

CENTER FOR TOBACCO PRODUCTS



U.S. FOOD & DRUG  
ADMINISTRATION

# CTP OMBUDSMAN'S REPORT *2023*

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## OMBUDS IN PRACTICE

The U.S Food and Drug Administration (FDA) Center for Tobacco Products (CTP) Ombudsman (Ombuds) serves as a confidential, impartial, independent, and informal resource that assists internal and external stakeholders. The CTP Ombuds' goal is to provide a "safe space" to investigate and settle disputes, resolve complaints, ask clarifying questions, determine desired outcomes, discuss options forward, and facilitate stakeholder communication.

Externally, the CTP Ombuds answers inquiries, acknowledges complaints about CTP's regulatory process, redirects contacts to the appropriate office, discusses dispute resolution options, and serves as an unbiased resource to stakeholders. Internally, the CTP Ombuds works toward CTP's mission and goals, helps develop guidance, facilitates the scientific dispute resolution process internal to CTP, and provides FDA staff with informal advice.

While maintaining independence by operating outside the business chain of command, the CTP Ombuds responds to inquiries and investigates complaints and disputes from all stakeholders. The CTP Ombuds acts as a source of early detection for emerging system-wide issues and works with CTP leadership on ways to assure that CTP's procedures, policies, and decisions are fair.

The CTP Ombuds follows a code of ethics and operating principles drawn from those established by the Coalition of Federal Ombuds, the United States Ombudsman Association, and the International Ombuds Association.

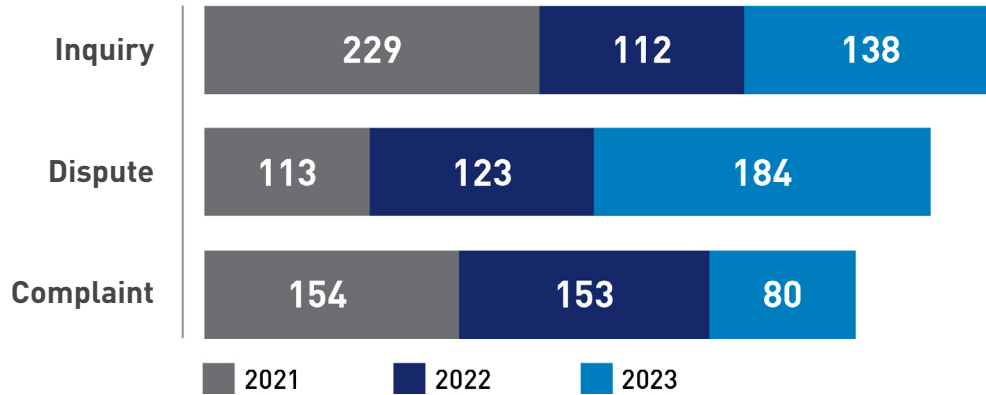
This report summarizes the CTP Ombuds' role in addressing the inquiries, complaints, and disputes received for the calendar year 2023, including the number of contacts, contact stakeholder, topics of interest, and comparisons to previous calendar years.

## CONTACT TRENDS

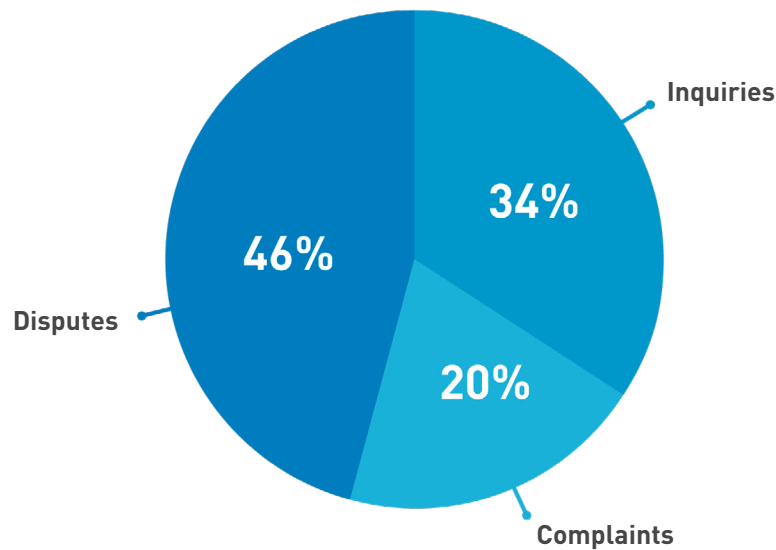
A contact addressed can be defined as any interaction between the CTP Ombuds and an external or internal stakeholder. The CTP Ombuds categorizes the contacts it addresses into disputes, complaints, and inquiries:

- **Disputes** may involve a disagreement with, a challenge to, or an appeal of a CTP decision or action.
- **Complaints** may be an expression of dissatisfaction with a CTP policy or action.
- **Inquiries** may be about an issue that does not rise to the level of a complaint or dispute, such as an inquiry about the regulatory process.

