Ombudsman's Annual Report for 2009
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, LCDR Ayoub Suliman. This report briefly explains the role of the CDER Ombudsman and details the number and variety of interactions between the Ombudsman's Office and its constituents for calendar year 2009.

I. The Ombudsman's Role

Ombudsman is a word that originated in Sweden, is derived from old Norse, and means 'representative, commissioner, or agent'; the term has evolved to denote someone in any organization who receives and investigates complaints in an informal, unbiased manner.

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."

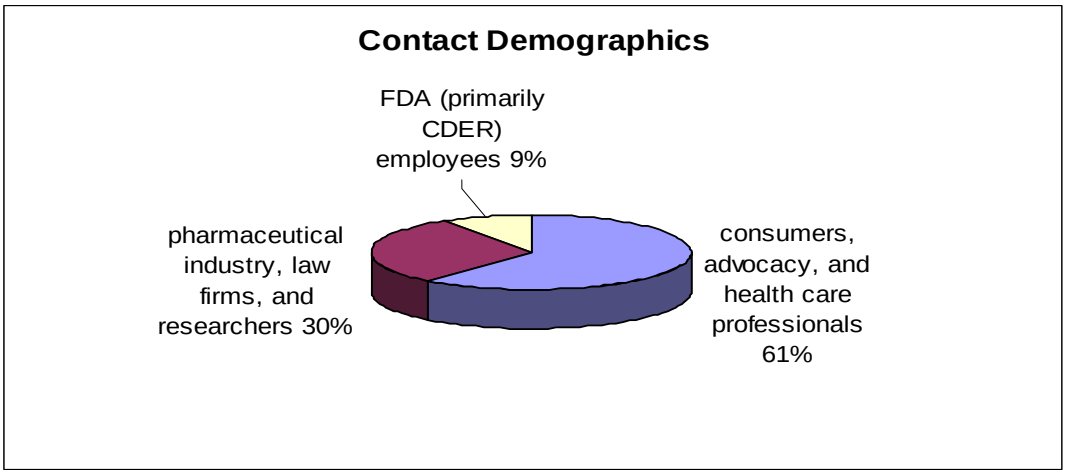
The CDER Ombudsman receives inquiries and investigates complaints from the regulated pharmaceutical industry (or the law firms representing them) and consumers and also provides general information on product development and regulation. If requested, the Ombudsman can informally resolve disputes or disseminate information about established appeals processes and other formal mechanisms for dispute resolution. The Ombudsman also receives comments from inside and outside the Center about problems that impede CDER's performance of its mission. The Ombudsman makes recommendations for Center improvement to the Center Director but cannot require action or mandate change because ombudsmen do not have disciplinary or enforcement powers.

The CDER Ombudsman's Office draws its ethical principles and standards 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

Consumers, law firms, researchers, and the pharmaceutical industry contact the Ombudsman's Office by fax, phone, postal mail, and electronic mail. In 2009, the Office received 764 communications, the vast majority (95%) 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). Below is a listing of the number of contacts and their demographics as well as a graphic illustrating them. A listing of the most common complaint topics follows the demographic data.



Number of contacts and demographics

- Phone = 227
  - Consumers and health care professionals = 88
  - Pharmaceutical industry, law firms, consultants, and public or private research institutions = 108
  - FDA employees (mostly CDER) = 31 (5 requests for assisting in resolution of scientific differences of opinion)
- Email = 502
  - Consumers and health care professionals = 361
  - Pharmaceutical industry, law firms, consultants, and public or private research institutions = 107
  - CDER employees = 34
- Fax (5) and Postal Mail (26) = 31
  - Consumers and health care professionals = 18
  - Pharmaceutical industry, law firms, consultants, and public or private research institutions = 13
- In person
  - 4 FDA employees

In no particular order, below is a list of the most common complaint topics received by the CDER Ombudsman's Office in 2009.

