CENTER FOR TOBACCO PRODUCTS

U.S. FOOD & DRUG ADMINISTRATION

CTP OMBUDSMAN'S REPORT *2022*

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The Center for Tobacco Products (CTP) Ombudsman (Ombuds) Team serves as a resource for external and internal U.S Food and Drug Administration (FDA) stakeholders. This Team investigates and assists in addressing inquiries, resolving complaints, and settling disputes between CTP and outside parties. While providing these services, the ombuds maintains its commitment to confidentiality, impartiality, independence, and informality.

This report summarizes the role of the CTP Ombuds Team surrounding the inquiries, complaints, and disputes received for the calendar year 2022, including the number of contacts, topics of interest, their source, and comparison to the previous calendar year 2021.

OMBUDS IN PRACTICE

What Is an Ombuds?

An Ombuds is a neutral resource that investigates and settles disputes and resolves complaints. The CTP Ombuds Team serves as a one-stop shop for informal advice or consultation for stakeholders who have complaints or inquiries. The CTP Ombuds Team follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombuds, the United States Ombuds Association, and the International Ombuds Association.

What Purpose Does the CTP Ombuds Team Serve?

The CTP Ombuds Team primarily listens. We provide a "safe space" for stakeholders to voice their questions, concerns, or complaints about FDA regulation of tobacco products. We ask clarifying questions, determine desired outcomes, discuss options forward, and help to facilitate communications between external stakeholders and FDA staff using our thorough understanding of center operations.

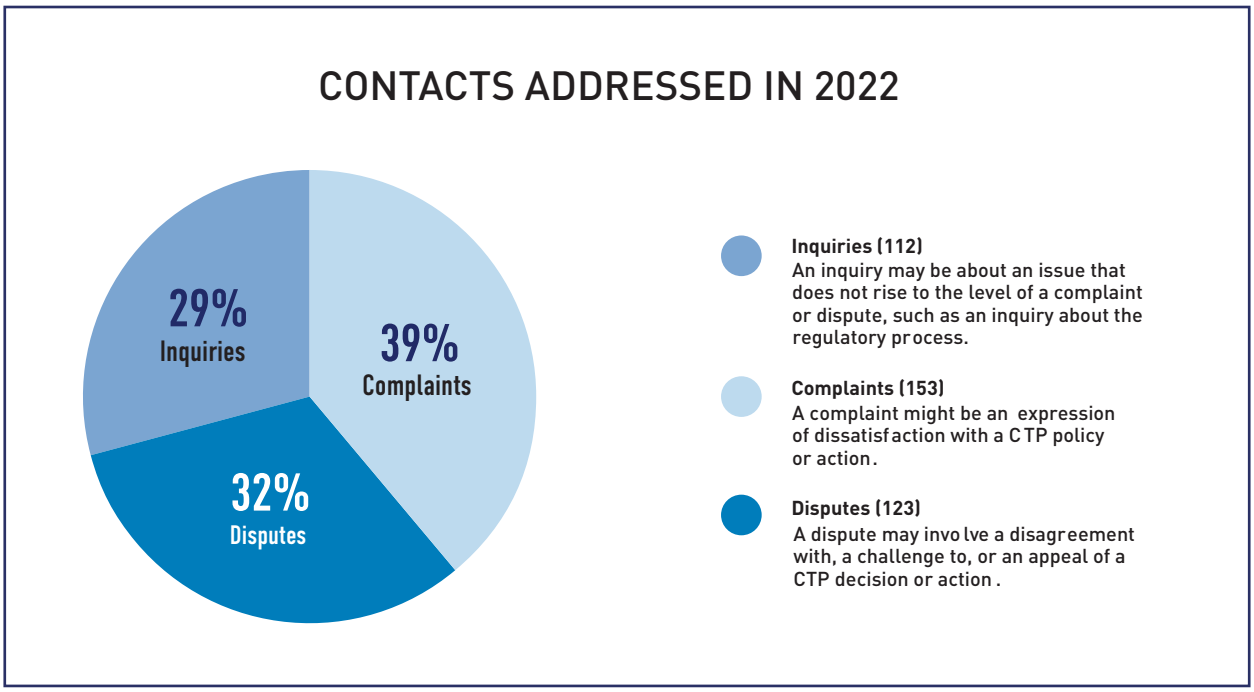
The CTP Ombuds Team reports directly to the Center Director on ways to assure that CTP's procedures, policies, and decisions are fair. We act as a source of early detection for emerging system-wide issues. While maintaining independence operating outside the business chain of command, the CTP Ombuds Team responds to inquiries and is charged to investigate complaints from all stakeholders who contact us. A stakeholder or contact can be defined as any interaction between the CTP Ombuds and tobacco manufacturers and retailers, law firms or consultants representing the tobacco industry, public health groups, research institutions, health care providers, consumers, and government personnel (local, state, and federal).