CONTACTS ADDRESSED IN 2021 - 2023



CONTACTS ADDRESSED IN 2023

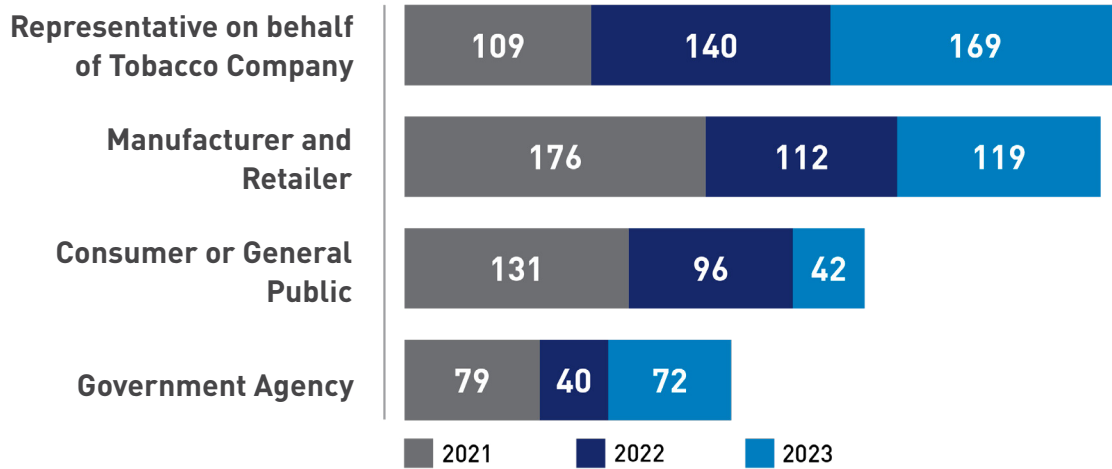


**The stakeholders that contact the CTP Ombuds include: <sup>1</sup>**

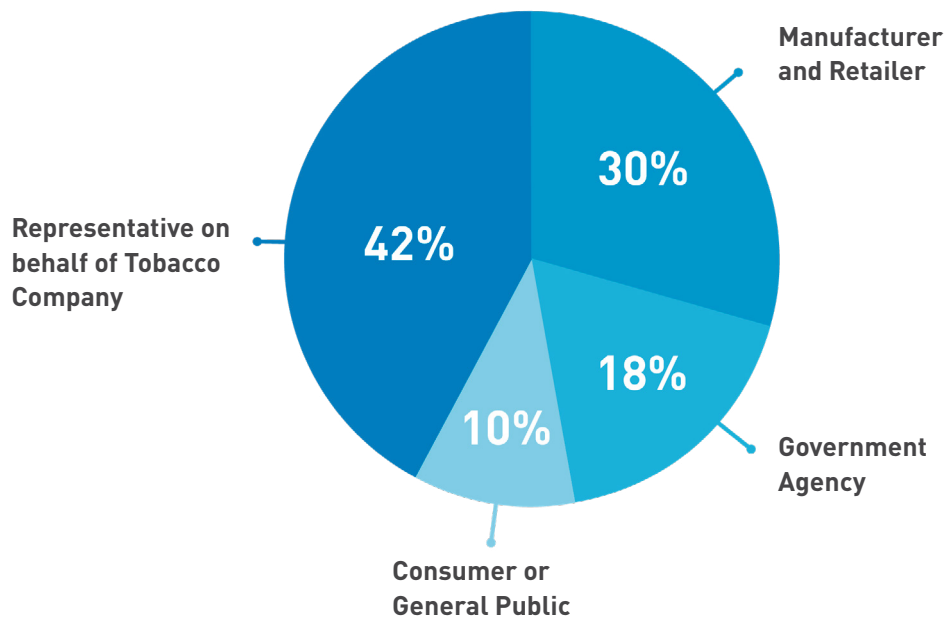
- law firms or consultants representing the tobacco industry
- tobacco manufacturers and retailers
- public health groups, research institutions, health care providers, and consumers
- local, state, and federal government personnel

<sup>1</sup> The CTP Ombuds previously categorized additional stakeholders in 2021 and before as unknown, importer or exporter; these categories have since been retired and rolled into current terminology.

