



CTP OMBUDSMAN'S 2017 ANNUAL REPORT



I am pleased to share our annual report, which summarizes the role of the Center for Tobacco Products (CTP) Ombudsman's Office and the complaints, disputes, inquiries, and comments the office received during calendar year 2017. I'd like to highlight two key items, which we expand upon later in this report. First, the number of contacts for the Ombudsman's Office was lower than in 2016, but higher than in previous years. Also, the number of requests for supervisory review, which are also called appeals, to the Office of the Center Director had a notable increase.

After being in the role of CTP ombudsman for a little over a year, I've gained a greater understanding of what it means to be an ombudsman. During my time in CTP's Office of Science, I gained understanding of the center's policies and processes and I began to communicate internally and externally. I wanted to take those lessons further and have a role in the development of fair and transparent policies and processes. I also felt I had more to offer in communicating the center's messages, both internally and to our external stakeholders; the role of ombudsman seemed like the right place to be. I believe in effective communication; we are here to be a listening ear when needed, answer questions, and help our contacts navigate CTP. The Ombudsman's Office is an avenue for stakeholders to provide feedback on center processes, whether we speak in confidence or I'm able to share the information within CTP. When we build and maintain relationships with center leadership as well as outside stakeholders, we have an increased opportunity to provide thorough communications and the ability to present an unbiased view on center processes.

During the 2018 calendar year, I want the Ombudsman's Office to continue the "yes we can" mentality we have developed. Being able to put a face to a name of those in public health, tobacco research, and the tobacco industry is important to us. Allison Monyei, CTP's associate ombudsman, and I attend conferences when we can to interact on an individual level with our stakeholders, expand the outreach and services of the Ombudsman's Office, and hear how things are going. After issuing the deeming rule, CTP has a larger number of stakeholders. Many within the newly regulated industry did not know who the ombudsman is or what the office does. We already have had conversations with these groups; listened to their stories, questions, and concerns; and let them know we are here to listen. We will continue this in 2018 and beyond.

Nathan Hurley
CTP Ombudsman
May 2018

OMBUDSMAN IN PRACTICE

What is an ombudsman?

An ombudsman is an impartial, independent person who confidentially receives and investigates complaints and facilitates the resolution of problems. The Ombudsman's Office within CTP follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombudsman, the United States Ombudsman Association, and the International Ombudsman Association.

What does the CTP Ombudsman's Office do?

The CTP Ombudsman's Office responds to inquiries and looks into complaints from all parties who contact us, including the tobacco industry, law firms or consultants representing industry, advocacy groups, public and private research institutions, health care providers, and consumers. We also facilitate the resolution of disputes between CTP and external parties and provide general information on the regulatory process. While providing this assistance, the Ombudsman's Office maintains its independence and impartiality. The Ombudsman's Office is an advocate for fairness.

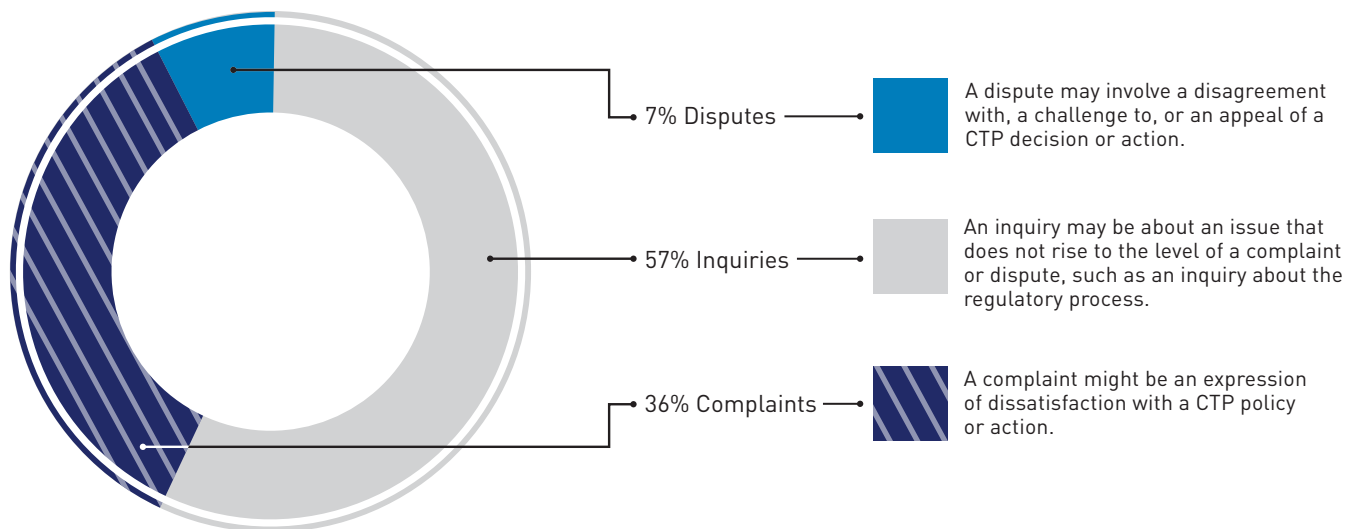
The Ombudsman's Office is available to listen to issues and concerns, even if they do not rise to the level of a complaint or dispute. The Ombudsman's Office also can help to facilitate a dialogue or discussion between outside parties and CTP offices and staff.

