

Ombudsman's 2014 Annual Report

FDA, Center for Drug Evaluation and Research

The Ombudsman's Office in FDA's Center for Drug Evaluation and Research (CDER) includes Virginia L. Behr, CDER Ombudsman, Kristi Lauritsen, PhD, Assistant Ombudsman and Product Jurisdiction Officer, and Ayoub Suliman, PharmD, Product Jurisdiction Officer. Dr. Lauritsen joined the team in June and Mr. Suliman departed federal service in December.

This annual report briefly explains their roles and activities. It also details the number and variety of interactions between the Ombudsman's Office and its constituents for calendar year 2014.

I. 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 practitioners, and consumers and also provides general information on product development and regulation. The disputes or questions can be of a regulatory, scientific, or administrative nature. The Ombudsman informally resolves disputes and disseminates information about established appeals processes and other formal mechanisms for dispute resolution. The Ombuds also receives feedback about CDER's programs and overall performance, advises management about program issues, and can assist with resolution of scientific differences of opinion amongst CDER staff. The Ombuds makes recommendations for Center improvement to the Center Director and 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, impartiality, and informality. The Office reports to the Director of the Office of Executive Programs who reports to the CDER Director.

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 2014, the Ombudsman received 322 communications, the majority of which came via electronic mail (66%) and phone (28%). In many instances, several emails or phone calls were exchanged per case; those follow-up correspondences were not counted for this report unless substantially different new issues were raised. Below are a list and graphic depiction of the number of contacts with the corresponding demographics, and a list of the most common contact topics.

Demographics (Number of Contacts)

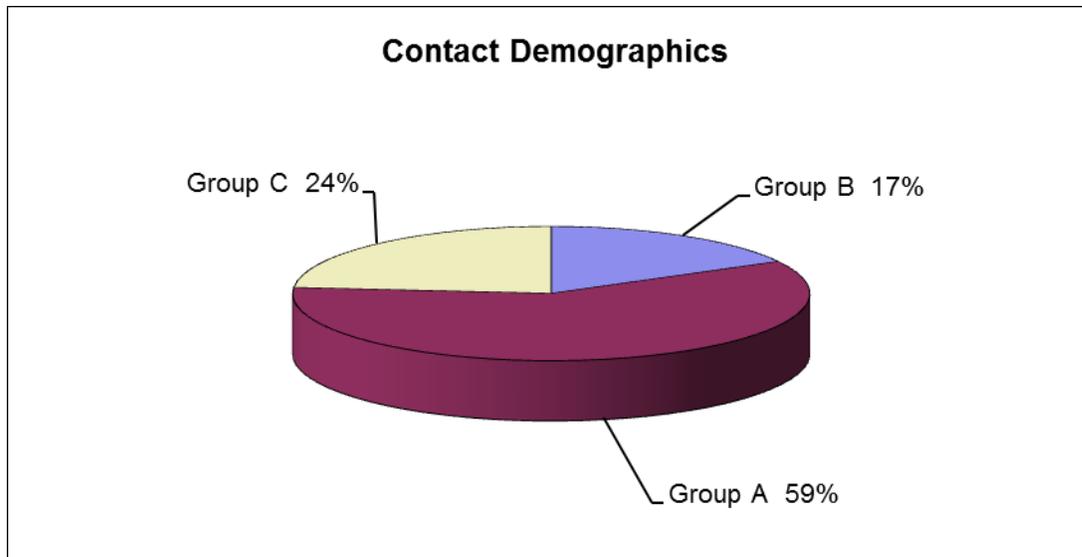
- Group A (191)
 - Industry: commercial sponsors, pharmaceutical industry (93)
 - Consultants (23)
 - Media/Press (0)
 - Whistleblowers (12)
 - Law firms (34)
 - Research sponsors (6)
 - Investors¹ (23)

- Group B (50)
 - Consumers (26)
 - Health care professionals (3)
 - Advocacy groups (3)
 - Other² (23)

- Group C (76)
 - FDA employees, including other FDA Centers (76)

¹ This new category was added in 2014 and includes contacts self-identifying as investors in a publicly traded pharmaceutical company.

² This category included other federal ombudsmen, other federal and state agencies, one law enforcement officer, and citizens interested in the ombuds profession (including students).



As shown by the chart above, 59% of the communications came from the group that includes regulated industry or those representing them, media, whistleblowers (usually those working in the industry in some capacity), and research sponsors.

In no particular order, below is a list of the most common complaint topics received by the CDER Ombudsman in 2014.

