OMBUDSMAN'S 2013 ANNUAL REPORT

CENTER FOR TOBACCO PRODUCTS

CTP established its Ombudsman's Office in 2010 and appointed Les Weinstein to serve as CTP's first Ombudsman. The Ombudsman's Office responds to a range of contacts, including complaints from various stakeholders and the public, and facilitates the resolution of disputes between CTP and the tobacco industry. While providing this service, the CTP Ombudsman strives to maintain impartiality and neutrality. This Annual Report summarizes the role of the Ombudsman's Office and the complaints, disputes, and inquiries/comments the Ombudsman's Office received for calendar year 2013, including the number of contacts, their source, subject matter, and status. Les Weinstein retired in October 2013, and the Acting Ombudsman is Ella Yeargin.

The Role of the CTP Ombudsman

What does the CTP Ombudsman do?

The CTP Ombudsman's Office responds to inquiries and looks into complaints from the tobacco industry, law firms or consultants representing industry, advocacy groups, public and private research institutions, health care providers, and consumers; facilitates the resolution of disputes between CTP and the tobacco industry; and provides general information on the regulatory process. While providing this assistance, the Ombudsman's Office maintains independence, impartiality, and neutrality. The office is an advocate for fairness.

As a primarily external Ombudsman, the Ombudsman's Office is the focal point for:

- addressing complaints,
- assisting in resolving disputes of a scientific, regulatory, or procedural nature,
- discussing appeal and dispute resolution options, and
- responding to inquiries.

The Ombudsman's Office is available to provide an empathetic ear to listen to issues and concerns even if they do not rise to the level of a complaint or dispute. The Ombudsman's Office can also help to facilitate a dialogue or discussion between stakeholders and CTP staff.

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

The Ombudsman is also an internal Ombudsman who will play a role in the resolution of internal scientific disputes in regulatory decision-making between CTP managers and staff.

This Annual Report summarizes the role of the Ombudsman's Office and the complaints, disputes, and inquiries/comments the Ombudsman's Office received for calendar year 2013, including the number of contacts, their source, subject matter, and status.

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. We welcome such input because it helps CTP to continually assess and improve the work that it does.

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

Complaints and Disputes: The Ombudsman's Office does our best to respond in a timely and effective manner. Although anyone may contact us 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. We welcome such input because it helps CTP to continually assess and improve the work that it does.

Confidentiality

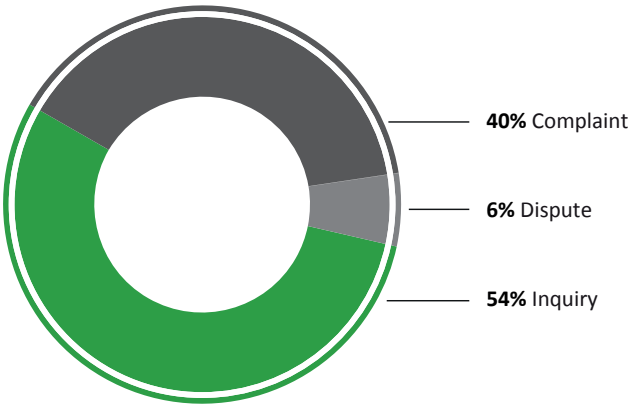
Parties who contact the Ombudsman's Office may prefer to keep their identity, name, company name, or even the nature of the complaint confidential. Generally, we can keep this information confidential if requested. Naturally, a pledge of confidentiality may preclude the Ombudsman from facilitating a resolution to a specific problem. If so, we 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 non-retaliation 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.