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

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

CONTACT TRENDS

CONTACTS RECEIVED IN 2017 TOTAL: 228



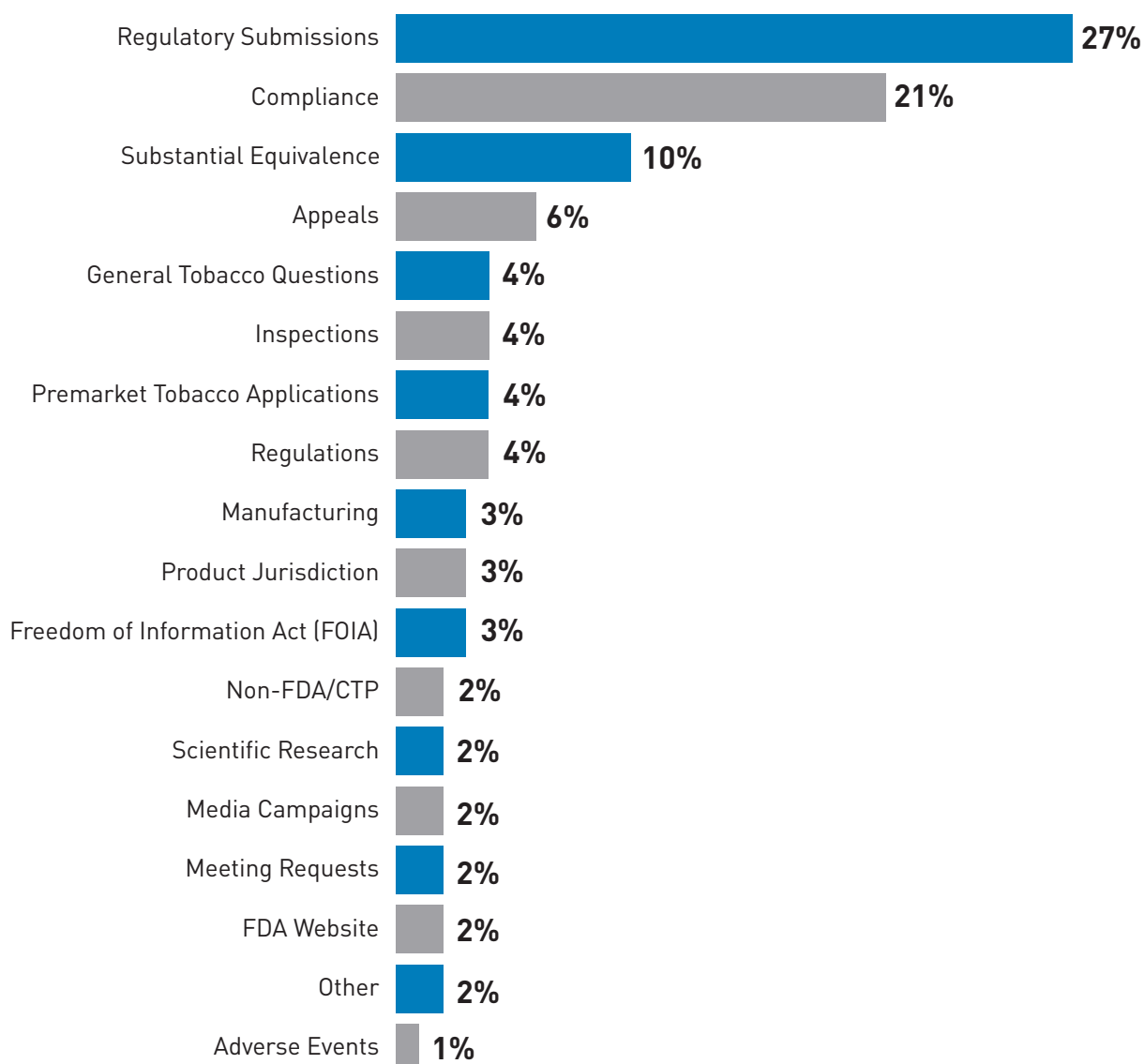
In 2017, the CTP Ombudsman’s Office received inquiries, complaints, and other communications about disputes from 228 contacts, a sizable decline from the 320 received in 2016. The percentage of contacts that were inquiries remained stable (57 percent of contacts in 2017, compared with 60 percent in 2016). The percentage of complaints was also similar (36 percent in 2017 and 39 percent in 2016). However, there was a higher percentage of disputes in 2017 (7 percent) than in 2016 (1 percent).