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

- Dispute resolution assistance
 - Usually a pharmaceutical firm (or a law firm or regulatory consultant representing them) disputing a CDER decision or action
 - Request for advice on how best to resolve a problem, whether seeking informal enquiry by the Ombudsman’s Office or exploring formal appeals processes
 - Exploring potential regulatory pathways to marketing approval
- Decision delays or response delays
 - Generic drug companies complaining of generic drug application approval delay
 - Issuance of Establishment Inspection Reports
 - Posting public comments to a docket
- Communication problems, including lack of response or miscommunication, primarily with the Office of Generic Drugs, Office of New Drugs, and Office of Compliance
- General inquiries, including, but not limited to:
 - Over The Counter (OTC) drug monographs
 - IND exemptions, IND requirements, and review Division assignments
 - Application of U.S. drug law in U.S. territories

- Complaint about a CDER decision
 - Application not approved (Complete Response Letter instead of an Approval Letter)
 - Refusal to receive an ANDA
 - Warning Letter
 - Detained product or import issue
 - Application requirements
- Industry whistleblower, often anonymous
 - Current Good Manufacturing Practices (CGMP) violations
 - Good Clinical Practice (GCP) violations
 - Misrepresentation of adverse event data and other drug safety data in an NDA
- Access to unapproved or compounded drugs
- User Fee assessments
 - Facility fees required under Generic Drug User Fee Amendments (GDUFA) of 2012, especially for small API manufacturers
- Complaints from companies questioning CDER's adherence to federal regulations or its own Guidances for Industry in making decisions about product development and manufacturing

Most Common Contact Topics from FDA employees (Group C)

In most cases, employees were asking for the Ombudsman's advice about a difficult situation, albeit an issue internal to FDA or with an external constituent. Examples include: responses to complaints, suboptimal interactions with sponsors, communication or policy issues, dispute resolution options for scientific or regulatory disputes internal to FDA, human resource problems (specifically, hiring process), cross-Center disputes or questions, requests for a facilitated discussion with other FDA staff or industry, management issues, personal security, and referral requests for inter-center collaborative work. The CDER Ombudsman welcomed enquiries and advice requests and policy questions from several new ombudsmen who filled the positions of FDA Center ombudsmen who retired from federal service in 2014.

Some employees sought assistance with workplace conflict, in which case the Ombuds 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

This section will briefly discuss notable differences in demographics and issues raised to the Ombudsman's Office in 2014 as compared to the previous year.

The number of contacts from commercial sponsors rose 26% from 2013 (93 to 117) and the number of law firm contacts almost tripled from 13 to 34. Companies often employ law firms to submit Formal Dispute Resolution Requests (FDRR) to CDER and sometimes ask the Ombudsman about the FDRR process.

There was an increase in complaints about import detentions and the reasons for the detentions.

Some FDA ombudsmen were new to the profession in 2014 and the CDER Ombudsman served as a resource for them. Also, many federal ombuds (not from FDA) asked the CDER Ombudsman about policies, procedures, and for advice about how to handle specific cases or situations.

Continuing a downward trend, only a few complaints were received about drug shortages; these few stemmed from perceived review delays for pending marketing applications for generic forms of a drug on the shortage list.

Continuing trends include:

- Advisory discussions with the Ombuds about appeals processes
- Complaints about generic drug review and decision delays. GDUFA brought many changes to the generic drug industry and FDA, and implementation and process improvements within the industry and FDA are ongoing.
- Complaints from investors in pharmaceutical companies stating that an FDA decision or decision delay was causing financial harm
- Whistleblower calls reporting manufacturing problems and protocol violations at clinical study sites

IV. Other Ombudsman Activities

In 2014, the CDER Ombudsman completed her stint on the Executive Committee of the [Coalition of Federal Ombudsman](#) (CoFO). She advised other federal ombudsmen about a variety of issues unique to the profession.

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

The Ombudsman closely collaborates with other FDA personnel, including ombuds in other Centers, in order to share best practices and develop dispute resolution policies and procedures.

In addition, the Ombudsman:

- Recruited and mentored Kristi Lauritsen, PhD, Assistant Ombudsman and Product Jurisdiction Officer
- Was the lead CDER representative in the creation of an intercenter SOP for dispute resolution, SMG 9010.2. Finalized and published January 6, 2014. <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM380522.pdf>
- Reviewed dispute resolution trends with CDER's Formal Dispute Resolution Project Managers

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

V. Outreach Efforts

The Ombudsman conducted outreach within FDA by frequently presenting to CDER New Employees, updating the ombuds intranet site, and serving as a panelist for CDER's New Reviewers Blended Learning Program.

In order to improve communications with industry, the Ombudsman:

- Moderated an Industry/FDA seminar focusing on regulatory affairs and project management
- Updates the CDER Ombudsman internet site annually

VI. Product Jurisdiction for Combination and Non-Combination 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, particularly for combination products. CDER's Product Jurisdiction Officers serve as CDER's experts on establishing the regulatory identity of products as drugs, biologics, devices, or a combination of two or more of these (e.g., a biologic and a device combined into one product), and in determining which FDA Center is most appropriate to lead the review of such products. The Product Jurisdiction Officers respond to all Requests for Designation (RFD) from sponsors via the FDA Office of Combination Products (OCP) under 21 CFR Part 3.7, as well as to other informal requests for designation and assignment of combination and non-combination products. The Product Jurisdiction Officers also represent CDER in inter-Center work groups tasked with developing standards and policies for the assignment and regulation of combination and non-combination products. More information about jurisdictional determinations can be found on the OCP website at <http://www.fda.gov/oc/combination/>.

In 2014 the CDER Product Jurisdiction Officers responded to hundreds of informal jurisdiction questions from within and outside FDA and put forth CDER's position on 9 RFDs and 3 requests for reconsideration.