



**CTP
OMBUDSMAN'S
REPORT *2021***

CTP OMBUDSMAN'S 2021 REPORT

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 2021, including the number of contacts, topics of interest, their source, and comparison to the previous calendar year, 2020.

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 will 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 Team of 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, including 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).

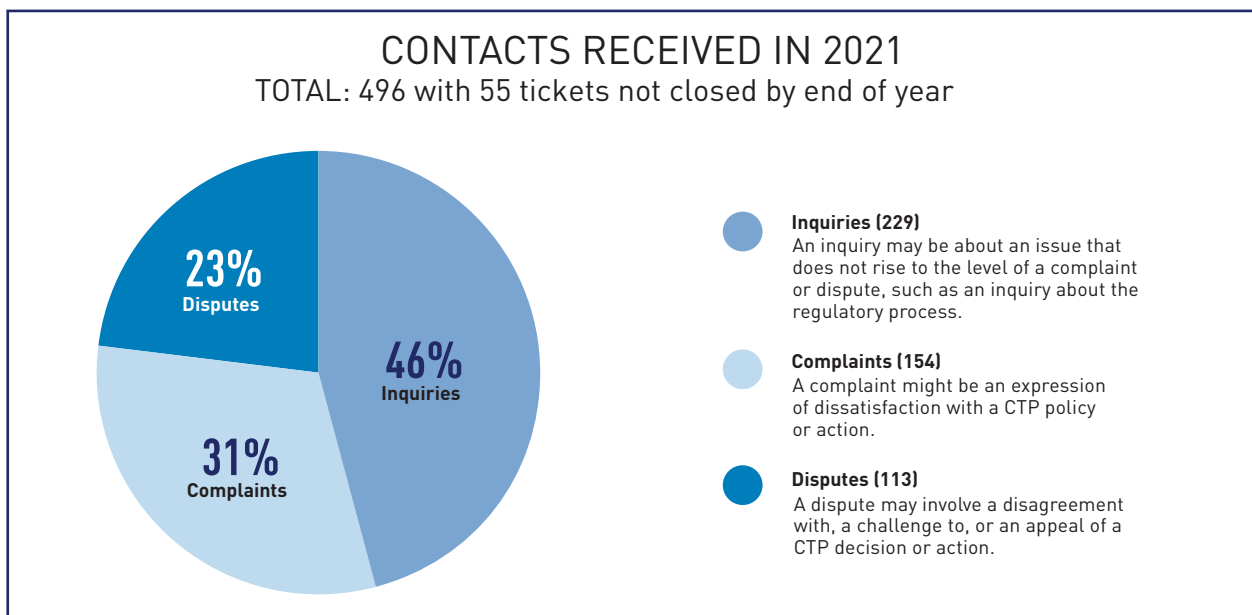
What issues will the CTP Ombuds handle?

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 Office 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 internal to CTP.

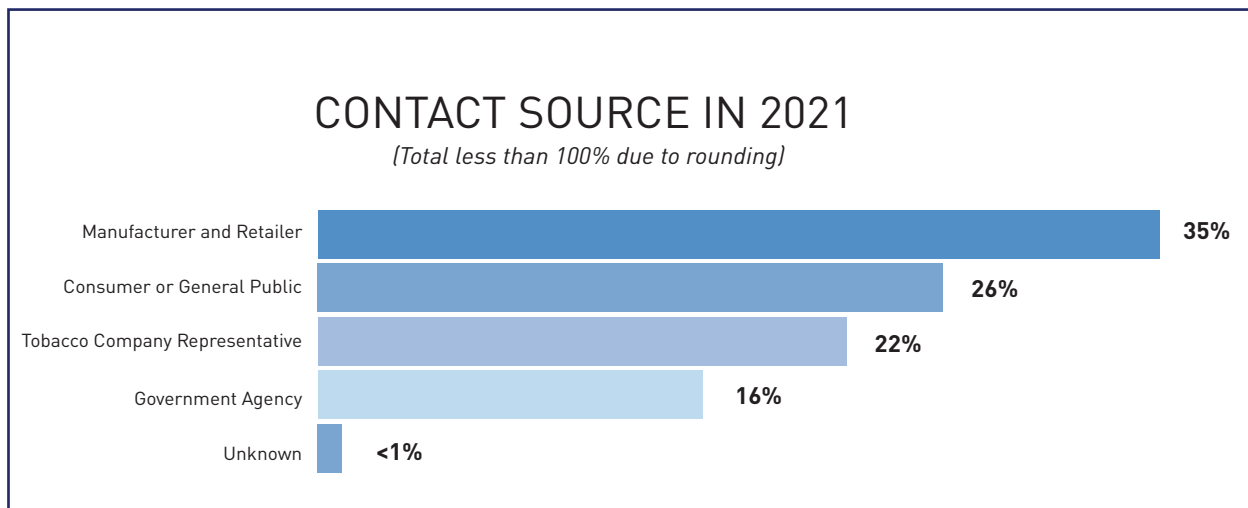
- Inquiry:**
An inquiry may be about an issue that does not rise to the level of a complaint or a dispute, such as an inquiry about the regulatory process.
- Complaint:**
A complaint might be an expression of dissatisfaction with a CTP policy or action. It might be a complaint about a tobacco manufacturer or retailer, or a consumer complaint about a product.
- Dispute:**
A dispute may involve a disagreement with a challenge to, or an appeal of, a CTP final agency action.

