

CTP Ombudsman's 2014 Annual Report



The Center for Tobacco Products (CTP) Ombudsman is responsible for responding to a range of contacts on matters, including complaints from various stakeholders and the public, and for facilitating the resolution of disputes between CTP and outside parties. While providing this service, the Ombudsman strives to maintain impartiality and neutrality.

The CTP Ombudsman is Ella Yeargin. She first joined the CTP Ombudsman's Office in 2012 and worked with two Center Ombudsmen, Les Weinstein and Lawrence "Jake" Romanell, before being appointed Ombudsman in January 2015. Her tenure at CTP also includes work in the Freedom of Information Office and the Office of Compliance and Enforcement. She also served as the Center's Acting Ombudsman for 8 months.

This annual report summarizes the role of the CTP Ombudsman's Office and the complaints, disputes, inquiries, and comments responded to by the Ombudsman's Office during calendar year 2014, including the number of contacts and their source, subject matter, and status.

The Role of the CTP Ombudsman

What does the CTP Ombudsman do?

The CTP Ombudsman responds to inquiries and looks into complaints from all parties who contact her, including the tobacco industry, law firms or consultants representing the tobacco industry, advocacy groups, public and private research institutions, health care providers, and consumers. She also facilitates the resolution of disputes between CTP and outside parties and provides general information on the regulatory process. While providing this assistance, she maintains independence, impartiality, and neutrality. The Ombudsman is an advocate for fairness.

Serving primarily with an external focus, the Ombudsman:

- Addresses complaints
- Helps resolve disputes of a scientific, regulatory, or procedural nature
- Discusses appeal and dispute resolution options
- Responds to inquiries

As a point of contact, the Ombudsman is available to listen to issues and concerns, even if they do not rise to the level of a complaint or dispute. She also can help to facilitate discussion between outside parties and CTP staff.

Based on the nature of inquiries and complaints received from the public, the Ombudsman advises the CTP Office of the Center Director, where the Ombudsman's Office is located, on ways to ensure that the Center's procedures, policies, and decisions are of the highest quality and are fair and equitable.

The Ombudsman also plays a role in the resolution of internal scientific disputes in regulatory decisionmaking between CTP managers and staff.

This annual report summarizes the role of the Ombudsman's Office and the complaints, disputes, inquiries, and comments the Ombudsman's Office received for calendar year 2014, including the number of contacts and their source, subject matter, and status.

How to Contact the Ombudsman's Office:

Ella Yeargin
301.796.3095
CTPOmbudsman@FDA.hhs.gov

Relation to FDA Office of the Ombudsman

The function of the CTP Ombudsman parallels that of the FDA Office of the Ombudsman, located in the Office of the FDA Commissioner, but provides an avenue for resolving issues involving CTP programs at a level closer to the source. Because the FDA Office of the Ombudsman has agency-wide jurisdiction, it is appropriate to contact that Office when an issue involves more than one FDA Center, when an effort to resolve a dispute or an appeal of a decision was not successful at the Center level, or at any time when involvement by someone outside CTP might be useful.

When to Contact the CTP Ombudsman

The Ombudsman does her best to respond in a timely and effective manner to complaints and disputes. Although anyone may contact her at any time, they should, if possible, first try to resolve any complaint or dispute within the responsible CTP Office. The Ombudsman does not get involved in matters that are in litigation.

General Comments and Suggestions

The Ombudsman is interested in hearing about the effectiveness of CTP's programs and about problems that may be getting in the way of carrying out the Center's regulatory responsibilities. She welcomes such input because it helps CTP to continually assess and improve the work that it does.

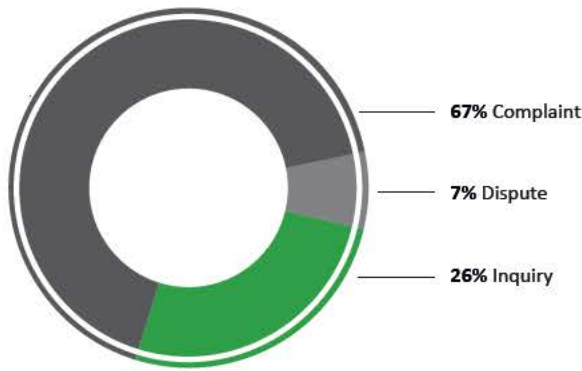
Confidentiality

Parties who contact the Ombudsman may prefer to keep their identity, name, company name, or even the nature of the complaint confidential. Generally, the Ombudsman can keep this information confidential if requested. Naturally, a pledge of confidentiality may preclude the Ombudsman from facilitating a resolution to a specific problem. If so, she will explain this conflict and will not proceed to look into a matter without permission to share the previously confidential information.