Most Common Contact Topics from the Pharmaceutical Industry, Law Firms, Consultants, and Public or Private Research Institutions

- Requirement for electronic drug establishment registration and listing too cumbersome
    - Beginning June 1, 2009, FDA no longer accepted paper registration and listing. Many companies, especially small businesses, complained that the 13 step electronic process was too complicated and lengthy.
- Perceived unfair handling of an issue
- Lengthy response times to Citizen Petitions and Suitability Petitions
- Import/Export issues, usually detained products and seizures
    - Most complaints came from companies attempting to import and sell electronic cigarettes and their product was detained. Electronic cigarettes are devices that contain flavoring, nicotine, and other chemicals which are inhaled by the user. They are generally marketed as smoking cessation products. FDA declared that the products potentially pose a safety risk and took appropriate compliance actions. The FDA press release can be found at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm173222.htm
- Generic drug application decisions delayed due to issues raised in citizen petitions
- Unresponsiveness and communication delays
- Office of New Drugs (OND) review delays resulting in slowed drug development
- Enforcement actions taken on marketed drugs that do not have FDA approval
- Investigational New Drug Application (IND) and New Drug Application (NDA) requirements; review and application process questions
- User Fee assessments and Orange Book listings
- Whistleblower reporting of unethical clinical research conduct including institutional review board issues and clinical study protocol violations
- Unlawful promotional activities by competitors

Most Common Contact Topics from Consumers, Advocacy Groups, and Health Care Professionals

- Reporting of drug adverse events and medication errors
- Reporting marketed drugs that do not have FDA approval
- Patients with Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's Disease), wanted access to Iplex, a product not FDA approved for ALS but is FDA approved for another indication. FDA ultimately decided to allow access to the product; however, there was limited supply available. Find more information at http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm118121.htm
- Problems finding information on new FDA internet site
- Violative conduct by pharmaceutical companies (off-label promotion)

- Drug costs and health insurance problems
- Drug shortages
    - Dessicated natural thyroid does not have FDA approval and its availability became quite limited in 2009. Many consumers complained to the ombudsman because of their preference for dessicated natural thyroid as thyroid replacement medication over the FDA approved synthetic versions.
- Concerns over a potential ban on Percocet and Vicodin
    - An advisory committee panel recommended a ban on prescription painkillers that contain a narcotic and acetaminophen; Percocet and Vicodin fall into this category. Patients who use these drugs were very concerned about their potential removal from the market. The advisory committee panel recommendations are still under consideration by CDER; however, the safe use of drugs containing acetaminophen is currently an integral part of FDA's Safe Use Initiative. You can read about that initiative at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm189081.htm
- Complaints from consumers about their doctors
- Contaminated or adulterated drug suspected
- Generic drug doesn't seem to work the same as the brand drug
- Oxycontin abuse and pleas to remove it from the market
- Misleading product websites

Some of the topics above carry over as common topics from 2008. Not reflected in the list is that there was an increase in the number of CDER employees who sought out the Ombudsman's assistance for resolution of scientific differences of opinion amongst CDER staff. This trend is possibly attributed to greater staff awareness of the ombudsman's role and CDER's policy regarding resolution of differences of opinion. The increased awareness occurred because of presentations to staff during CDER Town Hall meetings and in other forums. Another change from 2008 is that the Ombudsman's Office received far fewer complaints about the delay in responses to Freedom of Information Act requests; in 2009 there was a 12.4% reduction in the backlog from 2008.

III. Other Activities

The Ombudsman continued to serve as the representative on a FDA level working group to review the Agency level appeals process for resolving internal scientific disputes.

The Ombudsman created mission and vision statements for the CDER Ombudsman's Office. Its mission is to quickly and impartially investigate complaints and resolve disputes between CDER and CDER-regulated industry, health care providers, and consumers by offering an informal, confidential, and neutral environment. Its vision is to improve the functionality and transparency of CDER by providing efficient resolution of disputes and by fostering communications with stakeholders.

IV. Outreach Efforts

The Ombudsman presented information about federal government careers and ombudsman work to undergraduate students at Washington and Lee University in Lexington, Virginia. Internal to CDER, the Ombudsman's Office conducted outreach to explain the Ombudsman's functions including product jurisdiction and dispute resolution at the CDER New Reviewer's Workshops. The Office also updated an informative website for use by CDER employees.

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. LCDR 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 (noncombination) products.

This calendar year, the CDER Ombudsman's Office responded to hundreds of informal jurisdiction questions from within and outside FDA and put forth CDER's position on 30 RFDs and 4 requests for reconsideration, most of which were drug/device combinations. OCP received 73 RFDs, 35 of which were not filed. Of the 38 filed, OCP requested CDER consultation for 30 of them. More information about jurisdictional determinations can be found on the OCP website at http://www.fda.gov/oc/combination/.