What Issues Will the CTP Ombuds handle?

Externally, the CTP Ombuds Team answers inquiries, acknowledges complaints about CTP's regulatory process, redirects contacts to the appropriate office, discusses dispute resolution options including appeals under 21 CFR 10.75, and participates in meetings as an unbiased resource to stakeholders. The CTP Ombuds Team does not engage in a matter that is in litigation.

Internally, the CTP Ombuds Team works toward CTP's mission and goals, assists in guidance development, and facilitates Scientific Dispute Resolution (SDR) internal to CTP.

CONTACT TRENDS

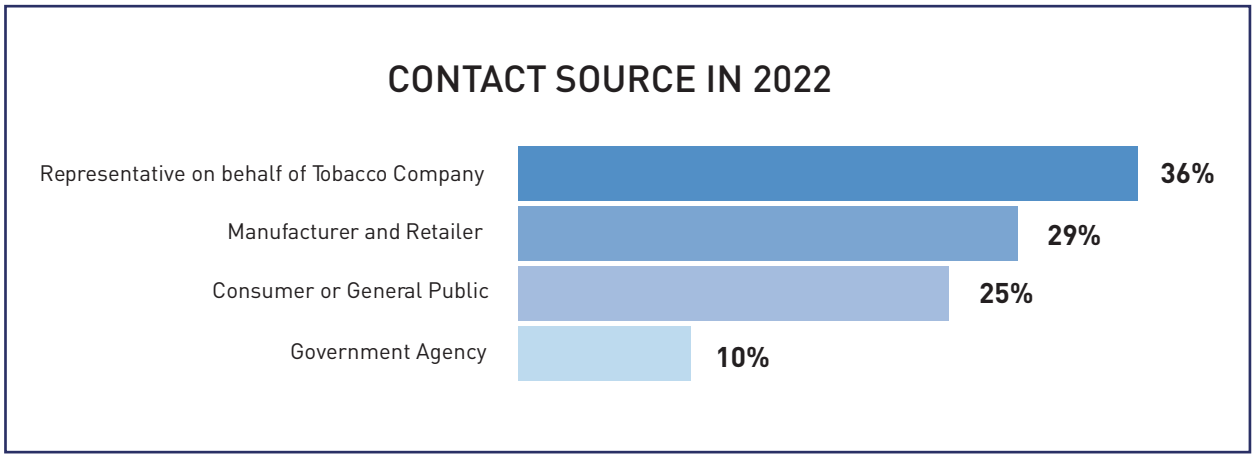


Of the total contacts addressed:

- 388 total contacts
- 316 new contacts
- 69 previous contacts

Out of the 388 contacts addressed (down from 496 in 2021), 75% reached resolution[1]. This means the inquiry was either responded to, referred outside CTP, withdrawn, or had no follow-up by the initiator after 1 month; the complaint was addressed; or the dispute or appeal was resolved. Compared to 2021 contacts addressed, complaints were up from 31%, disputes were up from 23%, and inquiries were down from 46%.

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. Contacts which were not fully resolved were held open into 2023 in an effort to continue processes and conversations until a resolution is achieved.

