RAPS' Regulatory Convergence

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Dispute Resolution with CDER

Options and Considerations

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RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

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Website includes annual reports and FAQs

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ContactCDER/CDEROmbudsman/default.htm

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CDER Ombudsman Mission

To quickly and impartially investigate complaints and resolve disputes between CDER and CDER-regulated industry, health care practitioners, and consumers by offering an informal, confidential, and neutral environment.

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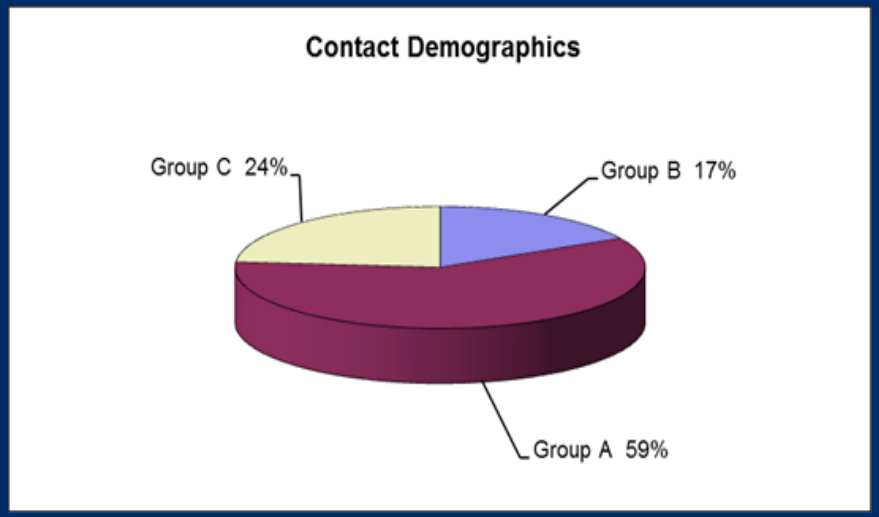
2014 Statistics

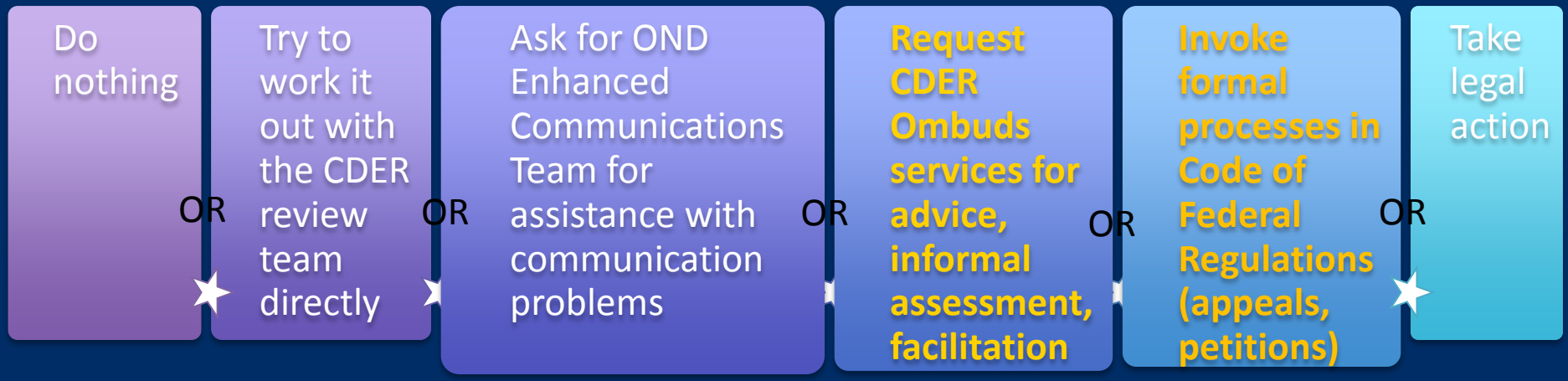
- 322 communications
  - A: Industry (sponsors, law firms, consultants)
  - B: Consumers, health practitioners, advocacy
  - C: FDA employees



Dispute Types

- Regulatory, scientific, administrative
- Industry trends noted in Ombudsman's annual reports. Examples from 2014:
  - Decision or response delays
  - Import detentions
  - GDUFA implementation (generic drug applications)
  - Interpretation of tentative final monographs
  - Inspection report delays
  - Whistleblowers (clinical sites, manufacturing)

What Are My Options?



What Does the Ombudsman Do?

- Receive and investigate complaints
- Help think through options and advise
- Exercise diplomacy
- Ferret out misunderstandings
- Promote good government. Fairness, transparency, accountability
- Report systemic issues; propose solutions

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Operating Principles and Ethics

- **Confidential**. If requested, holds all information confidential unless imminent harm is evident.
- **Neutral & Impartial.** Remains free from bias and treats all parties without prejudice.
- **Informal**. Voluntary; No formal investigations or binding decisions or mandates.
- **Independent.** CDER Ombuds is free from outside control or influence as much as possible.

Consider Before Contacting Ombudsman

- What attempts have you made to work it out with the decision-maker or Division?
- What exactly are you disputing?
- Was an official decision rendered?
- Information disclosure
  - FOIA exemptions
  - Some information already public (e.g. dockets)
  - Ombudsmen keep few formal records

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Consider Before Contacting Ombudsman

- History of the dispute and company culture
- Working relationships with Agency
- Time and Money
  - Legal and consultant costs, loss of sales
  - Statutory/regulatory/administrative time constraints

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What is the Ombudsman's Process?

- No formal submission needed
- Listen to complaint
- Ask about history
- Ask about desired outcome
- Review options
- If choose to use Ombuds, the Ombuds:
  - May request documentation or summary
  - Talk to FDA staff

The Ombudsman will NOT

- Become your personal advocate
- Violate trust of FDA employees
- Overturn a decision or action or force anyone to do so
- Engage in a matter that is in litigation or in formal appeals process
- Violate operating principles

Why Use the Ombudsman?

- Informal and efficient, saving money and time
- Improve communications and working relationships
- Sounding board; opportunity to explore options
- Deep understanding of operations and can help industry navigate complex FDA
- Adept at interacting with FDA staff
- Unique position: high level but not management

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What Does Resolution Look Like?

- Ask for A, B, C, get A, B, C
- Ask for A, B, C, get D and E
  - Develop alternative approaches and path forward

Applies to both formal and informal routes

Formal Dispute Resolution

- Requests supervisory review of decision
- Appeal progresses up the supervisory chain
- Guidance: “Formal Dispute Resolution: Appeals Above the Division Level”

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Formal Processes Outside Centers

- Office of Regulatory Affairs
  - Current good manufacturing practice requirements appeals, Guidance "Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP"
  - Import/customs issues
- Office of Commissioner
  - e.g. Part 12 hearings, 21 CFR Part 3 Request for Designation (reconsideration of product jurisdiction designation), certain petitions

Key Messages

- Ombudsman's role exists at FDA
- Try to work out your issue at the source (working level)
- Take time to think through your options
- Be realistic about what you might achieve with the different options
- Avoid "buckshot" approach

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