Eighty percent of contacts received in 2017 were closed. This means the complaint was addressed, the dispute or appeal was resolved, or the inquiry was responded to, referred outside CTP, withdrawn, or had no follow-up by the initiator after 1 month. This includes those contacts carried over from 2017 and closed in 2018.

The closure rate of 2017 was less than 2016 due to the complexity and breadth of some of the inquiries, many involving more than one office within the center and many follow-up correspondences. In many instances, several phone calls or emails were exchanged with a single contact; however, these follow-up correspondences are counted as a single interaction for the purposes of the annual report unless substantially different issues were raised.

CONTACT TOPIC OF INTEREST

(Total more than 100% due to rounding)



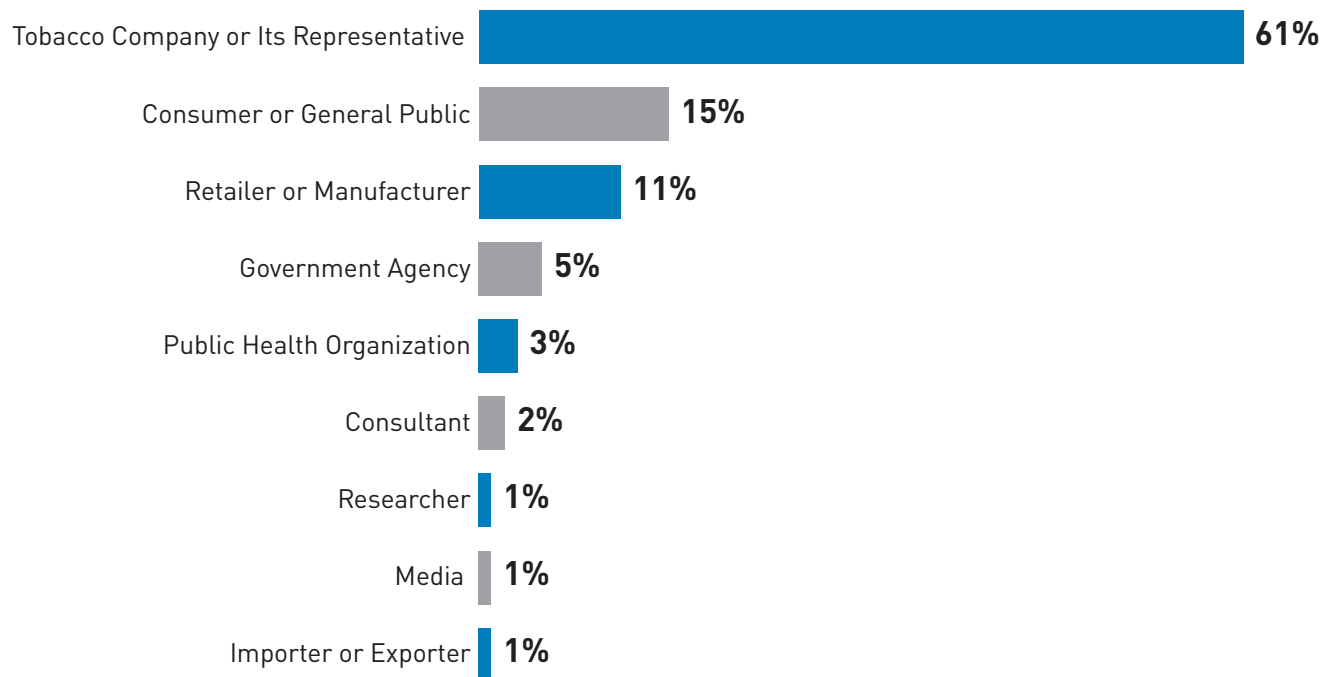
The contact topics of interest reflected a high level of engagement with CTP from parties outside of FDA in 2017. Regulatory submission deadlines, retailer and manufacturer compliance with the Food, Drug, and Cosmetic Act, and CTP's electronic submission gateways were the primary topics of interest this year. And, as in years past, contacts still had questions, comments, and concerns about the substantial equivalence product review pathway and tobacco product jurisdiction.