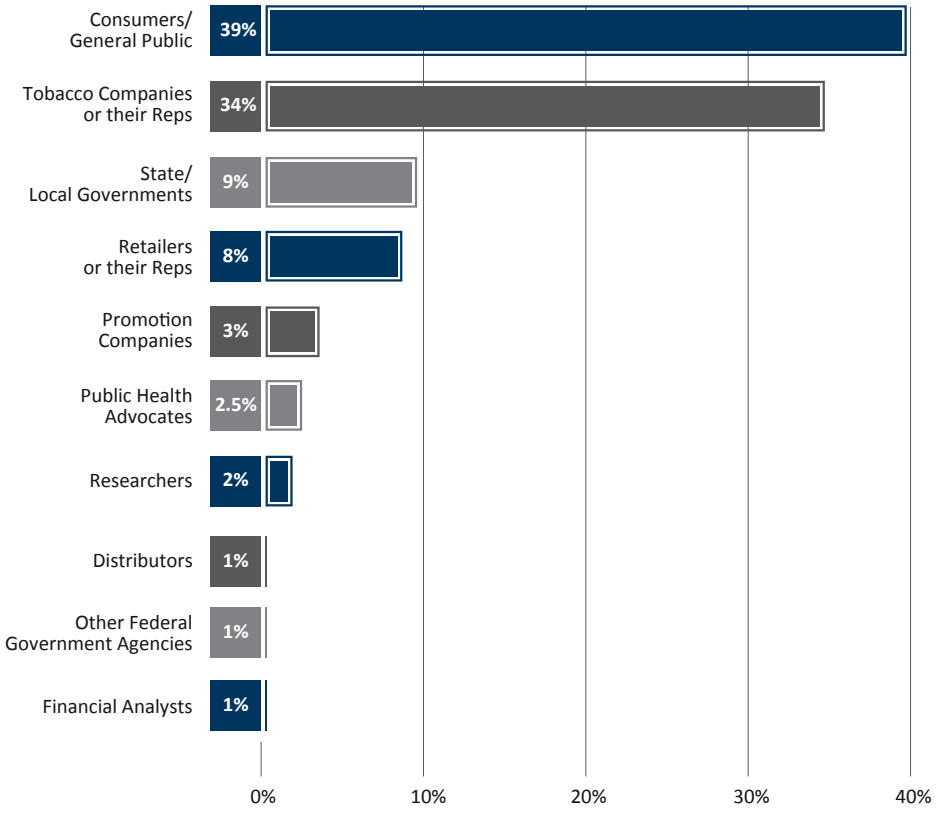
How to Contact the Ombudsman's Office

Ella Yeargin, Acting Ombudsman
Telephone: 301-796-3095
E-mail address: CTPOmbudsman@fda.hhs.gov

Types of Contacts Received: 121
(In 2012, there were 109.)



Source of Contacts



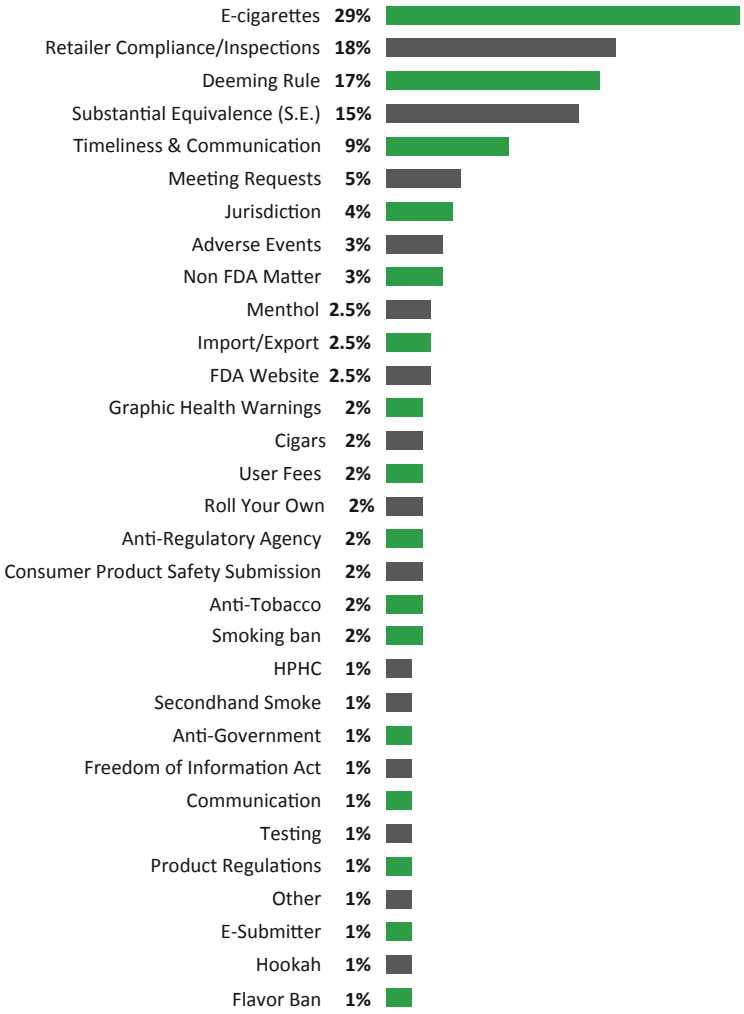
The CTP Ombudsman's Office receives inquiries, complaints, and contacts about disputes by phone, e-mail, postal mail, and in person.

Contacts in 2013

The CTP Ombudsman's Office receives inquiries, complaints, and contacts about disputes by phone, email, postal mail, e-mail, and in person. In many instances, several phone calls are exchanged 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% to reflect multiple topics per contact.)



Closed: 96% (Complaint addressed, dispute resolved, inquiry responded to, referred outside CTP, withdraw, or had no follow up by the initiator after three months. Includes those carried over from 2012 and closed in 2013).

Pending: 4%

Contacts wanted to know about e-cigarettes, retailer compliance, deeming, and substantial equivalence. These made up 79% of the topics included in calls or emails to the Ombudsman's Office in 2013.

Trends

The number of contacts increased from 109 in 2012 to 121 in 2013. Most of the percentages for contact source stayed steady with the exception of an increase in contacts from consumers/general public. In 2013, 39% of contacts were consumers/general public, while those contacts made up just 24% of contacts in 2012. The subject matter of the calls reflects a high level of engagement from outside FDA with CTP: contacts wanted to know about e-cigarettes, retailer compliance, deeming, and substantial equivalence. These made up 79% of the topics included in calls or emails to the Ombudsman's Office in 2013.