial disclosure reports and identify holdings in SROs, they issue a memorandum to the filer notifying the filer they must divest the prohibited financial interest.[21] Employee options to satisfy the divestiture requirements include: 1) include documentation to support the company is not significantly regulated, 2) divest of the prohibited stock, or 3) request an exception to hold the financial interest. According to DEI officials, employees are responsible for monitoring their financial interests. If an employee learns that a financial holding has become "prohibited," FDA policy requires the employee to immediately complete and submit Form HHS 717-2.

The HHS supplemental standards of conduct also require all employees, including FDA employees, to obtain advance approval for certain types of outside activities.[22] These activities include outside professional and consultative work, writing and editing, teaching and lecturing, and holding office or membership in professional societies.

FDA employees who wish to engage in an outside employment or activity for which advanced authorization is needed are required to file a Request for Approval of Outside Activity (HHS-520). This form is also used when employees need to make revised requests, when the outside activity or the employee's duties change significantly and for annual renewal requests when employees want to continue the outside activity.

DEI ethics officials, along with the employee's supervisor, evaluate and recommend approval, as appropriate, of outside activity requests for FDA employees. An agency ethics review of each outside activity request is performed by ethics specialist in DEI. Changes were made in the process so that DEI Director approves all outside activity requests.

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[18] *See* 5 C.F.R. § 2635.105.
[19] *See* 5 C.F.R. part 5501.
[20] *See* 5 C.F.R. § 5501.104.
[21] New employees who are not public or confidential filers must also complete and submit the HHS Form 717-2 within 30 days after entering on duty. Incumbent employees who acquire any prohibited financial interest must complete and submit the report within 30 days after acquiring the financial interest.
[22] *See* 5 C.F.R. § 5501.106.

To evaluate the implementation of HHS' supplemental regulations, OGE examined the outside activity approval system concurrent with its review of financial disclosure reports. OGE sought to determine whether there were HHS-520 approvals, as appropriate, for covered outside activities reported on the financial disclosures reports. OGE identified 28 outside activities reported on financial disclosure reports and requested the associated HHS-520 Forms. DEI was able to provide a response to the requested outside activities.

Conflict Remedies

The criminal conflict of interest law prohibits an employee from participating in an official capacity in a particular matter in which he or she has a financial interest.[23] Congress included two provisions that permit an agency to issue a waiver of this prohibition in individual cases. Agencies must consult with OGE, where practicable, prior to issuing such a waiver.[24]

According to DEI, in 2015 FDA did not issue any waivers for regular employees and issued only one waiver for a special Government employee serving on a Federal Advisory Committee Act committee. OGE was consulted regarding the special Government employee waiver.

Additionally, the Ethics in Government Act expressly recognizes the need for PAS nominees to address actual or apparent conflicts of interest by requiring written notice of the specific actions to be taken to alleviate the conflict of interest,[25] commonly known as an "ethics agreement."

The HHS OGC-Ethics Division is responsible for providing guidance to PAS officials and maintaining their ethics agreements. OGE determined that during the period under review, all of the FDA PAS officials complied with their ethics agreements and that the requisite evidence of actions taken to comply was submitted to OGE in a timely manner. OGE also determined that the OGC-Ethics Division maintained ethics agreements with each PAS official's financial disclosure report, as required.[26]

Enforcement

Agencies must concurrently notify OGE when a case involving an alleged violation of a criminal conflict of interest statute is referred to the Department of Justice (DOJ). Agencies are also required to report when DOJ declines to prosecute a potential violation, any follow-up actions on a referral, and the disposition of the referral.[27]

In 2015, FDA referred 11 cases of potential criminal violations of the conflict of interest laws to FDA's Office of Internal Affairs (OIA). At FDA, OIA works closely with HHS Office of the Inspector General's Special Investigations Bureau (OIA/SIB). HHS OIG/SIB determines if it

[23] *See* 18 U.S.C. § 208.
[24] *See* Executive Order 12674.
[25] *See* 5 U.S.C. app. § 110.
[26] See 5 C.F.R. § 2634.805.
[27] See 5 C.F.R. part 2638.

will work matters independently, jointly with OIA or refers the matters to OIA for any action OIA deemed appropriate. OIA will notify HHS OIA/SIB if during the course of an OIA investigation, OIA develops evidence of potential criminal violations. OIA can present cases involving criminal violations to DOJ.

