Ombudsman's 2017 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 Ombudsmen) for calendar year 2017.

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."

Simply put, the Ombudsmen receive inquiries and investigate complaints in an informal, unbiased manner. The complaints and inquiries come from the regulated pharmaceutical industry, law firms or consultants representing industry, advocacy groups, public and private research institutions, health care practitioners, and consumers. The complaints and inquiries 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, both for disputes between regulated industry and CDER and for resolving differences of opinion amongst FDA staff.

In addition, the Ombudsmen provide general information on product development and regulation. They receive feedback about CDER programs and advise management about program issues. Although the Ombudsmen make recommendations for Center improvement to the Center Director and senior managers, they cannot require action because ombudsmen do not have disciplinary or enforcement powers.

The Ombudsmen follow standards of practice drawn from those established by the Coalition of Federal Ombudsmen (COFO), USOA, the International Ombudsman Association (IOA), and the Administrative Conference of the United States (ACUS) report "Recommendation 2016-5: The Use of Ombuds in Federal Agencies[1]." These include standards for ensuring confidentiality, impartiality/neutrality, and informality and are described on the CDER Ombudsman's Office website.

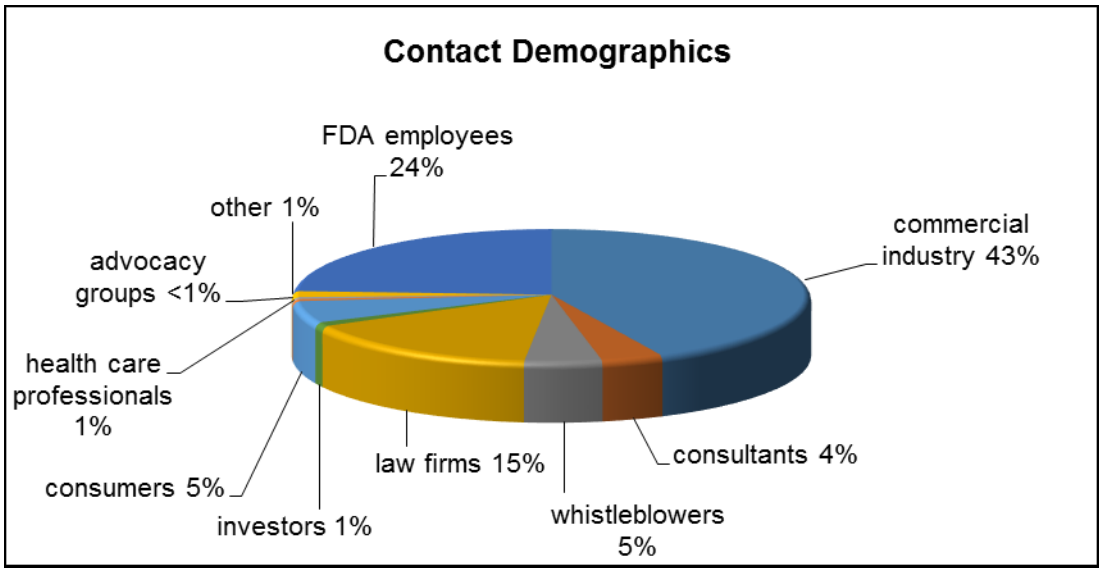
[1] https://www.acus.gov/recommendation/recommendation-2016-5-use-ombuds-federal-agencies

II. Contact Methods, Demographics, and Most Common Topics

The Ombudsmen receive inquiries and complaints by fax, phone, postal mail, email, and in person. In 2017, the Ombudsmen received 207 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 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.

<u>Demographics (Number of Contacts)</u>

- External parties (157)
  - Commercial industry, e.g. pharmaceutical company (89)
  - Law firms (32)
  - Whistleblowers (10)
  - Consumers (11)
  - Investors[2] (2)
  - Consultants (8)
  - Other[3] (3)
  - Research sponsors (0)
  - Health care professionals (1)
  - Advocacy groups (1)
  - Press (0)
- Internal parties, i.e. FDA employees, including other FDA Centers (50)



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

[3] This category may include 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, 76 percent of the communications came from the external parties, including regulated commercial industry or those representing them (i.e. law firms and consultants), 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 Ombudsmen in 2017.

Most Common Contact Topics from External Parties

- Dispute resolution assistance
    - Disputing a CDER action or decision, usually a pharmaceutical company (or a law firm or consultant representing them)
    - Requesting advice on how best to resolve a problem, whether seeking informal enquiry by the Ombudsmen or exploring formal appeals processes.
    - Advising industry about the final *Guidance for Industry: Sponsor Appeals Above the Division Level* that published in November 2017
- General enquiries such as questions about CDER programs, policies, and regulatory requirements
- Decision delays or response delays
    - Policy discussions holding up regulatory actions
    - Generic drug companies complaining of abbreviated new drug application (ANDA) decision delay, sometimes due to manufacturing or API facility issues or Drug Master File problems
- Limited or no access to drugs because of an FDA regulatory action
- Communication issues, such as misinterpretation of formal and informal correspondences
- Complaints that CDER wasn't following regulations or proper procedures
- Complaints about a CDER decision or action
    - Refusal to receive an ANDA
    - Detained product or import issue
    - Monies owed to the government under various user fee programs
        - Initial assessment decisions
        - Delay in waiver and refund request decisions
        - Decisions on appeals of assessments
- Industry whistleblower
    - Current Good Manufacturing Practices violations

Most Common Contact Topics from Internal Parties

In most cases, FDA employees asked for the Ombudsmen's advice about a difficult situation, albeit an issue internal to FDA or with an external constituent. Examples include: managing contacts from external whistleblowers, assessing responses to complaints, how to improve interactions with sponsors and consumers or patients,

addressing communication or policy issues, and improving cross-Center collaboration. Additionally, the Ombudsmen discussed dispute resolution options for scientific or regulatory disputes internal to FDA.

Six 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

The most notable change was a 28% decrease in the number of total contacts in 2017 as compared to the previous year, from 289 to 207 contacts. Based upon percentage decreases from 2016 to 2017, the two demographic categories[4] with the most significant drops were the number of whistleblowers which went from 21 to 10 and investors from 16 to 2.

IV. Other Ombudsmen Activities

In 2017, the Ombudsmen continued to advise and mentor other federal ombudsmen about a variety of issues unique to the profession. Ms. Behr served as expert panelist during a COFO information session targeting senior leaders of federal agencies interested in establishing ombudsman offices and was designated as a mentor for the COFO annual meeting. The Ombudsmen collaborated with other FDA personnel, including ombudsmen in other Centers, to share best practices and develop and refine dispute resolution policies and procedures.

Ms. Behr continues to serve as a 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 Sharing Neutrals program.

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

V. Outreach Efforts

The Ombudsmen recorded a training video for new CDER employees about the role of the CDER Ombudsmen and internal scientific/regulatory dispute policies.

[4] Categories with four or fewer contacts in 2016 were not included.