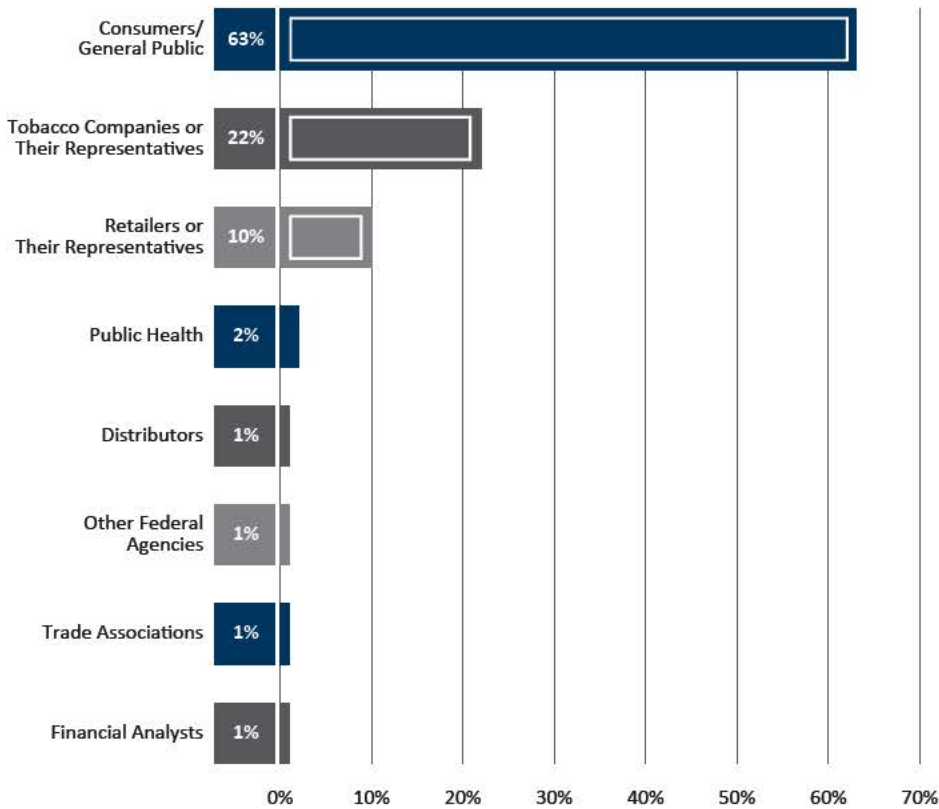
There are a few areas, however, in which confidentiality cannot be preserved, such as allegations of criminal activity, which must be reported to the FDA Office of Criminal Investigations. Even in these situations, though, the identity of a confidential source may be protected from disclosure to the public. Also, FDA has a very strict nonretaliation policy that protects anyone who complains about the Agency or any of its employees.

The CTP Ombudsman follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombudsmen, the United States Ombudsman Association, and the International Ombudsman Association. These include standards for ensuring confidentiality, impartiality, and informality.

Types of Contacts Received: 137
 (In 2013, there were 121.)



Source of Contacts



The CTP Ombudsman’s Office receives inquiries, complaints, and contacts about disputes by phone, email, postal mail, and in person.