CTP OMBUDS STAKEHOLDERS IN 2021-2023



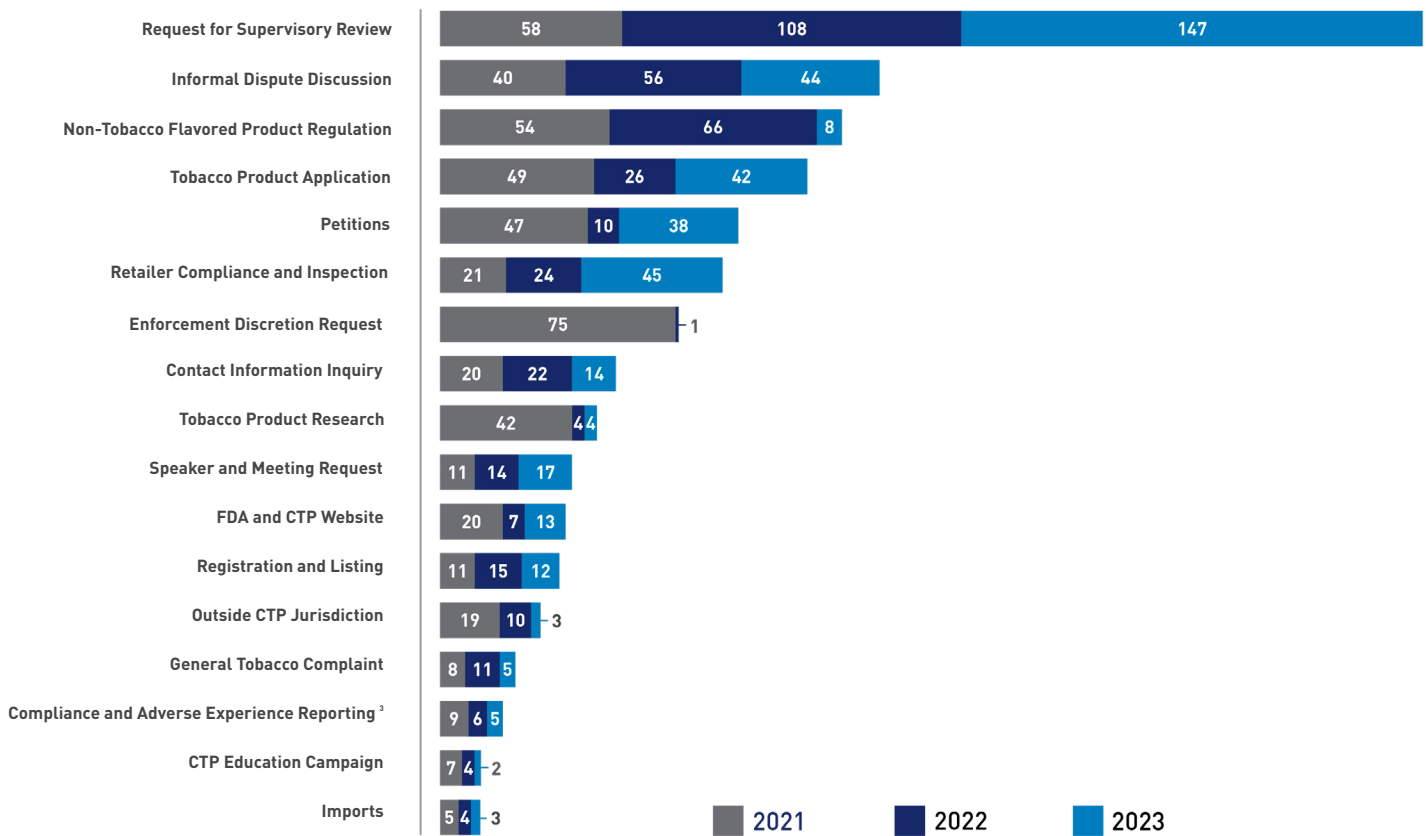
CTP OMBUDS STAKEHOLDERS IN 2023



Of the 402 contacts that the CTP Ombuds addressed in 2023, 79% reached resolution.<sup>2</sup> For inquiries, resolution means:

- CTP Ombuds responded to the inquiry
- CTP Ombuds referred the inquiry outside of CTP
- The stakeholder withdrew the inquiry
- The stakeholder did not follow up