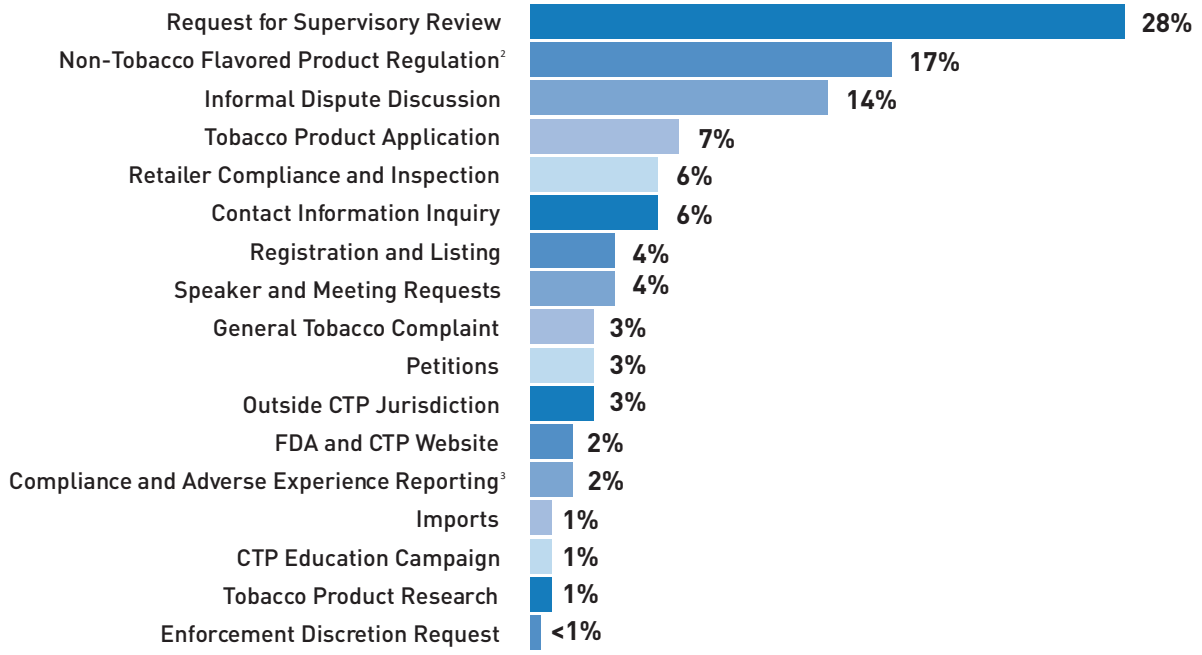


Compared to 2021 total contact sources, representatives on behalf of tobacco companies were up from 22%, manufacturers and retailers were down from 35%, consumers or general public were down from 26%, and government employees were down from 16%.

[1] Some contacts received may be opened in one calendar year and rolled over to the next until a resolution is reached.

CONTACT TOPIC OF INTEREST 2022

(Total greater than 100% due to rounding)



The contact source and topic of interest in a given year is most commonly a reflection of CTP actions and announcements (e.g. PMTA actions, announcements of proposed rules, etc.).

In 2021, enforcement discretion request were the most common contact topic (15%). In 2022, those became the least common while the primary topic of interest became manufacturer or tobacco company representatives requesting supervisory review filed pursuant to 21 CFR 10.75. The CTP Ombuds Team held several conversations with stakeholders discussing informal and formal disputes with CTP. Information was provided to these stakeholders regarding the appeals process, how to submit a CTP FOIA request and what to include on the supervisory review request.

Complaints regarding non-tobacco flavored product regulation for menthol and other flavored tobacco products were the second most common topic of interest.

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[2] Previously called Flavored Tobacco Product Regulation, the term Non-Tobacco Flavored Product Regulation incorporates both menthol and other flavored tobacco products.

[3] Previously called Compliance and Adverse Event Reporting, while the term event, effect, and experience are interchangeable, the CTP preferred language is Adverse Experience Reporting.

DISPUTE RESOLUTION PROCESS

Of the total requests for supervisory review:

- 108 total requests
- 49 new contacts
- 59 previous requests

Out of the 108 requests for supervisory review, 13% reached resolution[4]. The CTP Ombuds Team 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 requests for supervisory review.

The CTP Ombuds Team received numerous requests from both external and internal stakeholders to discuss dispute resolution. The process of supervisory review is utilized by external applicants after receiving a final agency action. Prior to submitting a request for supervisory review, the CTP Ombuds Team can discuss the process and potential outcomes of the review. The 21 CFR 10.75 supervisory review is an opportunity for stakeholders to dispute CTP's scientific determinations, allegations of misinterpretation of other data leading to a finding, or explanations of mistakes or procedural errors the appellant believes CTP has made.

The CTP Ombuds facilitates the Scientific Dispute Resolution process within CTP. If a disagreement is scientific in nature, and could adversely impact public health, CTP employees may discuss scientific disputes prior to initiation and have the option to initiate a formal dispute. During the discussion, the CTP Ombuds Team can discuss the review process and potential outcomes of the review. These disputes are a chance for CTP employees to formally voice their opinions on a scientific decision.

For more information about the external or internal dispute resolution processes, including how to submit an appeal, please contact the CTP Ombuds Team at CTPOmbudsman@fda.hhs.gov.

[4] *Some contacts received may be opened in one calendar year and rolled over to the next until a resolution is reached.*

Center for Tobacco Products
Ombuds Team

Nathan Hurley
Ombudsman

Arielle Patno
Associate Ombudsman

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 Ombuds 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
OMBUDS TEAM

FDA U.S. FOOD & DRUG ADMINISTRATION

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www.fda.gov/tobacco-products/contact-ctp/ctp-ombudsman

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