



**CTP
OMBUDSMAN'S
REPORT** *2020*

CTP OMBUDSMAN'S 2020 REPORT

CTP OMBUDSMAN'S 2020 REPORT

The Center for Tobacco Products (CTP) 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 outside parties. While providing these services, the ombudsman strives to maintain confidentiality, impartiality, independence and informality. 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.

This report summarizes the role of the CTP Ombudsman's Office surrounding the inquiries, complaints, and disputes received for the calendar year 2020, including the number of contacts, topics of interest, their source, status, and comparison to the previous calendar year 2019.

OMBUDSMAN IN PRACTICE

What is an ombudsman?

An Ombudsman is a neutral resource who investigates and settles disputes and resolves complaints. The CTP Ombudsman's Office serves as a one-stop-shop for informal advice or consultation for stakeholders who have complaints or inquiries.

What does the CTP Ombudsman's Office do?

The Ombudsman's Office responds to inquiries and is charged to investigate complaints from all stakeholders who contact us, including the tobacco industry, law firms or consultants representing industry, tobacco control and public health groups, public and private research institutions, health care providers, consumers, and government personnel (local, state and federal).

The CTP Ombudsman's Office provides a "safe space" for stakeholders to voice their questions, concerns, or complaints about FDA regulation of tobacco products. Using our thorough understanding of center operations, we can help to facilitate communications between external stakeholders and FDA staff.

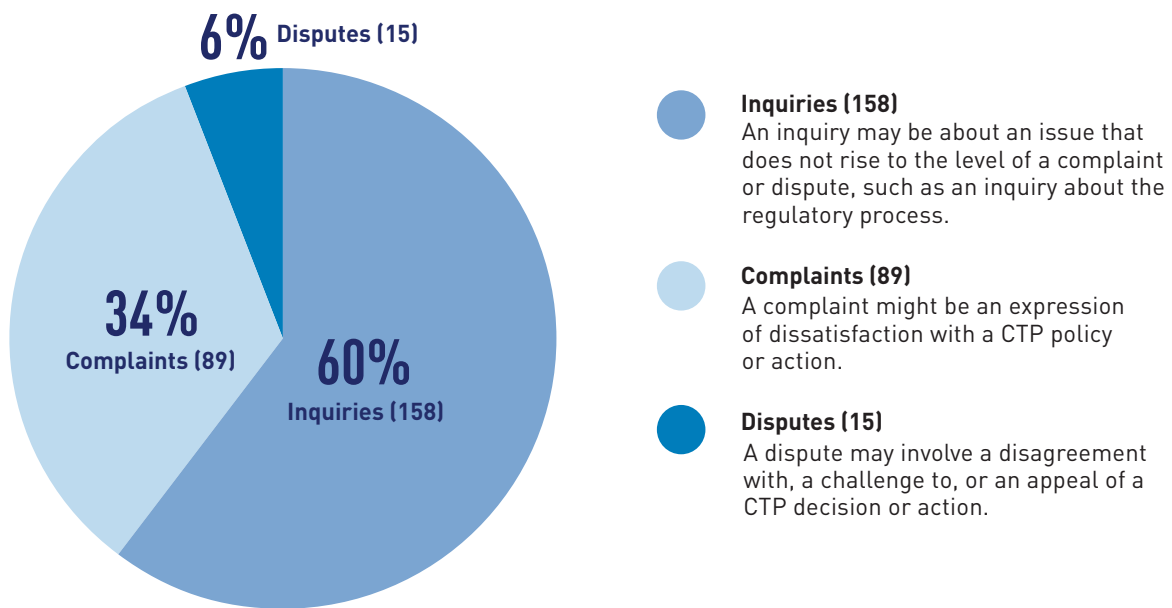
Based on the nature of the contacts received from the public, the Ombudsman reports directly to the Office of the Center Director (OCD), on ways to assure that CTP's procedures, policies, and decisions are fair. We also act as a source of early detection for emerging system-wide issues.

What issues will the CTP Ombudsman handle?

The CTP Ombudsman's Office answers inquiries, acknowledges complaints about CTP's regulatory process, redirects contacts to the appropriate party, discusses dispute resolution options including appeals under 21 CFR 10.75, and participates in meetings as an unbiased resource to stakeholders. The Ombudsman's Office also facilitates the resolution of disputes of a scientific, regulatory or procedural nature between CTP and stakeholders. The Ombudsman's Office cannot get involved in matters that are in active litigation.

