# Ombudsman's 2018 Annual Report
# FDA, Center for Drug Evaluation and Research

Virginia L. Behr, CDER Ombudsman, and Melissa Sage, Assistant CDER Ombudsman, fulfill ombudsman duties in FDA's Center for Drug Evaluation and Research (CDER). Ms. Behr and Ms. Sage 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 Sage (referred to as Ombudsmen) for calendar year 2018.

## 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 look into 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, consumers, and FDA staff. 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 professional 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 decisional, disciplinary, or enforcement powers.

The Ombudsmen follow the core standards of practice and exhibit the common ombudsman characteristics recommended by 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, independence, and impartiality as well as the common characteristics of a commitment to fairness, credible process, and informality.

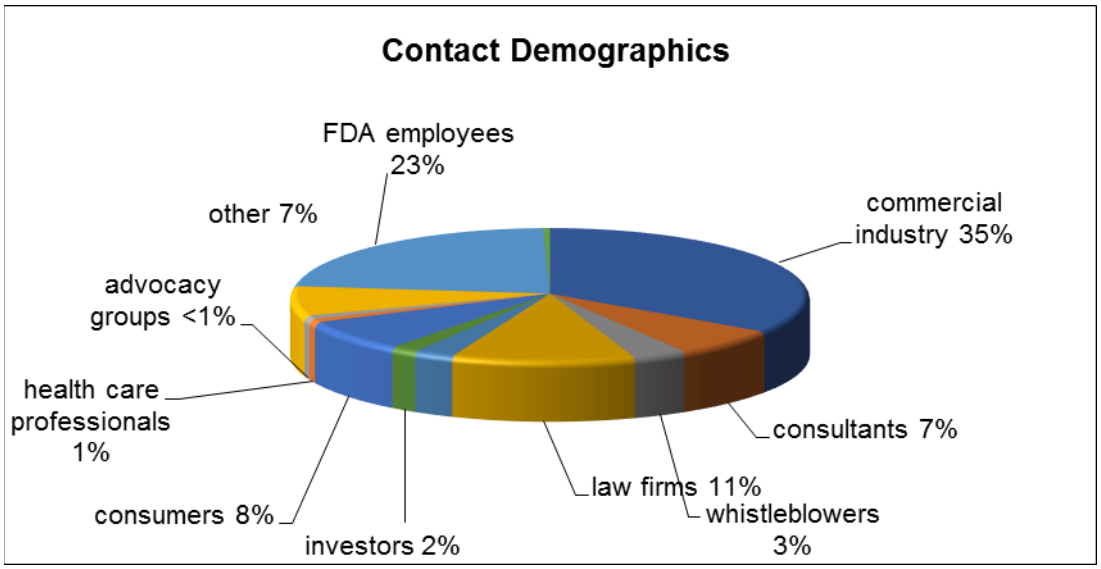
[1] https://www.acus.gov/recommendation/recommendation-2016-5-use-ombuds-federal-agencies

## II. Contact Methods, Demographics, and Most Common Topics

The Ombudsmen receive inquiries and complaints by fax, phone, postal mail, email, and in person. In 2018, the Ombudsmen received 237 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.

Demographics (Number of Contacts)

- External parties (183)
    - Commercial industry, e.g. pharmaceutical company (82)
    - Law firms (27)
    - Whistleblowers (8)
    - Consumers (18)
    - Investors[2] (4)
    - Consultants (16)
    - Other[3] (17)
    - Research sponsors (6)
    - Health care professionals (2)
    - Advocacy groups (2)
    - Press (1)
- Internal parties, i.e. FDA employees, including other FDA Centers (54)




[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, 77 percent of the communications came from 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 2018.

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.
    - Disagreements about study requirements
- 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 decision delays on their requests for reconsideration (of a previous decision)
    - Delays for issuance of export certificates
    - Delays for issuance of formal meeting minutes
- 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
    - Detained product or import issue
    - Monies owed to the government under various user fee programs
        - Delay in waiver and refund request decisions
- 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, either 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, helping staff identify and address communication or policy issues, and improving cross-Center collaboration. Additionally, the Ombudsmen discussed dispute resolution options for scientific or regulatory disputes internal to FDA.

## III. Trends

There was a 15% increase in the number of total contacts in 2018 as compared to the previous year, from 207 to 237 contacts. The demographic categories with notable increases were Consultants, which went from 8 to 16, Research Sponsors from 0 to 6, and Others from 3 to 17. The number of FDA employees seeking assistance with workplace conflict dropped from 6 to 1 between 2017 and 2018.

## IV. Other Ombudsmen Activities

In 2018, the Ombudsmen continued to advise and mentor other federal ombudsmen about a variety of issues unique to the profession. 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 served on the inaugural Mentoring Committee for the Coalition of Federal Ombudsmen (COFO) which launched an interagency mentoring program for federal ombudsmen. She was designated as a featured ombudsman at the American Bar Association Ombuds Day event and both she and Ms. Sage served as mentoring hosts at the COFO annual meeting. 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 held several outreach events at CDER, in order to solidify employees' understanding of the ombudsman role and to build working relationships with staff.