CONTACT TRENDS



In 2021, the CTP Ombuds Team received 496 contacts, an increase from 262 in 2020. Of the contacts received in 2021, 46 percent were inquiries (down from 60% in 2020), 31 percent were complaints (down from 34% in 2020), and 23 percent were disputes (up from 6% in 2020).

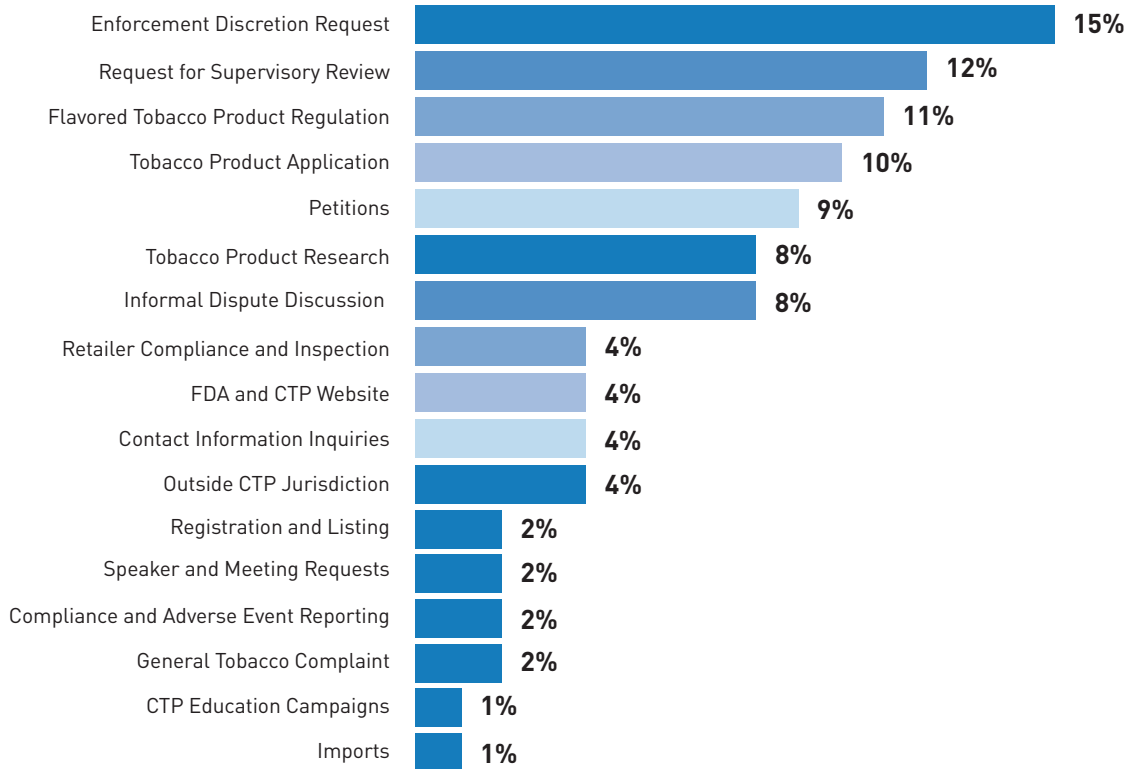
Of the contacts received in 2021, 89 percent reached resolution. This means the inquiry was either responded to, referred outside CTP, withdrawn, or had no follow-up by the initiator after 1 month; the complaint was addressed; or the dispute or appeal was resolved. In many instances, several phone calls 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. For contacts which did not reach a resolution in 2021, these were held open into 2022. Processes and conversations continue until a resolution is achieved which can carry over into another calendar year.



The majority of contacts came from manufacturers and retailers (35% in 2021, up from 24% in 2020). There was a decrease in the times we were contacted by the consumer or general public (26% in 2021, down from 34% in 2020) and tobacco company representative (22% in 2021, down from 33% in 2020). There was an increase in the number of contacts to the CTP Ombuds Team by government employees (16% in 2021, up from 6% in 2020).

CONTACT TOPIC OF INTEREST IN 2021

(Total less than 100% due to rounding)



The primary topic of interest during 2021 was manufacturers, retailers, or tobacco company representatives requesting enforcement discretion for their electronic nicotine delivery system products, and other deemed products on the market without premarket authorization that were required to comply with the September 9, 2020, court ordered deadline for submission of applications.

The second most common topic of interest included a request for supervisory appeals filed pursuant to [21 CFR 10.75](#), flavored tobacco product regulations, and applications of tobacco products currently submitted.

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

DISPUTE RESOLUTION PROCESS

CTP received 58 requests for supervisory review in 2021, an increase from 15 in 2020, and issued 14 center director decisions. 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.

In 2021, 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 present the merits as to why they do not agree with final action the agency took.

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 opposing 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.

Center for Tobacco Products Ombudsman's Team



Nathan Hurley
Ombudsman



Arielle Patno
Associate Ombudsman

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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
OMBUDSMAN'S OFFICE



FDA U.S. FOOD & DRUG
ADMINISTRATION



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