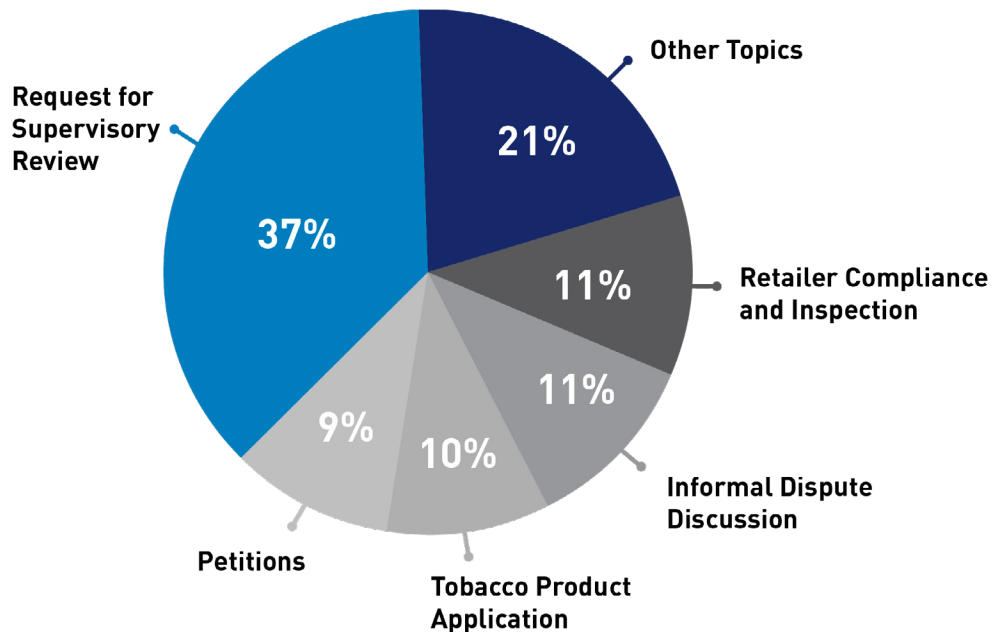
### CONTACT TOPICS OF INTEREST 2021 - 2023



<sup>2</sup> Some contacts received may be opened in one calendar year and rolled over to the next until a resolution is reached.

<sup>3</sup> Previously called Compliance and Adverse Event Reporting, while the term event, effect, and experience are interchangeable, the CTP preferred language is Adverse Experience Reporting.

## TOP FIVE TOPICS OF INTEREST 2023



For complaints or disputes, resolution means the matter was addressed or the associated appeal was resolved.

Although the CTP Ombuds may exchange several phone calls or emails with a single stakeholder, these follow-up correspondences are counted as a single interaction for the purposes of the annual report unless substantially different issues were raised. Inquiries, complaints, and disputes that were not fully resolved were held open into 2024 to continue working towards reaching a resolution.

The distribution of stakeholders contacting the CTP Ombuds and topics of interest each year commonly reflects CTP's actions and announcements that year (e.g., premarket tobacco product application actions, announcements of proposed rules.)

## DISPUTE RESOLUTION PROCESS

### Of the 147 total requests for supervisory review in 2023:

- 53 were new requests
- 94 were requests started in previous years
- 46% reached resolution <sup>4</sup>

The primary topic of interest in 2022 and 2023 was a request for supervisory review filed pursuant to **21 CFR 10.75**, which states that “An interested person outside the agency may request internal agency review of a decision through the established agency channels of supervision or review.” A supervisory review is an opportunity for stakeholders, such as manufacturer or tobacco company representatives, to present why they do not agree with the agency’s final action. The CTP Ombuds helps to resolve requests for supervisory review, and other CTP staff assist with processing and managing requests. In 2023, CTP published a **webpage with information on the supervisory review process**.

The CTP Ombuds also facilitate the internal scientific dispute resolution process, which is when CTP employees disagree with a scientific decision and believe that decision could adversely impact public health. These disputes are opportunities for CTP employees to formally voice their opposing opinions on a scientific decision.

In 2023, numerous external and internal stakeholders requested to discuss dispute resolution processes with the CTP Ombuds before submitting official disputes. Before external applicants submit requests for supervisory review, the CTP Ombuds and external applicants can discuss the process, how to submit **online Freedom of Information Act requests to FDA**, what to include in the supervisory review request, and potential outcomes of the supervisory review. A number of external applicants who request information for supervisory review do not submit an official appeal. Before internal stakeholders submit scientific disputes, the CTP Ombuds can confidentially discuss the dispute process, how to begin the process, and potential outcomes of a dispute.

For more information about the external or internal dispute resolution processes or how to submit an appeal, please contact the CTP Ombuds at **[CTPOmbudsman@fda.hhs.gov](mailto:CTPOmbudsman@fda.hhs.gov)**.

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<sup>4</sup> Some of the requests for supervisory review may have been opened in one calendar year and rolled over to the next until resolution is reached.

## Center for Tobacco Products Ombuds 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 TEAM**



**FDA** **U.S. FOOD & DRUG**  
ADMINISTRATION



301.796.3095



CTPOmbudsman@fda.hhs.gov



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