

# Transparency by FDA

Session: Transparency - Who is Imposing  
Disclosure Requirements and What is being  
Required?

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FDLI's Enforcement and Litigation Conference

October 14, 2009

# Agenda

- 1. Policy-making v. adjudication**
2. Transparency in policy-making
3. Transparency in adjudication and individual decision-making



# Transparency in Administrative Functions

- For an agency like FDA, two basic administrative functions should be transparent:
  1. Rule and policy-making
  2. Individual decision-making and adjudication.
- Good guidance is transparency!

In the interests of transparency,  
these are the views of the  
Combination Products Coalition



# Rulemaking v. Guidance v. Adjudication

Factor	Rulemaking	Guidance	Adjudication
Purpose	Broad delineation of law	Broad delineation of agency expectations	Person-specific decision applying law
Example	CFR	Guidance	Approval decision or enforcement decision
Legal Effect	Binding law	Persuasive and instructive	Binding on affected individuals
Governing Law	APA	GGP section of FFDCA	APA and FFDCA
Process	Rigorous notice and comment	Notice and comment “lite”	Due process

# Agenda

1. Policy-making v. Adjudication
- 2. Transparency in policy-making**
  - A. Rule making**
  - B. Guidance development**
3. Transparency in adjudication and individual decision-making



# Vast Improvements Made with GGPs

<b>Before GGPs</b>	<b>After GGPs</b>
Guidance lacking in detail and comprehensiveness	Consistently higher quality guidance
Outdated drafts	Avoided superseded drafts
No clear agency sign off/support	Clarified agency sign off and support and improved developing cross-center guidance
Hard to find	Much easier to find on the agency's website
Frequently used speeches to announce new policy	Fewer instances of "podium policy"
Implemented while in draft form	Guidance clearly marked with regard to draft status (though sometimes still applied in this form)
Applied as rules	Guidance clearly phrased as non-binding recommendations
Often not responsive to the public's needs for clarity	Sometimes more responsive to the public's need for clarity; for example, publishing the annual guidance development plan

# More improvements needed

- CPC is proposing that it is time for GGPs 2.0
- Based on substantial outreach to other groups, CPC has identified 8 areas where further improvements are needed to policy-making transparency



# Needed Transparency

**1. Embrace** the idea that the agency can freely communicate with the public before and during the guidance development process outside the notice and comment mechanism.

- o Informal rulemaking does not preclude contact between the agency and the public
  - Even clearer before the proposed rule is published
  - But it is wise to keep records
  - Also, FDA cannot give advanced notice of what is in a proposed rule (fairness issue)
- o Guidance development rules contain no restrictions on meetings with the public
  - The FR notices announcing the GGP's explained the goal of facilitating early communication.



# Needed Transparency

## 2. Producing more guidance.

- Many critical areas where guidance needed to clarify agency objectives
- The agency has made recent progress
  - Combination product proposed rules
  - REMS guidance
- But more is needed
  - Companion technologies
  - Internet promotion
  - Adaptive trial design



# Needed Transparency

- 3. Adopting** procedures designed to ensure that the content of guidance addresses the public's key questions.
- Sometimes guidance addresses agency's theoretical concerns and doesn't quite reach the "practical" issues
    - Good Importer Practices
    - Injector guidance for devices and combination products
    - IVDMA Guidance



# Needed Transparency

## 3. Adopting procedures (con't)

- Design control principles could help ensure agency guidance meets stated objectives

Quality System Design Controls	Guidance Development Processes
Design and development planning	Decision-making on the need for guidance
Design input, including assessing user requirements	Identifying the needs of the intended audience, including the agency and the public if both are intended
Design output	First draft of the guidance
Design review	Comment opportunity
Design verification and validation	Testing the final draft by allowing agency leadership to review through the prism of the comments and by stakeholder use of the guidance
Design transfer	Publication of final guidance document

# Needed Transparency

## 4. **Responding** to comments.

- o Ideally, written preamble responding to comments in final guidance
- o Benefits
  - Clarify agency thinking; help public better understand the guidance
  - Encourage future comments
  - Help persuade stakeholders to comply by providing a rational basis for compliance



