OMBUDSMAN

2011 ANNUAL REPORT

U.S. Food and Drug Adminstration
Center for Drug Evaluation and Research

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2011 Annual Report

Food and Drug Administration (FDA)

Center for Drug Evaluation and Research (CDER)

The CDER Ombudsman's Office includes both the CDER Ombudsman, Virginia L. Behr, and CDER's Product Jurisdiction Officer, Ayoub Suliman. This report briefly explains their roles and details the number and variety of interactions between the Ombudsman's Office and its constituents for calendar year 2011.

I. The Ombudsman's Role

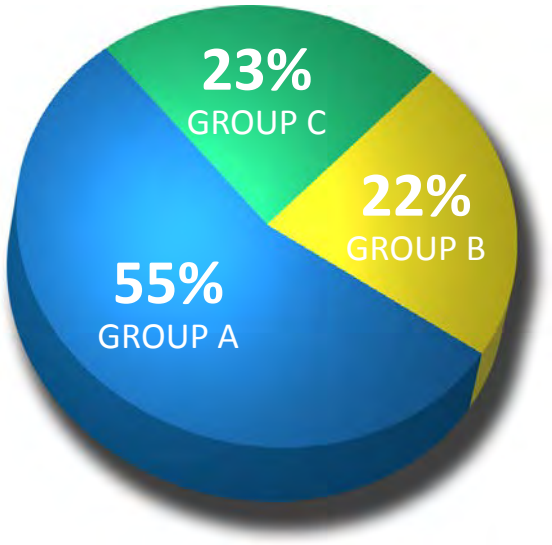
The United States Ombudsman's Association (USOA) defines a governmental ombudsman (also called ombuds) as "an independent, impartial public official with authority and responsibility to receive, investigate or informally address complaints about governmental actions, and, when appropriate, make findings and recommendations, and publish reports."

The CDER Ombudsman receives inquiries and investigates complaints (in an informal, unbiased manner) from the regulated pharmaceutical industry, law firms or consultants representing industry, advocacy groups, public and private research institutions, health care providers, and consumers and also provides general information on product development and regulation. The Ombudsman can informally resolve disputes or disseminate information about established appeals processes and other formal mechanisms for dispute resolution. The Ombudsman also receives internal and external feedback about CDER's programs and overall performance and advises Center management about program issues. The Ombudsman makes recommendations for Center improvement to the Center Director and other senior managers but cannot require action or mandate change because ombudsmen do not have disciplinary or enforcement powers. The CDER Ombudsman works with other FDA ombudsmen to attend to cross-Center issues and to resolve inter-center disputes.

The CDER Ombudsman follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombudsmen (CoFO), the United States Ombudsman Association (USOA), and the International Ombudsman Association (IOA). These include standards for ensuring confidentiality, neutrality, and informality. The Office reports to the Director of the Office of Executive Programs within the Office of the Center Director. The Ombudsman is a member of the Coalition of Federal Ombudsmen.

II. Contact Methods, Demographics, and Most Common Topics

The CDER Ombudsman receives inquiries and complaints by fax, phone, postal mail, electronic mail, and in person. In 2011, the Ombudsman received 282 communications, the vast majority (94%) of which came via electronic mail and phone. In many instances, several emails or phone calls were exchanged per case; those follow-up correspondences were not counted for this report (i.e. the numbers refer to initial contacts only). Here is a graphic depiction of the number of contacts with the corresponding demographics and a list of the most common contact topics.



As shown by the chart, more than half of the communications came from the group that includes regulated industry or those representing them, media, whistleblowers (usually those in industry), and research sponsors.

In no particular order, on the next page is a list of the most common complaint topics received by the CDER Ombudsman in 2011. Please note that, starting with this 2011 annual report and going forward, the CDER Ombudsman's annual report will no longer include inquiries and complaints that are re-directed by the CDER Ombudsman to CDER's Division of Drug Information (DDI). Past annual reports included contacts from consumers that were then referred to DDI; however, including that data portrayed an untrue representation of the Ombudsman's time, effort, and responsibility.