Special Government Employees

A special Government employee (SGE) is an officer or employee of the executive or legislative branch retained, designated, appointed or employed to perform official duties, full-time or intermittently, for not more than 130 days in any 365-day period.[28] SGE's at FDA generally fall into two basic groups: SGEs who serve as standing or temporary members of Federal Advisory Committee Act (FACA) committees and SGEs who serve as non-FACA committee Science Advisors.

FACA Committee SGEs

At FDA, FACA committees are comprised of standing and temporary members that are identified within each committee charter as SGEs. Clinicians, academicians, consumer representatives, and patient representatives are standing members appointed under FACA. Temporary members are selected from other FDA committees, as well as from a pool of experts and consultants available to provide expertise at a single committee meeting. The Advisory Committee Oversight and Management Staff (ACOMS) is responsible for ensuring that ethics services are provided to FACA committee standing and temporary SGE members by officials at the centers to which the committees report.

Ethics Training

Officials at each FDA center are responsible for providing initial ethics orientation and annual ethics training to FACA committee SGEs from committees reporting to their center. These officials use ACOMS-developed materials for initial ethics orientation and annual training covering the Principles, the Standards of Conduct, HHS supplemental standards of conduct, ethics contact information, and the criminal conflict of interest statutes. OGE's examination of this material determined that it meets the minimum content requirements.

OGE's review determined that FDA's process for providing and tracking initial ethics orientation and annual ethics training for FACA committee SGEs required improvement. For example, during its review of training documentation, OGE observed that the Center for Devices and Radiological Health reported that only14% (147 of 1,038) of SGEs serving on its FACA committees received annual training in calendar year 2015. In addition, only 38% (56 of 149) of SGEs from FACA committees reporting to the Center for Biologics Evaluation & Research and the Center for Devices & Radiological Health received initial ethics orientation or completed annual training. Finally, SGEs serving on the Science Board, a stand-alone board that reports to the Office of the Commissioner, did not receive annual training because the officials responsible for providing it were unaware of the training requirements.

[28] *See* 18 U.S.C. § 202(a).

Beginning in 2016, ACOMS has undertaken efforts to improve the training program for FACA committee SGEs. ACOMS now requires FDA centers to use a standardized process for tracking and submitting training confirmation to ACOMS. Specifically, ACOMS requires the FDA centers use one method, an excel spreadsheet, to track ethics training. Additionally, ACOMS established an initial ethics orientation and annual training schedule that requires FDA centers to provide initial ethics orientation within 90 days of appointment and to provide annual training to (and collect confidential financial disclosure reports from) FACA committee SGEs on or before December 31 of each year.

Financial Disclosure

ACOMS has developed guidance and procedures pertaining to identifying conflicts of interest and determining eligibility for participating in FDA FACA committees,[29] and making publicly available any committee member's financial interest that has been waived.[30] In accordance with the guidance and procedures, FACA committee SGEs are screened for conflicts of interest prior to participating in advisory committee meetings. In particular, FDA requires newly appointed SGEs and any SGE that has not participated in an advisory committee meeting in the calendar year to file an OGE Form 450 (Confidential Financial Disclosure Report). SGEs are required to file an FDA Form 3410, (Conflict of Interest Disclosure Report for Special Government Employees) an OGE-approved alternative form, in lieu of the OGE Form 450, prior to participating in an advisory committee meeting addressing product-specific issues. The filing of a FDA Form 3410 satisfies the annual financial disclosure requirement for SGEs.

OGE selected a sample of financial disclosure records for SGEs who attended 12 FACA committee meetings in 2016. In accordance with the aforementioned procedures, all of these SGEs were required to file an FDA Form 3410. OGE determined that 100% of the FDA Form 3410 reports for the 149 SGEs included in OGE's sample were collected, reviewed, and certified prior to each of their committee meetings in calendar year 2016.

According to the DEI Director, ACOMS was recently informed that advice to SGEs can only be provided by the HHS OGC-Ethics Division or the DEI. However, OGE found that prior to this change in policy, ACOMS had developed procedures, training, and FAQ documents covering conflict of interest matters for SGEs involved in advisory committee activities. Further, OGE's examination of these review tools found that ACOMS conducted an extensive conflict of interest analysis for advisory committee SGEs. In light of these efforts, ACOMS officials reported to OGE that they plan to discuss with the HHS OGC-Ethics Division and DEI, what

[29] *See* "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees," http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf. This document describes FDA's policy in applying the statutory and regulatory requirements for SGEs and regular government employees who are invited to participate in FDA FACA committees.