Complaints and inquiries related to substantial equivalence included concerns about communication with CTP and the overall timeliness of the application process, and most disputes involved a negative action by CTP, usually a Not Substantially Equivalent order for a tobacco product.

Inquiries and complaints about the requirement for tobacco product manufacturers to register and list their businesses increased this year, as this was one of the first compliance activities newly regulated industry needed to perform. The electronic systems that CTP used to accept regulatory submissions, such as FDA Unified Registration and Listing Systems (FURLS), eSubmitter, and CTP Portal, were the main source of anxiety for most contacts.

CONTACT SOURCE

(Total more than 100% due to rounding)



As in years prior, tobacco companies and their representatives reached out to the CTP Ombudsman's Office more than other sources did in 2017. FDA's 2016 deeming rule extended our regulatory authority to previously unregulated tobacco products such as e-cigarettes, hookah tobacco, and cigars, thereby increasing the number of tobacco companies and representatives.

FORMAL DISPUTE RESOLUTION AND APPEALS

The CTP Ombudsman's Office monitors the resolution of appeals filed pursuant to [21 CFR 10.75](#). Under 10.75, "an interested party outside the agency may request supervisory review of a decision through the established channels of supervision or review."

In 2017, CTP received 14 appeals, which is a noticeable increase from years past. Final decisions were issued on five appeals, while two were withdrawn. CTP refused to accept three requests. CTP now has dedicated staff to assist with processing and managing appeals. For more information about formal dispute resolution options, including how to submit an appeal, please contact the ombudsman.

SUMMARY

In 2017, a wide variety of individuals, companies, and small business owners with questions, complaints, or disputes with CTP's regulatory authorities and processes contacted the Ombudsman's Office for assistance. Additionally, many consumers, retailers, manufacturers, public health officials, representatives from the tobacco industry, and others reached out to share concerns: Is this product regulated by CTP? What options are available if I disagree with a decision that CTP has made? How can someone report potential tobacco product violations? Would CTP grant additional time to submit product listings or health information documents?

In the coming year, we look forward to broadening our engagement with all interested parties. If you have a question or a concern you would like to discuss with the CTP ombudsman, please do not hesitate to contact us at 301.796.3095.

CTP OMBUDSMAN'S OFFICE AT A GLANCE

Why is there a CTP ombudsman? The Center for Tobacco Products (CTP) Ombudsman's Office is responsible for responding to a range of contacts, including complaints from various stakeholders and the public, and facilitating the resolution of disputes between CTP and outside parties.

CONFIDENTIALITY

We will keep what you tell us confidential unless we have serious concerns about your or someone else's safety or unless disclosure is required by law.

IMPARTIALITY

We do not advocate for one side or the other, but we do advocate for a fair process.

INDEPENDENCE

We are outside of the business chain of command. The ombudsman reports to the CTP deputy director and has direct access to the CTP director.

INFORMALITY

We are here to help. It is important for us to understand what the issue is, to hear what solution you are hoping for, and to figure out what we can do to help.

Why should I contact the CTP ombudsman? We can help resolve issues by facilitating discussions, brainstorming and evaluating options and resources, offering an impartial perspective, ensuring confidentiality of someone's identity, engaging in shuttle diplomacy, and providing recommendations, among other options.

When should I contact the CTP ombudsman? Try us when you have not had success with existing CTP processes to address your concerns or because you want to keep your concerns confidential. You are welcome to call or email us any time, but we encourage you to work with your existing CTP contact first.

CENTER FOR TOBACCO PRODUCTS
OMBUDSMAN'S OFFICE

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<https://www.fda.gov/tobaccoproducts/aboutctp/contactus/ucm2023130.htm>



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