DEMOGRAPHICS
(Number of Contacts)

Group A (153)
- Industry: commercial sponsors, pharmaceutical industry (106)
- Consultants (15)
- Media/Press (3)
- Whistleblowers (13)
- Law firms (11)
- Research sponsors (5)

Group B (63)
- Consumers (31)
- Health care professionals (18)
- Consultants (15)
- Advocacy groups (3)
- Other[1] (11)

Group C (66)
- FDA employees, usually CDER (66)

[1] This category includes, but is not limited to, other federal ombudsmen, students, and foreign regulators. Other federal ombudsmen were often requesting information about the operation of FDA or CDER ombudsman's offices; students usually had questions about alternative dispute resolution and the ombuds profession; other foreign regulators asked about Agency internal scientific dispute resolution policies.

Most Common Contact Topics from the Pharmaceutical Industry, Law Firms, Consultants, Consumers, Whistleblowers, Media/Press, Advocacy Groups, Health Care Professionals, and Public or Private Research Institutions (Groups A and B)

- Appeals processes, including formal dispute resolution assistance
  - -- Pharmaceutical industry (or those representing them) and research sponsors
  - -- CDER employees – handling individual differences of professional opinion, as well as difference of opinion across offices and across Centers
- Problems with new electronic drug registration process – many fewer than previous years, but did receive 10 complaints
- Drug nonapproval
- INDs put on clinical hold
  - -- Multiple INDs were put on clinical hold because of severe cGMP violations by a shared supplier.
- Industry whistleblower, often anonymous
  - -- unethical practices
  - -- manufacturing and pharmacy compounding violations
  - -- manufacturer's making counterfeit drugs
  - -- off-label promotion of prescription drugs
- Office of Regulatory Affairs and Office of Compliance documentation, decisions, and enforcement actions
  - -- disputing a 483, a form reflecting an FDA inspector's observations
  - -- export certificates
  - -- enforcement action on an unapproved drug
  - -- detained product
- Not reaching agreement with review Division on a Special Protocol Assessment
- General inquiries, most often about:
  - -- ANDA requirements
  - -- combination product development
  - -- information about ombuds office functioning; giving advice on establishing a new ombuds office
- Protocol violations
  - -- clinical study
  - -- manufacturing

Most Common Contact Topics from FDA employees, usually CDER (Group C)

Most contacts from CDER employees were general enquiries about the Ombudsman's role or requests for help with external constituents, but some sought assistance with workplace conflict. In those cases, the Ombudsman referred the employee to the Conflict Prevention and Resolution Staff in FDA's Office of Equal Employment Opportunity and Diversity Management or to FDA's Employee Assistance Program.

III. Trends

Several upward trends were evident in 2011. When compared to data from 2010, there was an increase in the number of general inquiries and as well as an increase in both overall number of contacts from commercial sponsors (106, up from 77 in 2010). Within Group A, 69% of contacts came from commercial sponsors, up from 53% in 2010. More of the commercial sponsors were smaller, emerging biotechnology and pharmaceutical companies with less experience interacting with the FDA than larger, more established pharmaceutical companies. The smaller companies often asked the Ombudsman for advice and help understanding their options when they hit a "snag" in their drug development plan. The Ombudsman partially attributes this pattern of smaller companies contacting the Ombudsman more often than "Big Pharma" to several factors:

- They are less familiar with regulatory requirements and CDER organization
- Though a disagreement between a company and CDER is not desirable for any company, small companies postulated (to the Ombudsman) that the short-term financial fitness of a small company might be more at risk. Therefore, any rapid means of resolving a dispute, including contacting the CDER Ombudsman, is a preferred option.
- Smaller companies often develop novel drug and biotechnology products that have no established regulatory path. Though welcome, this can be a challenge both for CDER and companies during development and review.

