

# ONE WAY TO ENGAGE WITH FDA'S CTP: THE OMBUDSMAN'S OFFICE

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*Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.*

**CENTER FOR TOBACCO PRODUCTS**

# OVERVIEW OF TODAY'S PRESENTATION

- Role of the Ombudsman
- When to Contact the CTP Ombudsman
- Inquiries, Complaints, Disputes
- Q&A

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# THE OMBUDSMAN PRINCIPLES



We follow a code of ethics and operating procedures drawn from those established by the Coalition of Federal Ombudsman, the United States Ombudsman Association, and the International Ombudsman Association. These principles include *independence, impartiality, objectivity, and confidentiality.*

We are set up to receive and review complaints (in an informal manner) about CTP and seek to mediate, or otherwise resolve these disputes between CTP and outside entities. Where and when appropriate, we may make recommendations to external parties or CTP on a course of action to a potential resolution.

Part of our role is to promote good government practices, fairness, transparency, and accountability.

# WHEN TO CALL US



- When possible, try to *first* resolve any complaint or dispute with your point of contact in the CTP office involved
- We are here to listen to anyone who contacts my office
- If we are not the right resource, we will try to find it

# WHY EXTERNAL PARTIES CONTACT THE OMBUDSMAN'S OFFICE



- *We Listen*, informal, efficient, saving resources
- Assess difficult situations, identify options
- Improve communications and working relationships
- Deep understanding of Center operations
- Adept at interacting with FDA staff
- Respond to simple inquiries and informally look into complaints
- Facilitate de-escalation of conflicts between CTP and outside parties
- Discuss informal dispute resolution options
- Can be an unbiased sounding board, recognizing that we *are* CTP employees

# WHAT TO EXPECT FROM THE OMBUDSMAN'S OFFICE



- To listen, ask questions (including desired outcome), and review possible options
- To get involved informally at any stage in the Center's decision-making process by request
- Telephone call, formal meeting, informal emails or conversations
- May keep your identity confidential for some or all of the process (unless threats to self/others made)
- We are available to provide informal advice on the formal appeal process (21 CFR 10.75)
  - Informally provide options other than appeal, possible outcomes, clarification, manage expectations, etc.

# WHAT TYPES OF CONCERNS DO WE HEAR ABOUT



- You haven't heard back from your point of contact
- You've raised a concern with a CTP office, but it still has not been resolved
- You have an issue to discuss, but you're unsure with which office to request a meeting or whom to speak with
- You have feedback to provide about CTP's processes
- There's a topic you'd like to discuss anonymously
- You have questions or need counselling of a CTP decision prior to filing a formal appeal under 21 CFR 10.75
- You have general inquiries that may not fit a specific office or CTP process

Remember: any party may ask us to sit in at any stage of a process without retaliation

# HOW DO WE MAINTAIN CONFIDENTIALITY?



Communications with the CTP Ombudsman are kept confidential by request except in rare instances such as risk of injury to self or others.

Keep in mind, it may be difficult to move forward with a complaint if you request that your identity be kept in confidence. In such cases, we may request permission to disclose identifying details about you.



# WHAT'S THE ISSUE?



We are also interested in hearing about the effectiveness of CTP's programs and about problems that may be getting in the way of carrying out the Center's regulatory responsibilities.

We welcome this input as it helps CTP to continually assess and improve the work that it does.

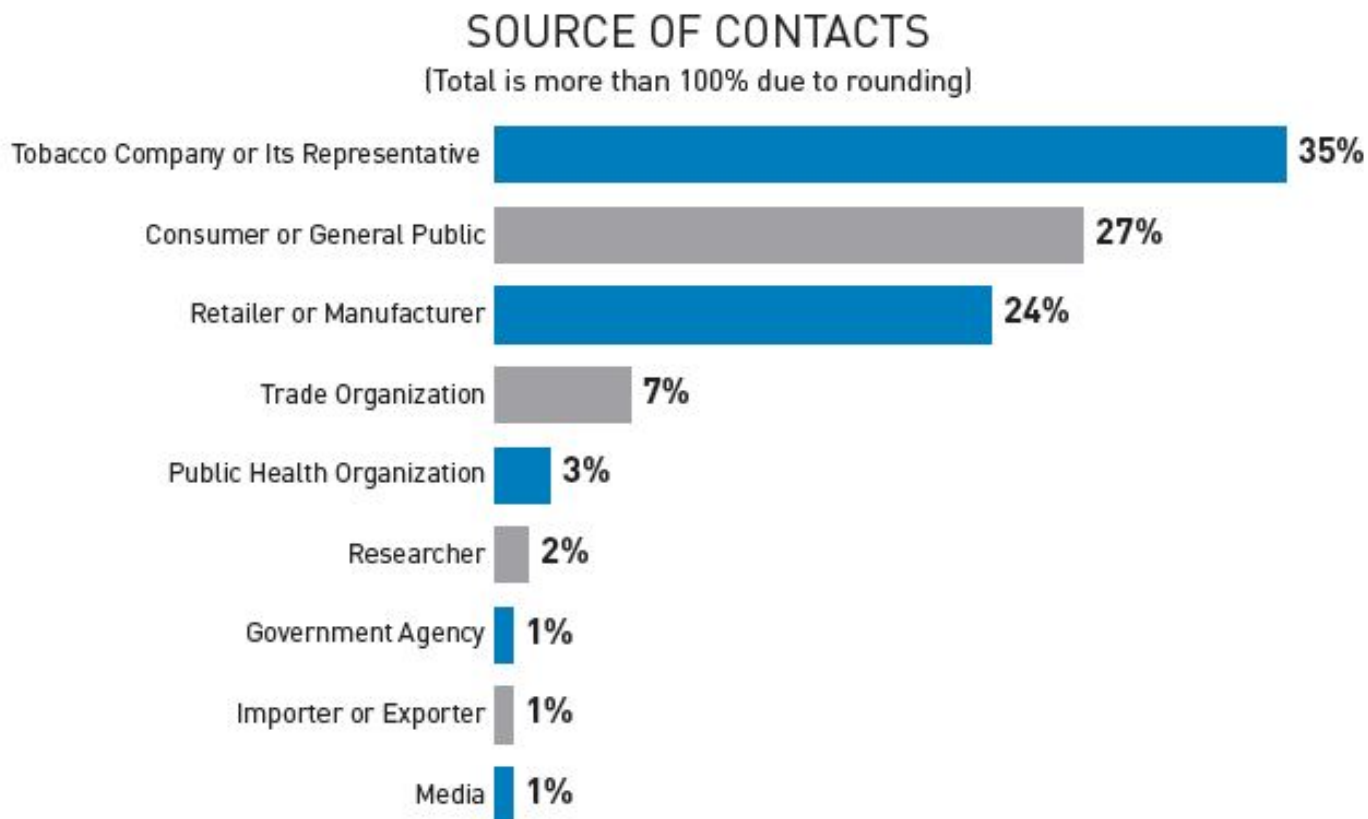
- We cannot:
  - Become anyone's personal advocate
  - Violate trust (of FDA employees or external parties)
  - Overturn a decision or action; or force anyone to do so
  - Become involved with cases in litigation
  - Violate the Ombudsman ethics and operating principles