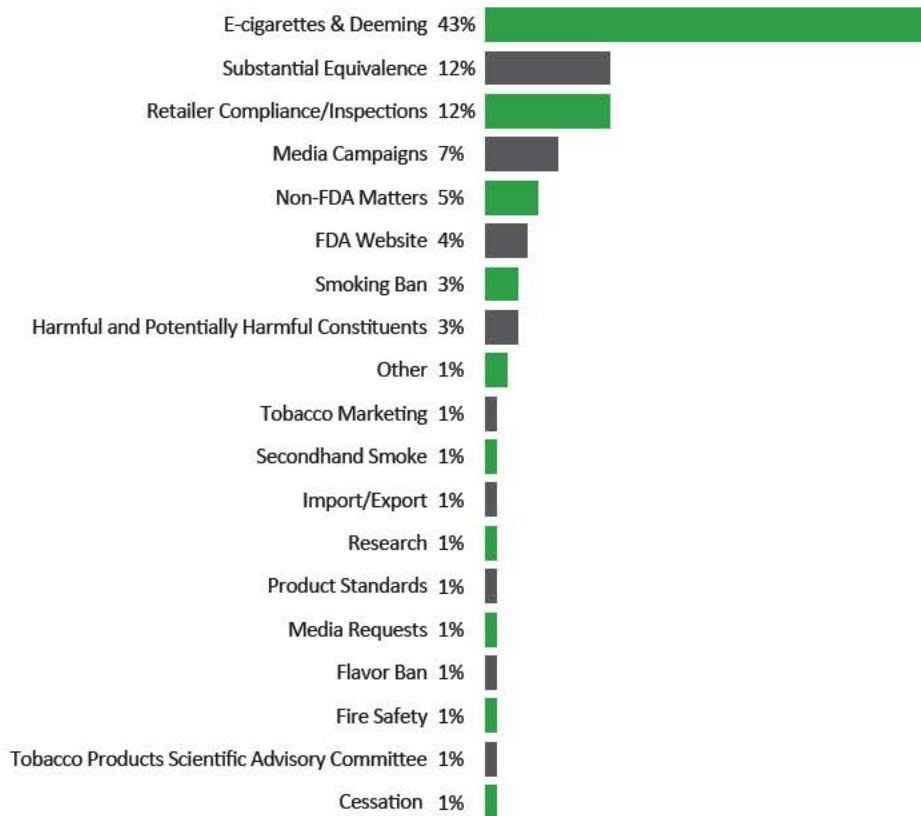
Contacts in 2014

The CTP Ombudsman receives inquiries, complaints, and contacts about disputes by phone, postal mail, email, and in person. In 2014, the CTP Ombudsman received communications from 137 contacts. In many instances, she exchanges several phone calls with a single contact; however, these follow-up correspondences are counted as a single interaction for purposes of the annual report unless substantially different issues were raised.

A complaint might be an expression of dissatisfaction with a CTP policy or action. It might be a trade complaint about a tobacco company or retailer or a consumer complaint about a product or type of product. A dispute may involve a disagreement with, a challenge to, or an appeal of a CTP decision or action. An inquiry may be about an issue that does not rise to the level of a complaint or a dispute, such as an inquiry about the regulatory process.

Subject Matter

(Total is more than 100% due to rounding.)



Closed: 100% (Complaint addressed, dispute resolved, inquiry responded to, referred outside CTP, withdrawn, or had no follow-up by the initiator after 3 months. Includes those carried over from 2013 and closed in 2014).
Pending: 0%

Appeals

For the first time, the CTP Ombudsman's Office was contacted to help resolve conflicts pursuant to 21 CFR 10.75. Under Section 10.75, "an interested person outside the agency may request internal agency review of a decision through the established agency channels of supervision or review." The CTP Ombudsman coordinates this process for the Center. For more information about how to submit an appeal pursuant to Section 10.75, please contact the Ombudsman.

In 2014, CTP processed a total of seven appeals—three at the Center level and four at the Office level. Of those seven, two have received a final decision; three remain under review; and two were withdrawn. This includes one appeal that was received in 2013 and withdrawn in 2014.

Summary

In 2014, the Ombudsman's Office was contacted by a wide variety of individuals interested in CTP's regulatory authorities and processes. Consumers, retailers, manufacturers, public health officials, representatives from the tobacco industry, and others reached out to ask questions, give feedback, and seek resolution of conflicts. The coming year promises to be an exciting one for CTP, and the Ombudsman looks forward to broadening her engagement with all interested parties. If you have a question or a concern that you'd like to discuss with the CTP Ombudsman, please do not hesitate to contact Ella Yeargin at 301.796.3095.

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Trends

The number of contacts increased from 121 in 2013 to 137 in 2014. In 2014, as in years past, the subject matter of the contacts reflects a high level of interest in and engagement with CTP from outside of FDA. Contacts had questions, comments, and concerns about e-cigarettes and the proposed deeming rule, retailer compliance and inspections, substantial equivalence, and CTP's "The Real Cost" media campaign. Complaints and inquiries related to substantial equivalence included industry feedback about timeliness and communication, while members of the public typically wrote and called the CTP Ombudsman's Office with questions and opinions about the media campaign and e-cigarettes.