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