Joshua Sharlin, Ph.D.

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FDA Regulatory Expert Witness Summary

Provide Food and Drug Administration (FDA)-related regulatory support to attorneys in cases involving; (i) death or injury caused by drugs, biologics, or medical devices, (ii) patents, (iii) insurance claims, (iv) wrongful termination, (v) trade secrets, (vi) merger and acquisitions, (vii) stock fraud, (viii) software development, (ix) data integrity.

Hands-on experience in the entire lifecycle of FDA-regulated product development, from creating an initial regulatory strategy, thru protocol development, data collection, data analysis, and report writing, to review and approval at FDA.

Skilled at writing expert reports that describe and explain regulatory and compliance-related issues involving FDA-regulated companies. Specialist in analyzing FDA compliance information to answer three questions: 1) What did the company know and when did they know it? 2) What should the company have known and when should they have known it? 3) What should the company have done and when should they have done it? (See page 3 for a description of expert witness projects.)

Key Skills, Experience & Qualifications

• Worked as an expert witness on 50 cases, deposed 20 times, testified 5 times	• Former FDA reviewer
• Develop and present more than 40 FDA-related technical, regulatory and compliance topics to over 50,000 people	• Create lawsuit-specific information from FDA databases of safety information about medical devices and drugs
• Critique adverse event reporting	• Perform statistical analysis
• In-depth understanding of the FDA approval process for drugs, biologics & medical devices	• Identify, prevent & solve FDA compliance problems for drug, biologic, and medical device companies
• Expert in data integrity and software development	• Write FDA submissions, standard operating procedures (SOPs), and clinical study reports
• Vast experience auditing companies, vendors, and contract research organizations (CROs) for FDA compliance	• Speaker at FDA meetings with drug, biologic, and medical device companies

Work History

Consultant & Principal, 06/1994 to Current

Sharlin Consulting – Washington, D.C.

- Advise senior Department of Defense leadership on changes to tactical and strategic regulatory actions that improve the path to FDA approval of 19 products (drugs, vaccines and medical devices) under development intended as defense against biological weapons. Attend all meetings with FDA. Write white papers for all programs identifying regulatory strengths, weaknesses and risks affecting progress toward FDA approval. Develop and implement recommendations for improving regulatory strategy.
- Expert witness in court regarding matters related to FDA's regulatory process for drugs, biologics, and medical devices.
- Audit drug companies, contract research organizations (CROs), clinical sites, labs and software vendors for good clinical practice (GCP) compliance. Identify and close compliance gaps in anticipation of an audit by FDA.
- Write, review, and improve INDs, NDAs, IDEs, PMAs, 510(k)s, SAPs, protocols and SOPs.
- Solve compliance problems identified by FDA auditors and answer questions posed by FDA reviewers.
- Develop and present more than 40 FDA-related technical, regulatory and compliance topics to over 50,000 people.
- Assist drug companies and CROs in FDA compliance of electronic records, software products, databases and software development.
- Investigate, analyze and improve data quality and data integrity in FDA-related activities.
- Prepare information for, and present information at FDA meetings with drug, biologic, and medical device companies

Drug Reviewer, 05/1992 to 06/1994

Food and Drug Administration (FDA) – Rockville, MD

Manage the drug review process. Instruct firms on how to proceed with drug approval. Summarize outstanding problems and issues with protocols and studies. Determine if deficiencies were adequately addressed. Review statistical methodology of studies. Author all written communication to the sponsoring firm and integrate comments from other reviewers.

Education

Ph.D. - Physiology, **University of Georgia** – Athens, GA

M.S. - Physiology **University of Maryland** – College Park, MD

B.A. - Zoology, **University of Iowa** – Iowa City, IA

Partial List of Dr. Sharlin's FDA Expert Witness Experience

1. Explain how a generic drug company's failure to meet FDA's regulatory requirements for supplying a Medication Guide with a drug prescription supports a legal case for failure to warn.
2. Analyze FDA's drug safety database to show there was significant evidence of serious cardiovascular events among men taking hormone replacement therapy.
3. Support a medical device company's claim for monetary damages by showing how infringement of their patent solved a regulatory compliance problem of the defendant.
4. For a hip implant, identify pre- and post-approval actions and inactions by the medical device manufacturer that were noncompliant with FDA's regulatory requirements.
5. Explain how a drug company's manufacturing compliance failure negated their business loss insurance claim made after physical damage to their manufacturing facility.
6. For a hip implant, describe the medical device manufacturer's lack of FDA compliance in their efforts to obtain a 510(k) approval.
7. Conduct an FDA compliance review of a medical device company's actions after the installation of their implantable pulse generator (intended to relieve pain) caused harm.
8. For a low risk Class I medical device, identify the company's regulatory failures related to safety that resulted in a death.
9. Write a report explaining why the Warning Section in the label for a generic version of sulindac was deficient.
10. Write a report confirming a drug manufacturer's processes for establishing the stability of a drug product met FDA's compliance requirements.
11. Review a clinical study intended to compare the effectiveness of two drugs. Show the study's design was manipulated to mask the weakness of one drug over the other.
12. Evaluate FDA compliance in reporting adverse event information about Actos.

13. Deposed about the responsibilities of an Institutional Review Board in a wrongful firing case.
14. Testify for the defendant in a fertility clinic damages case. Explain the process and predictability of FDA approval of a drug under development.
15. Analyze the content of a drug IND submission to identify trade secret content.
16. Identify FDA regulatory deficiencies in the adverse event reporting of a breast cancer drug and describe the resulting deficiencies in the drug's label.
17. Analyze the adverse event reporting for a drug that treats Attention Deficit Hyperactivity Disorder (ADHD) to determine if the drug's label meets FDA regulatory requirements.
18. For a schizophrenia drug, analyze the growing body of scientific literature about the drug and determine if the company's updates to the drug label's safety information were FDA compliant.
19. Analyze FDA's medical device safety database to show a company failed to report incidents about their medical device resulting in death.
20. Explain how achieving drug development milestones triggered a disputed $100 million dollar payment in a merger agreement between two companies.