

Ombudsman's 2015 Annual Report

FDA, Center for Drug Evaluation and Research

Virginia L. Behr, CDER Ombudsman, and Kristina J. Lauritsen, PhD, Assistant Ombudsman, fulfill ombudsman duties in FDA's Center for Drug Evaluation and Research (CDER). Ms. Behr and Dr. Lauritsen report to the Director of the Office of Executive Programs who reports to the CDER Director.

This annual report details the number and variety of interactions with Ombudsman Behr and Assistant Ombudsman Lauritsen (referred to as CDER Ombudsmen) for calendar year 2015. In previous CDER Ombudsman annual reports, a Section VI. Product Jurisdiction for Combination and Non-Combination Products was included. Historically, the CDER Ombudsman was the lead on jurisdiction work for the Center but, over time, it became apparent that the volume and complexity of the work warranted personnel dedicated to that role. Although Product Jurisdiction Officers continue this work for CDER, they do not report to the CDER Ombudsman and in-depth reporting on jurisdictional determinations is covered by FDA's Office of Combination Products [Annual Report to Congress](#). A description of the Product Jurisdiction Officer's role is included in previous [CDER Ombudsman annual reports](#).

I. Ombudsman's Role

The United States Ombudsman's Association (USOA) defines a governmental ombudsman 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 Ombudsmen receive inquiries and investigate 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 Ombudsmen informally resolve disputes and disseminate information about established appeals processes and other formal mechanisms for dispute resolution. The Ombudsmen also receive feedback about CDER's programs and overall performance, advise management about program issues, and can assist with resolution of scientific differences of opinion amongst CDER staff. The Ombudsmen make recommendations for Center improvement to the Center Director and senior managers but cannot require action because ombudsmen do not have disciplinary or enforcement powers. The CDER Ombudsmen work with other FDA ombudsmen to attend to cross-center issues and to resolve inter-center disputes.

The CDER Ombudsmen follow 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/neutrality, and informality and are described on the [CDER Ombudsman's Office website](#).

II. Contact Methods, Demographics, and Most Common Topics

The CDER Ombudsmen receive inquiries and complaints by fax, phone, postal mail, electronic mail, and in person. In 2015, the Ombudsmen received 274 communications, mostly via email and phone. 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.

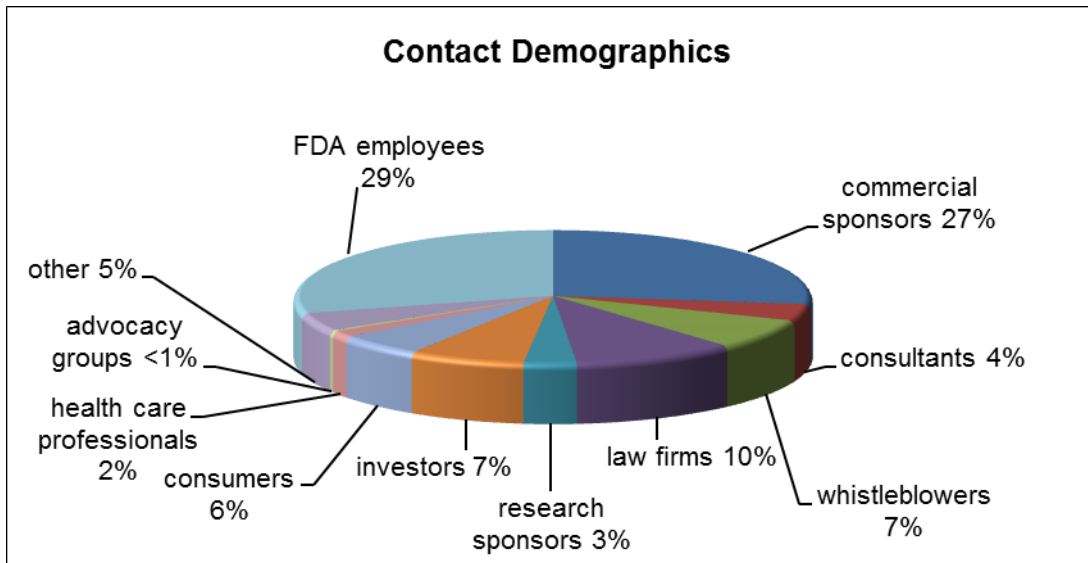
Demographics (Number of Contacts)

- External parties (162)
 - Industry: commercial sponsors, pharmaceutical industry (74)
 - Consultants (11)
 - Whistleblowers (20)
 - Law firms (28)
 - Research sponsors (9)
 - Investors¹ (20)
 - Consumers (15)
 - Health care professionals (4)
 - Advocacy groups (1)
 - Other² (12)

- Internal parties (i.e., FDA employees, including other FDA Centers (80))

¹ This group is comprised of contacts self-identifying as investors in a publicly traded pharmaceutical company.

