



What CDER Can & Can't Do

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Our discussion for today

- CDER Mission
- Opportunities for Engagement with CDER
 - *Types of Engagement*
- Value of Patient Engagement
- What CDER can't do or say



CDER's Public Health Mission

CDER's mission is to:

- Promote and protect public health by assuring that safe and effective drugs are available to Americans

Ultimately, patients are the focus of all CDER activities and we need to engage with them





Opportunities for Engagement at CDER

- External Stakeholder Meeting Requests (ESMR) System
- Patient-Focused Drug Development meetings (PFDD)
 - Focused on better understanding the disease and patient experience.
- Advisory Committee Meetings
 - Open Public Hearing Portion
- Patient Representative Program
- Ad hoc FDA meetings
 - Typically scheduled with the Review Division





Opportunities for Engagement at CDER

(continued)

- Citizen Petitions
- Comments to the docket for Federal Register Notices
- Guidance development
- Emails, letters and phone calls





Why Patient Recommendations are Valued



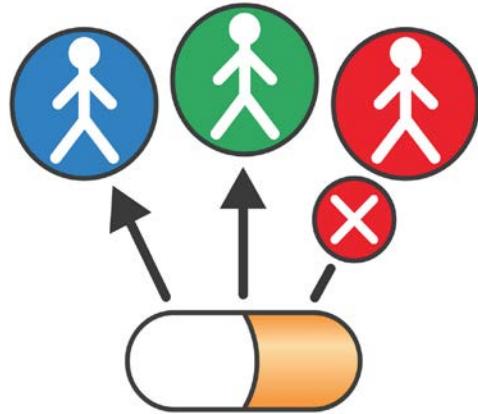
Patient Voice



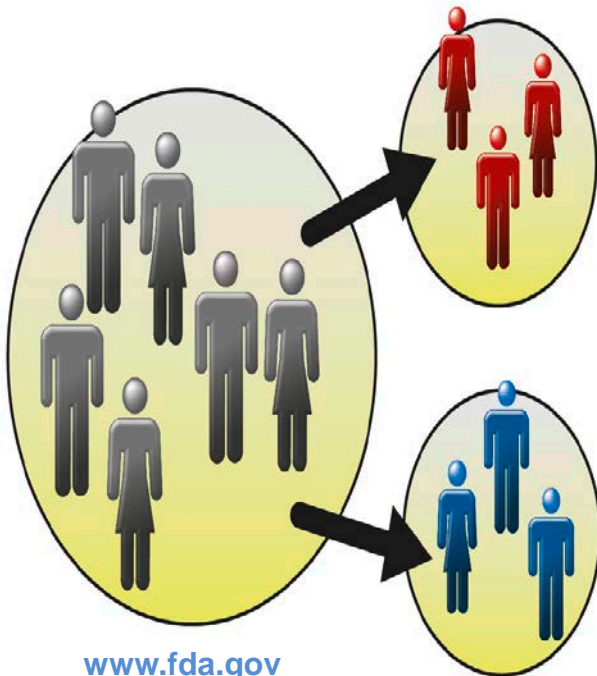
- Identify what matters/what is important to patients
- Benefit in development of clinical trials that are meaningful and realistic
- Raise FDA's Awareness



The Value Patient Engagement Adds



- Patient input can direct drug development in many ways:
 - helps with the understanding of diseases and their impact
 - helps identification of specific symptoms that are significant to patients
- Helps design better clinical trials



We want to hear from you...



Transparency, The Law, and Confidentiality (What we can't do or say)



THE FDA CODE OF FEDERAL REGULATIONS

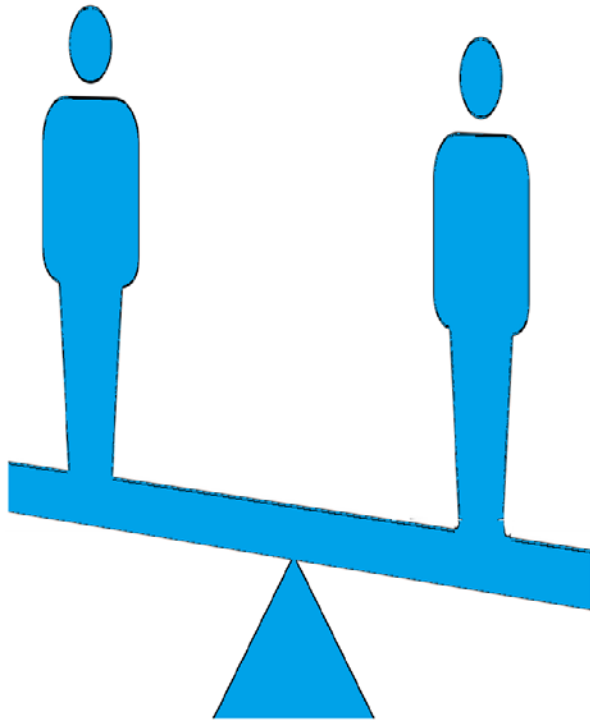
- ◉ FDA Code of Federal Regulations (CFR) is a huge sea of regulations that the FDA has created for regulating all products that come under its purview of regulation. The FDA codes of federal regulations are numbered and cover all products, processes and the activities that go into their creation.





Bias, Fairness, and Consistency

- Avoid bias to one company over another
- Focus on the specific scientific facts presented
- Meetings are granted free of bias
- Fairness, and consistency
- Open dialogue with patients and industry
- Points of view connected with sponsor support (financial for example) may have less credibility





Patient Recommendations are Valued, But...We Can't Always Follow Them

- Statute
- Differences of opinion on interpretation of underlying facts
- Differences in views on practicality
- Conflict with laws or regulations creating legal risk
- Inconsistency with policy position or previous decisions
- Evolution of underlying data



Thank you



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