# Needed Transparency

## 5. Finalizing draft guidance.

- o Some seem to be left in draft interminably
  - Recent informal review of CDER guidances showed that 64 left in draft form after at least 5 years
  - Specific examples
    - Bioengineered food
    - Drug adverse events – succession of draft guidances
- o Little incentive to finalize due to non-binding nature
- o Some proposed rules also left in draft too long



# Needed Transparency

- 6. Employing** metrics designed to track the agency's progress in guidance development.
- o Overall volume of guidance documents published in final, broken down between the two levels and by the issuing office.
  - o Average duration a guidance stays in draft, with further reporting on those that exceed 1 year, 2 years, 3 years, etc
  - o Number of pending guidance documents proposed or requested by the public and the average time until they are fully addressed.
    - Would also be useful for tracking citizen's petition responses.
  - o Number of meetings (conference calls, etc) held with public to discuss guidance development.



# Needed Transparency

## 7. **Continuing** to avoid “podium policy”

- o GGPs prohibit agency from informally communicating new or different regulatory expectations to a broad public audience for the first time
- o Avoid using speeches, warning letters and other such communications to announce new policy that should be in guidance.



# Needed Transparency

- 8. Investing** more time in planning guidance development.
  - o More proactive in planning guidance topics
  - o Follow the plan – recently the annual guidance development plan has not been realistic



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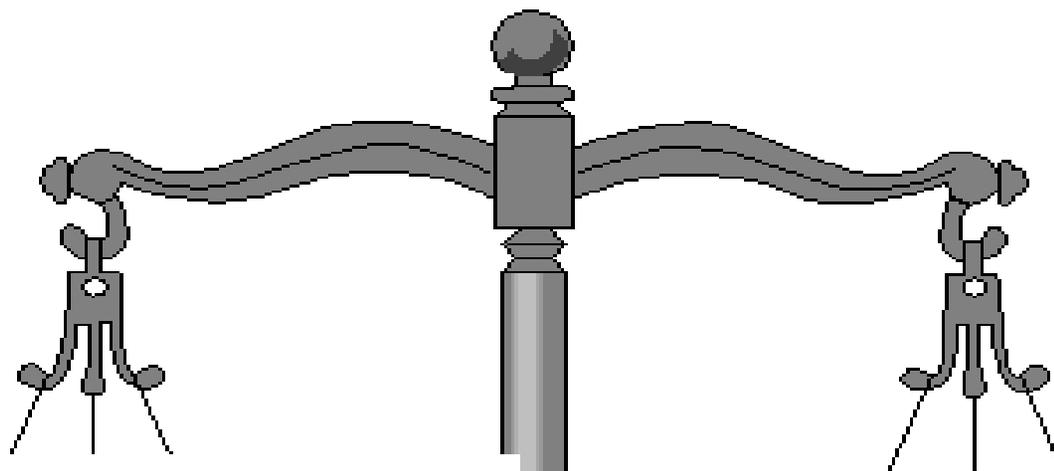


# Needed Transparency

- **Preserve** access to carefully chosen regulatory information while maintaining rights of information owners.
  - o Regulatory information is distinct from company information
  - o Protection is for both government and information submitters
    - Voluntary, reliable submissions
    - Preserves competitive advantages



# Striking a Balance: Freedom of Information Act



## Agency records and information

- Enforcement letters
- Inspectional observations
- Approved marketing applications
- Jurisdictional information
- Product recalls
- Safety events

## Trade secrets and confidential commercial or financial information

- Scientific and technical data
- Product development plans
- Records reviewed during inspections

# FDA's Recent FR Notice

- Announces meeting on Nov. 3
- Appears exclusively focused on individual adjudication.
- Three panels on:
  1. Emerging safety issues concerning FDA-regulated products,
  2. Product applications that are abandoned or withdrawn by the applicant before approval, and
  3. Agency decisions about pending product applications.
- Observes that witnesses should not feel constrained by the statutes or regulations
- FDA transparency in policy-making is not on the agenda



# Questions?

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