² This category included federal ombudsmen, foreign regulators, trade groups, other federal and state agencies, and citizens interested in the ombudsman profession (including students).



As shown by the chart above, 71% of the communications came from the external parties, including regulated industry or those representing them, whistleblowers (usually those working in the industry in some capacity), research sponsors, advocacy groups, health care professionals, investors, and consumers.

In no particular order, below is a list of the most common complaint topics received by the CDER Ombudsmen in 2015.

Most Common Contact Topics from External Parties

- Dispute resolution assistance
 - Disputing a CDER action or decision, usually a pharmaceutical firm (or a law firm or regulatory consultant representing them)
 - Requesting advice on how best to resolve a problem, whether seeking informal enquiry by the Ombudsmen or exploring formal appeals processes
 - Disagreeing with a CDER Office's position about potential regulatory pathways to marketing approval
- Decision delays or response delays
 - Generic drug companies complaining of abbreviated new drug application (ANDA) decision delay
 - Investigational New Drug Application (IND) exemption requests from research sponsors
 - Policy discussions holding up regulatory actions
 - Facility re-inspection delays
- Communication problems, including lack of response or miscommunication, primarily with the Office of Generic Drugs, Office of New Drugs, and Office of Compliance
- Complaint about a CDER decision or action
 - Refusal to receive an ANDA

- Warning Letter
- Detained product or import issue
- Industry whistleblower
 - Current Good Manufacturing Practices violations
 - Good Clinical Practice violations
 - Fraudulent data in a New Drug Application (NDA)
- FDA not posting comments to public dockets (see section III. Trends)
- Speaker requests for the CDER Ombudsman
- User Fee assessments
 - Fees required under Generic Drug User Fee Amendments (GDUFA) of 2012, especially for small API manufacturers
 - Delay in refund request assessments

Most Common Contact Topics from FDA employees

In most cases, employees were asking for the Ombudsmen's advice about a difficult situation, albeit an issue internal to FDA or with an external constituent. Examples include: a need for enhanced customer service, assessing responses to complaints, how to improve interactions with sponsors, addressing communication or policy issues, discussing dispute resolution options for scientific or regulatory disputes internal to FDA, and improving cross-Center collaboration. In keeping with an established collegial atmosphere, the CDER Ombudsmen gave advice on policy issues from other FDA ombudsmen.

Ten employees sought assistance with workplace conflict; in most cases the Ombudsmen referred the employee to FDA's Conflict Prevention and Resolution Staff or FDA's Employee Assistance Program.

III. Trends

This section will briefly discuss notable differences in issues brought to the CDER Ombudsmen in 2015 as compared to the previous year.

Several self-identified investors in pharmaceutical firms noted that FDA did not post their individual comments to a public docket. Those complaints came prior to FDA publishing a new policy in a [Federal Register Notice](#), which states that all comments submitted to a docket after Oct 15, 2015 will now be publicly posted.

More companies than in previous years asked for advice on how to best approach or interact with a review division in the Office of New Drugs.

There was an increase in complaints about CDER Compliance's conclusions or actions, including import alerts and detentions. Also, there were a large number of complaints related to GDUFA, focused mainly on action dates, ANDA filing decisions, and ANDA user fee refund requests. GDUFA brought many regulatory and operational changes to the generic drug industry and FDA, and implementation and process improvements within the industry and FDA continue.

IV. Other Ombudsman Activities

In 2015, the CDER Ombudsmen continued to advise and mentor other federal ombudsmen about a variety of issues unique to the profession. The Ombudsmen closely collaborate with other FDA personnel, including ombudsmen in other Centers, in order to share best practices and develop dispute resolution policies and procedures.

Ms. Behr 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.

In addition, the Ombudsmen reviewed dispute resolution trends with CDER's Formal Dispute Resolution Project Manager, Division of Drug Information, and Small Business Assistance.

V. Outreach Efforts

Ms. Behr conducted outreach within FDA by frequently presenting to CDER New Employees, presenting to the Office of Generic Drugs and Office of Compliance, updating the ombudsman intranet site, and serving as a panelist for CDER's New Reviewers Blended Learning Program.

In order to improve communications with industry, Ms. Behr:

- Spoke at the May 13th Consumer Health Products Associations (CHPA) Regulatory and Scientific Affairs Committee meeting
- Spoke at the Sept 30th Coalition of Federal Ombudsman Annual Meeting.
- Spoke at the October 27th Regulatory Affairs Professional Society Annual Meeting.
- Updates the CDER Ombudsman internet site annually
- Worked on revisions to the draft [CDER/CBER Guidance for Industry, Formal Dispute Resolution: Appeals Above the Division Level](#)