Strategies for Preparing for Meetings with FDA

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Presentation Goals

- Overview of Types of Sponsor Meetings
- Sponsor Best Practices
- Pitfalls to Avoid

Sponsor – FDA Meetings

PDUFA 2 Defined 3 Types of Meetings:

- Type A
  - Needed Immediately for Otherwise Stalled Development Program
- Type B
  - Pre-IND, End-of-Phase II, Pre-NDA Meetings
- Type C
  - Any Other Meeting Not a Type A or Type B

Managing the Project Team

Identifying the Need for an FDA Meeting:

- What Questions Do We Need Addressed?
- When Do We Need It?
- Do We Need a Face-to-Face Meeting? Is a Teleconference an Option?
- What is the Goal of a Meeting?
- What is the Desired Outcome?

Pre-IND Meetings

Special Considerations:

- First-in-Man or Phase II/III Study
- Design and Scope of Nonclinical Program
- Fast-Track Designation Request
- Orphan Drug Designation Request
- Specific Safety Issues

Not Needed for Every Drug

End of Phase II Meetings

- Agree on Efficacy Criteria for Phase III Studies That Will Be Basis of Approval
  - Endpoints
  - Duration of Studies
  - Number of Studies
  - Comparators
- Agree in Principle That Studies Will Support Target Indications
- Discuss Pediatric Requirements
- Identify Any Other Requirements

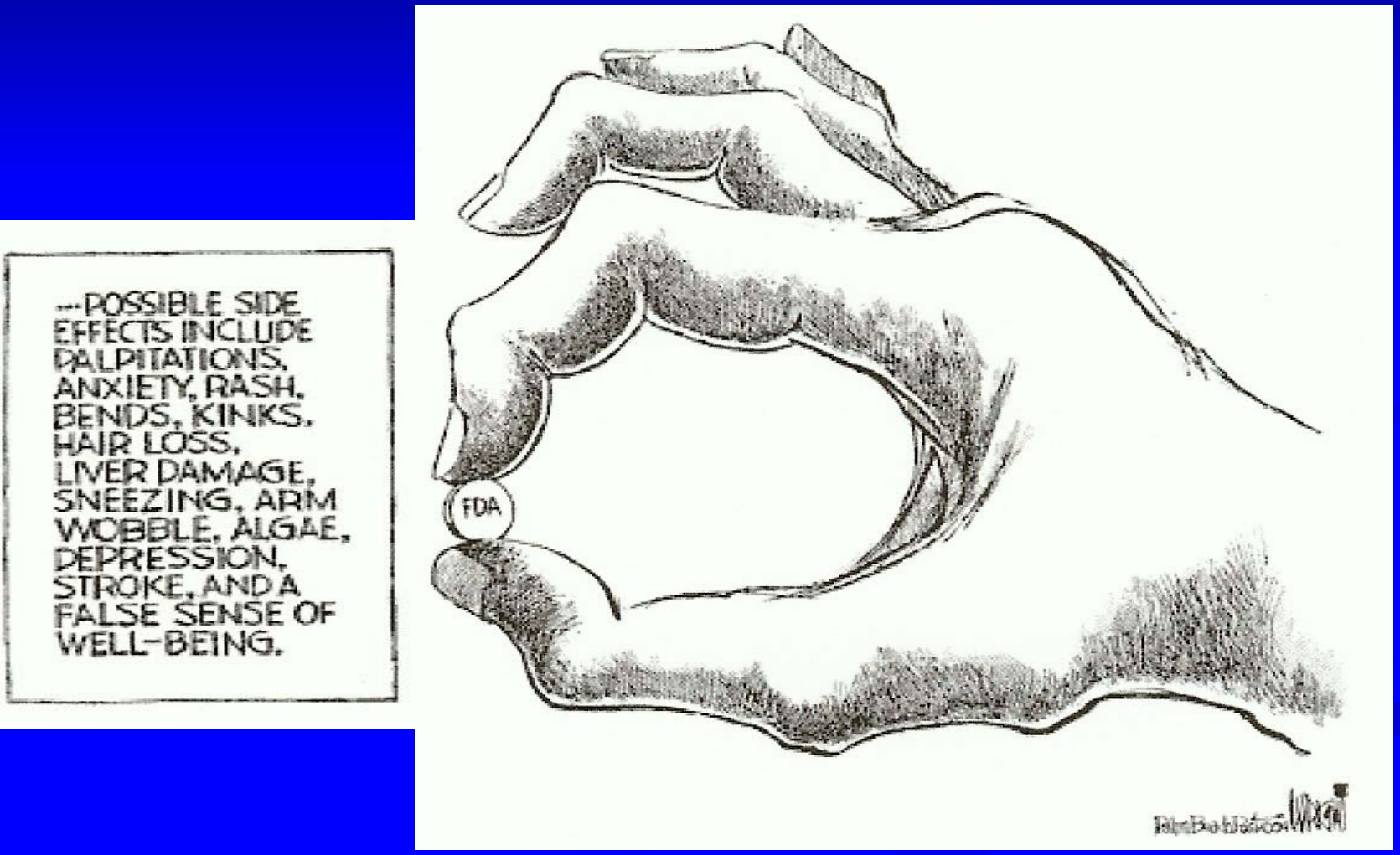
Pre - NDA Meetings

- Format and Content of NDA
  - Efficacy and Safety Data Presentations
  - Statistical Analyses
  - Datasets and Programs
- Electronic or Paper
- Status of Pediatric Program
- Standard or Priority Review
- Special Issues

Other Meetings

- General Guidance
- Agree on FDA Protocol Comments
- Share Information
- Renegotiate Phase III Clinical Requirements or Phase IV Commitments
- Specific Safety Issues
- Negotiate Labeling

Alleviating Meeting Stress



Best Practices

Start With the End in Mind!

- Ultimate Goal is the Patient
- Company Goals and Objectives

Meeting Request

- Follow Guidance Document
- Clearly Identify Goals and Objective of Meeting
- Well-Structured Questions
- FDA Attendees Needed
- Appropriate Technical Representation and Decision Makers
- Be Realistic

Meeting Briefing Package

- Appropriate Background Information so FDA Can Address the Questions
- Focused
- Concise
- Brief
- Reviewer Friendly
- Allow Time for Management Review Prior to Submission

Meeting Preparation

- Identify Issues
- Identify Key Negotiation Points and Acceptable Fallback Positions
- No Presentation Unless Requested
- Prepare Only Key Slides That Might Be Needed
- Rehearsal
  - Logistics and Travel
  - Time of FDA Meeting

Other Preparation

- Contents of Briefing Package
- Relevant Guidance Documents and Regulations
- Regulatory History of Any Issues
- Regulatory Playing Field (Other Drugs)

Elements for a Successful Meeting

- Role of Regulatory Affairs
- Prepare Responses for Likely Questions
- Identify Potential Speakers
- Be Honest
- Use Consultants Judiciously
- Designate Note Takers
- Summarize Key Agreements

Pitfalls to Avoid

- Introducing New Data
- Not Being Prepared
- Being Late
- Not Being Empowered to Make Commitments
- Not Controlling Company Speakers or Consultants
- Arguing Over Policy or Regulation

Post-Meeting

- Debrief and Summarize
- Write Meeting Minutes
- Submit Company Minutes and Follow-up to Obtain FDA's
- Review Minutes for Misunderstandings or Discrepancies

FDA's Version is the Official Minutes