CONTACTS RECEIVED IN 2020

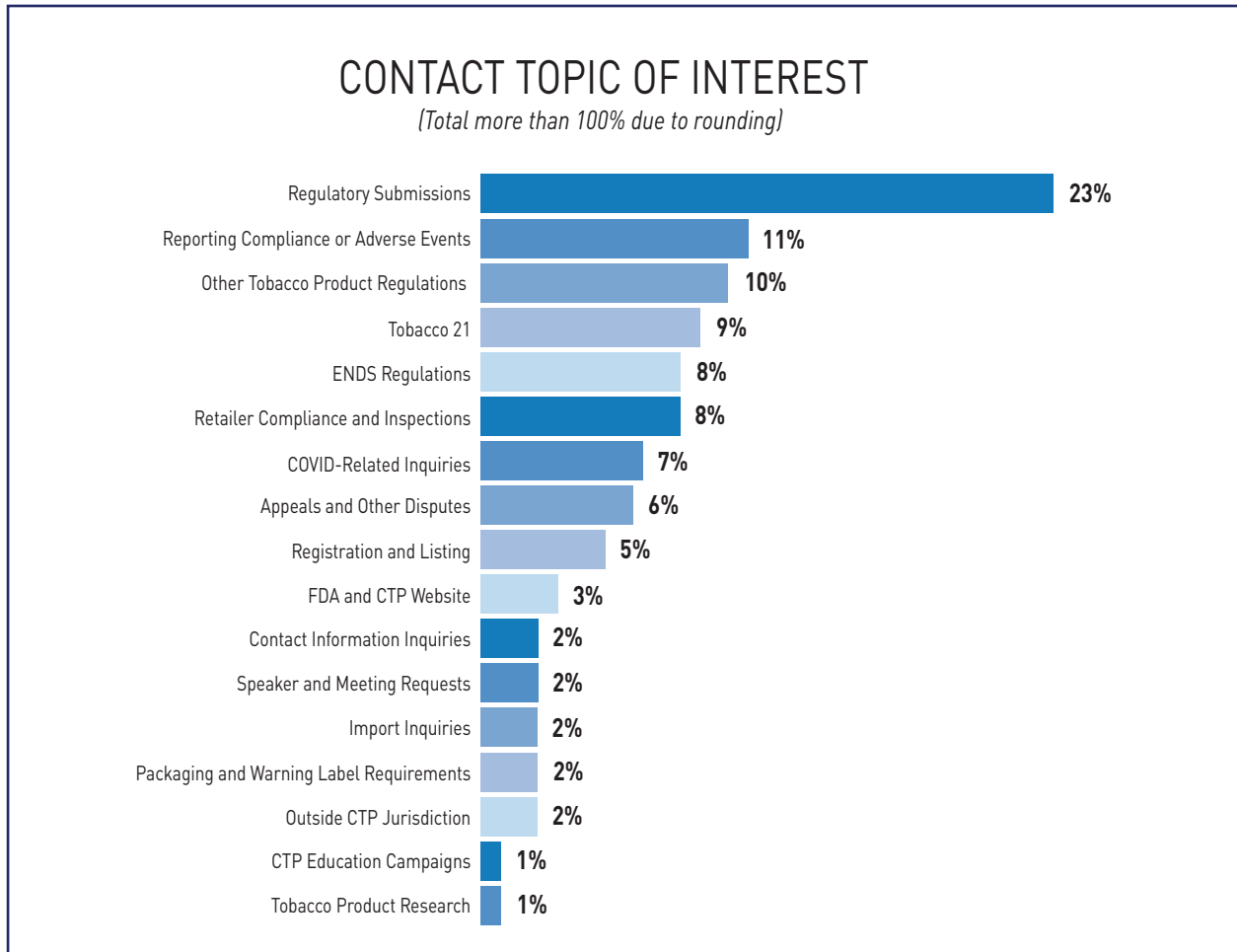
TOTAL: 262



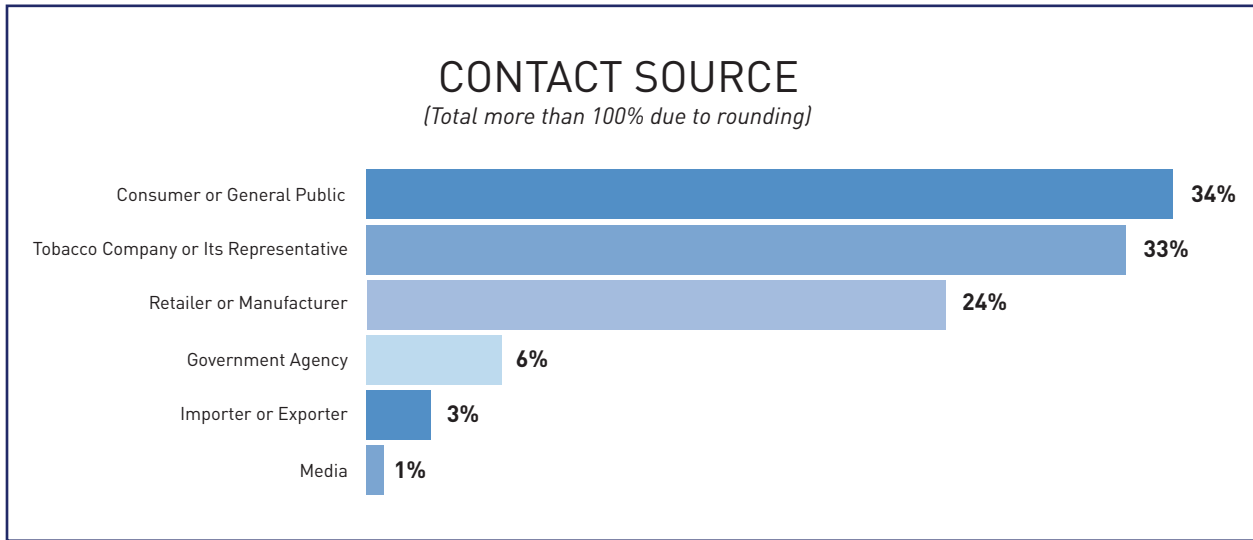
CONTACT TRENDS IN 2020

In 2020, the CTP Ombudsman’s Office received inquiries, complaints, and disputes from 262 contacts, a decrease from the 331 received in 2019. From 2019 to 2020, inquiries increased from 127 to 158, complaints decreased from 185 to 89, and disputes decreased from 19 to 15.

Of the contacts received in 2020, 98% were closed. This means the inquiry was either responded to, referred outside CTP, withdrawn, or had no follow-up by the initiator after one month; the complaint was addressed; or the dispute or appeal was resolved. 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.



The primary topic of interest during 2020 was regulatory submissions because of the September 9th, 2020 court-ordered deadline for submission of applications for electronic nicotine delivery systems (ENDS) and other deemed products on the market without premarket authorization. Secondary topics of interest included reporting potential violations of the law or FDA regulations to the Potential Tobacco Product Violations Reporting System or reporting tobacco-related adverse events through the Safety Reporting Portal. Contacts were also interested in regulation of all tobacco products. Various stakeholders contacted the CTP Ombudsman’s Office with business process inquiries due to the impact of COVID-19. As in years past, contacts still had general questions for CTP about tobacco regulation and commented specifically about pathways to market a new tobacco product.