[30] *See* "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers," http://www.fda.gov/RegulatoryInformation/Guidances/ucm391034.htm. This document describes FDA's policy regarding public availability of information about financial interest and waivers granted by FDA to allow individuals to participate in FDA FACA committee meetings.

constitutes advice and counsel, and options for extending their authority to provide ethics-related counseling.

Non-FACA Committee SGE Science Advisors

FDA's Office of Regulatory Affairs (ORA) manages SGEs who serve as non-FACA committee Science Advisors. ORA officials provide these SGEs with ethics services under the oversight and guidance of DEI.

Ethics Training

ORA officials, under the oversight and guidance of DEI, are responsible for providing initial ethics orientation and annual training materials to the SGEs serving as Science Advisors. OGE reviewed of a sample of ethics records for ORA and found that only 63% (10 of 16) of ORA's SGE Science Advisors completed initial ethics orientation or annual training in calendar year 2015. Further, for those that received training, OGE was unable to determine whether the initial ethics orientation or annual ethics training materials were compliant because ORA did not provide these requested materials to OGE. However, OGE received the materials used to provide ethics training in calendar year 2016 and determined that the materials met applicable requirements. OGE was also able to document that ORA Science Advisors received the required ethics training.

Financial Disclosure

SGEs are required to file a new entrant report within 30 days of starting a position, and each year upon the individual's reappointment or redesignation.[31] However, OGE authorizes agencies to specify one date each year to collect follow-on new entrant reports from all SGEs who serve for terms in excess of one year.[32] DEI requires Science Advisors to file follow-on new entrant confidential financial disclosure reports on a specific date each year. Science Advisors were required to submit confidential financial disclosure reports by July 29, 2016. ORA officials are responsible for collecting confidential reports from Science Advisors and DEI reviews and certify reports.

OGE reviewed 15 confidential reports and found 9 reports (60%) were filed and certified timely. OGE was unable to determine filing and certification timeliness for 6 reports (40%) because ethics officials did not record receipt dates for these reports.[33] OGE also found that there was disagreement regarding who was responsible for maintaining confidential reports, and technical or substantive issues on all 15 reports. Although DEI is currently working with ORA officials to establish a process for maintaining financial disclosure reports and communicating the confidential financial disclosure requirements to the ORA Science Advisors, DEI's quality of review and filing and certification timeliness also requires improvement.

[31] *See* 5 C.F.R. § 2634.903(b).
[32] *See* OGE DAEOgram DO-95-019
[33] *See* "Confidential Financial Disclosure Guide: OGE Form 450," https://www.oge.gov/Web/OGE.nsf/Resources/Confidential+Financial+Disclosure+Guide+(2016). This document is a reference manual for use by reviewers of the Executive Branch Confidential Financial Disclosure Report (OGE Form 450) and describes how to analyze entries for technical sufficiency.

Commissioned State Health Officials

The HHS OGC-General Law Division made a determination in November 2011 that state health officials commissioned by FDA to conduct examinations and investigations are considered federal employees. Since these state health officials serve less than 130 days per calendar year, FDA designated them as SGEs. In 2016, 3,697 state health officials were commissioned by FDA to conduct examinations and investigations. In August and December 2016, DEI informed OGE that these state health officials had not received ethics training or filed financial disclosure reports because FDA was exploring ways to address their filing and training requirements. In January 2017, DEI provided OGE an HHS OGC memorandum from 1994 that determined that these FDA commissioned state health officials did not meet the statutory definition of SGEs, but rather were similar to independent contractors. OGE reviewed documentation and found FDA is currently working with the HHS OGC-Ethics Division to establish the employment status of the state health officials and will ensure state health officials comply with all financial disclosure and training requirements, if there is a definitive legal determination that state health officials are SGEs.

Recommendations

3. Ensure all SGEs receive initial ethics training.

4. Ensure all SGEs serving multi-year terms receive ethics training each year.

5. Develop effective procedures for tracking completion of ethics training for SGEs.

6. Ensure confidential financial disclosure reports for the Science Advisors are filed timely.

7. Improve the quality of review for confidential financial disclosure reports filed by the Science Advisors.

8. Securely maintain confidential financial disclosure reports filed by the Science Advisors.

9. Make a determination about the employment status of the state health officials and provide OGE a formal legal opinion from the HHS OGC-Ethics Division.

Agency Comments

FDA's comments in response to this report are attached as a separate letter below.

May 10, 2017

The Honorable Walter M. Shaub, Jr.
Director
Office of Government Ethics
1201 New York Ave., N.W.
Suite 500
Washington, D.C. 20005

Dear Mr. Shaub,

We appreciate the opportunity to review and comment on the U.S. Office of Government Ethics (OGE) Ethics Program Review Report for the Food and Drug Administration (FDA) covering calendar year 2016.