A trend continued from the past couple of years with the receipt of complaints about enforcement actions made by the Office of Compliance, primarily coming out of the Unapproved Drugs Initiative (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm118990.htm). The Ombudsman received complaints about inspector's observations made on Form 483 and the receipt of Warning Letters, as well as denials for Certificates of Pharmaceutical Product (CPP). CPPs are requested by companies planning to export their product to foreign countries but FDA only issues a CPP if the drug product is legally marketable in the U.S.; some companies expected a CPP to be issued even though their drug is considered an unapproved drug in the U.S.

Notably, there was a precipitous drop in the number of overall contacts reported for this year as compared to 2010 (1015 in 2010 to 282 in 2011), possibly because:

- The CDER Ombudsman's annual report no longer counts contacts referred to CDER's Division of Drug Information
- The Rare Diseases Program was created, housed in the Office of New Drugs Immediate Office, which answered many questions from industry and the public. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm221248.htm
- The CDER Ombudsman's internet site was updated with an extensive Frequently Asked Questions section. Many potential enquirers likely found their answer or a more appropriate contact on that site.
- There were fewer questions and complaints about User Fees, possibly because a revised User Fee Guidance was issued (draft in March 2011 and the final issued in September 2011). http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079298.pdf
- The Bad Ad program was launched in 2010, targeting healthcare providers to help identify and report misleading prescription drug promotion. Providers who used to call the Ombudsman to report misleading promotional materials now have a direct avenue for reporting. See http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm

Lastly, although drug shortages were a "hot" topic in 2011, CDER's Drug Shortages Program was responsible for managing and responding to most enquiries. They present continuously updated information for the public at http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

IV. Other Ombudsman Activities and Outreach

In 2011, the CDER Ombudsman was selected to serve on the Executive Committee of the Coalition of Federal Ombudsmen (CoFO) and continued her participation in the CoFO Ombudsman Resource Committee (aka Standing Up an Ombuds Office Committee) which provides resources for new ombudsman offices.

She continues to serve as collateral duty mediator for the FDA's alternative dispute resolution program in FDA's Office of Equal Employment Opportunity and Diversity Management. She also mediates cases for the federal government-wide Shared Neutrals program.

The Ombudsman remains as the CDER representative on an Agency level working group to review the Agency level appeals process for resolving internal scientific disputes.

The Ombudsman's Office conducted outreach within CDER to explain the Ombudsman's functions including product jurisdiction and dispute resolution at the CDER New Reviewer's Workshops.

V. Product Jurisdiction for Combination and Single Entity Products

Many proposed products must be regulated by the FDA, but it is often not obvious which Center within FDA should take the lead for product review and regulation, particularly for combination products. Ayoub Suliman is the Center's Product Jurisdiction Officer, serving as CDER's expert on establishing the regulatory identity of products as drugs, biologics, devices, or a combination of two or more (e.g. biologic and a device combined into one product), specifically to determine which FDA Center is most appropriate for reviewing each product. The Product Jurisdiction Officer responds to all Requests for Designation (RFD) from sponsors via the FDA Office of Combination Products (OCP) under 21 CFR Part 3.7 and to other informal requests for assignment of combination and single entity (non-combination) products. More information about jurisdictional determinations can be found on the OCP website at http://www.fda.gov/oc/combination/.

In 2011, the CDER Product Jurisdiction Officer responded to hundreds of informal jurisdiction questions from within and outside FDA and put forth CDER's position on 33 RFDs and 4 requests for reconsideration.

He also participated in a joint seminar between FDA and the Consumer Healthcare Products Association (CHPA) on combination products. He also contributed to and worked closely with OCP, the Center for Devices and Radiological Health (CDRH), and the Center for Biologics Evaluation and Research (CBER) on two draft Guidances for Industry that issued in June. These are:

- Classification of Products as Drugs and Devices and Additional Product Classification Issues http://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm
- Interpretation of the Term "Chemical Action" in the Definition of Device Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act http://www.fda.gov/RegulatoryInformation/Guidances/ucm259059.htm

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