



FDA Engagement with Patients

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Opportunities for Engagement

- Patient Focused Drug Development meetings
- Advisory Committee
 - Patient Representative
 - Public speaker
- Citizens Petition
- Comments to the docket for Federal Register Notices
- External meetings, ad hoc FDA meetings
- Guidance development
- Emails and letters

Transparency, the Law, Confidentiality

- FDA desires to be transparent but often can't be because of the law
- We operate under strict laws regarding confidentiality in regard to our knowledge, opinions, and interactions with sponsors during drug development and review
- This greatly restricts our ability to discuss specific products that are under review or development
- This is designed to protect sponsors from disclosure of commercially sensitive information

Bias, Fairness, Consistency

- We must try to be consistent in our approaches and avoid showing bias to one company over another, rather must focus on the scientific facts presented to us
- Similarly we try to incorporate and dialogue broadly with patients and industry and not just deal with one group vs another.
- Points of view that are associated with sponsor support (financial for example) may have less credibility



Your Recommendations are Valued, But....We Don'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