# CTP OMBUDSMAN'S ANNUAL REPORT - 2016

# WHO CONTACTED US IN 2016?

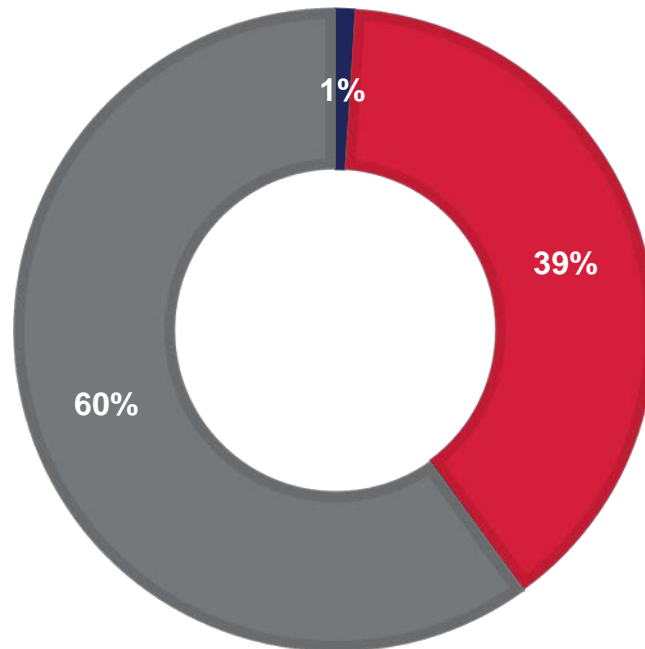
You can find our 2016 Annual Report on the CTP website by searching for Ombudsman Annual Report or clicking:

<https://www.fda.gov/downloads/TobaccoProducts/AboutCTP/ContactUs/UCM546047.pdf>.



## CONTACTS RECEIVED IN 2016

■ Disputes ■ Complaints ■ Inquiries



Total: 320

# OTHER PATHWAYS FOR CORRESPONDING WITH CTP



## General Information

If you have questions, contact [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov) or 1-877-287-1373 (9am EST-4pm EST).

All written correspondence, including regulatory correspondence, should be sent to the following address:

Center for Tobacco Products  
Attn: Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

## Center Email Addresses

Tobacco Industry Questions: [TobaccoIndustryQuestions@fda.hhs.gov](mailto:TobaccoIndustryQuestions@fda.hhs.gov)

Small Business Industry Questions: [smallbiz.tobacco@fda.hhs.gov](mailto:smallbiz.tobacco@fda.hhs.gov)

Formal Correspondence, Speech and Meeting Requests: [ctpexecsec@fda.hhs.gov](mailto:ctpexecsec@fda.hhs.gov). Submit a proposed agenda and attendee list

Stakeholder Relations Office: [CTP-StakeholderRelations@fda.hhs.gov](mailto:CTP-StakeholderRelations@fda.hhs.gov)

To contact the Ombudsman, email: [ctpombudsman@fda.hhs.gov](mailto:ctpombudsman@fda.hhs.gov) or call 301-796-3095

## CTP Website

- Sign up for regular updates; CTP News, CTP Connect, and Spotlight on Science
- Webinars, trainings, publications, tweets
- Warning letters, SE/NSE decisions, etc.
- Guidance, regulations, opportunities to comment

## CTP Ombudsman Website

- Learn more about who we are and what we do
- Read our annual reports (2012 through current publication)

## Freedom of Information (FOIA) Website

- Familiarize yourself with what the Federal Government can/can't share and why
- Read FAQs
- Learn how to make a FOIA request

QUESTIONS?

FDA