The majority of contacts came from consumers or the general public (34% in 2020, down from 55% in 2019) and tobacco companies or their representatives¹ (33% in 2020, up from 21% in 2019). There was an increase in contact from the retailer or manufacturer category (24% in 2020, up from 6% in 2019). This provided an opportunity for stakeholders to engage and gain additional educational resources from the CTP Ombudsman’s Office.

DISPUTE RESOLUTION AND APPEALS

CTP received fifteen appeals or other disputes and provided fourteen responses². The CTP Ombudsman’s Office facilitates 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.” CTP has dedicated staff to assist with processing and managing appeals and formal disputes. The CTP Ombudsman plays a role in the Internal Formal Scientific Dispute Resolution process when a difference in regulatory opinion arises.

For more information about the external or internal dispute resolution process, including how to submit an appeal, please contact the CTP Ombudsman’s Office.

¹ Tobacco company or its representative includes consultants, regulatory experts, lawyers, or any point of contact designated by the tobacco company.

² This total does not take into account previous appeals and other disputes received prior to 2020.

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.

CENTER FOR TOBACCO PRODUCTS
OMBUDSMAN'S OFFICE



U.S. FOOD & DRUG
ADMINISTRATION



301.796.3095



CTPOmbudsman@fda.hhs.gov



<https://www.fda.gov/tobacco-products/contact-ctp/ctp-ombudsman>