The FDA is firmly committed to promoting an ethical culture and ensuring employees understand their responsibilities to comply with applicable ethics laws. With the support of senior agency leadership, FDA has made tremendous improvements in its ethics program in the past year. To this end, we thank you for identifying areas in which we need to focus our efforts as we continue to grow and improve FDA's ethics program.

We have reviewed the final report and concur with all the recommendations. We have already begun to implement many of the recommendations in the report and will be sure to keep you updated on our progress. For instance, the final report discussed reviewing the filing criteria for confidential filers to ensure that filers are properly designated, which may also reduce the volume of filers. Indeed, the sheer volume of confidential filers at FDA, approximately 12,000 or 70 percent of all FDA employees, makes timely review and certification a considerable challenge. FDA has thoroughly examined its current filing designation criteria and decided to revise it in a manner more consistent with OGE's regulatory standards and guidance. We anticipate that the revised criteria will decrease the number of confidential filers to below 10,000 or about 58 percent of all FDA employees.

Additionally, the report suggests that FDA prioritize reports by complexity and risk to prevent backlogs. Notably, FDA established a triage process when reviewing confidential reports, creating different queues for complex and simple reports. FDA also streamlined and standardized various processes to increase the accuracy and efficiency of the review.

Finally, despite the Government-wide hiring freeze, FDA was able to enlist assistance from about 40 employees throughout the agency who volunteered to review reports at the initial level. In January 2017, FDA conducted a two-day bootcamp for all FDA ethics officials and these temporary helpers to provide the necessary training to review confidential reports and to explain FDA's new and improved processes.

As a result of these improvements, FDA has, at this time, reviewed and certified 8,840 annual reports or 77 percent of all annual reports (including those on approved extension) and 334 new entrant reports or

69 percent of all new entrant reports filed in 2017. Except for a handful of reports, FDA also has initially reviewed almost all of the remaining annual reports submitted in 2017, as the ethics regulations require, and we are actively working to certify those remaining reports and tracking those on extension.

In relation to FDA's 2016 annual ethics training, the report notes that OGE's sample showed that 20 percent of public filers and 9 percent of confidential filers completed the training in calendar year 2017. In 2016, FDA implemented a new platform to roll out the annual ethics training, which allows FDA to have better oversight and tracking of employees who completed the training. There were some minor delays in establishing a new contract for this training platform. As a result, FDA extended the deadline to complete the training to January 6, 2017. To ensure compliance, FDA terminated the employee's network access if the employee did not complete the training by the due date. FDA was able to ensure that all employees, not only covered employees, took the training by the deadline with the exception of some employees who were unable to complete the training due to extended leave status, and those employees are being tracked. FDA does not anticipate any delays to implement the 2017 annual ethics training and will be sure to impose a deadline to complete the training before the end of the year.

Recently, FDA's Division of Ethics and Integrity (DEI) has implemented a more stringent process for identifying OGE 278e filers and ensuring their new entrant reports are timely filed. The program review report mentioned that "[d]espite these procedures, the timely collection of new entrant reports requires improvement." To this end, please note that since November 2, 2016, FDA has had 17 employees enter OGE 278e filing positions. All of these employees have timely filed their new entrant reports – the majority of which (75 percent) filed their new entrant report before assuming the OGE 278e filing position as part of the pre-clearance process required by HHS.

For the ethics training requirements of the special Government employees (SGEs) serving on FDA's advisory committees, FDA's Advisory Committee Oversight and Management Staff (ACOMS) has standardized the process for tracking and submitting SGE training completion data and intends to automate the process through an electronic system later this year.

With respect to the report's recommendations relating to the Office of Regulatory Affairs (ORA) Science Advisors that serve as non-FACA SGEs, DEI met with ORA staff in March 2017 to establish more robust processes to ensure the Science Advisors timely file their OGE 450 reports. Those who are unable to timely file will not be permitted to provide any service to FDA. FDA will maintain the SGE ethics records electronically and we are exploring the possibility of requiring ORA Science Advisors to submit their reports through EFDS, the electronic confidential report filing system generally used throughout the Department. DEI will require ORA to provide updated CVs and specific duties being performed by the Science Advisors to improve the quality of the conflicts review. FDA will provide OGE an update of our progress in this area.

We thank the OGE program review team for their professionalism and efforts to identify areas of improvement for our ethics program.

Sincerely,

Asim A. Akbari

Asim A. Akbari
Director
Division of Ethics and Integrity