The Application Integrity Program (AIP): A Little History

Presentation to the Food & Drug Law Institute
Annual Enforcement, Litigation & Compliance
Conference for the Drug, Device, Food,
and Tobacco Industries

December 6, 2017
Washington, D.C.

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APPLICATION INTEGRITY PROGRAM (AIP)

- **Spawned by the Generic Drug Scandal**
  - Dyazide Switch
  - Maxzide Switch
- **Formerly known as the "Alert List"**
- **Formally announced – September 10, 1991**
  - 56 Fed. Reg. 46191
- **See also -- Compliance Policy Guide (CPG) 7150.09/aka CPG Sec. 120.200 – "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" (*https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073837.htm*)**

AIP

- **Triggers --** "actions subverting FDA process," such as:
  - Fraud in applications or other falsifications
  - Bribery or gratuities
- **If FDA has significant questions surrounding the reliability of the data in an application, it will defer substantive scientific review of *all* the data in the application - and, possibly, other applications**
- **Deferral will continue until all questions regarding the reliability of the data have been resolved**
- **Will need to resubmit new application to fix tainted application**

AIP …

- **Corrective Action Plan -- what you need to do if fall under AIP:**
  - Cooperate fully with FDA and other federal investigators
  - Identify all wrongdoers and remove them from authority
  - Conduct an internal review with outside consultants to uncover all other wrongdoing
  - Written action plan to assure safety, effectiveness, and quality of products, signed by your CEO
    - Procedures and controls to preclude in future
    - Ethics programs
- **FDA Verification --** reinspection

Impact of AIP

- **Only a handful of companies have survived being on the AIP**
  - those that did, typically were on it for at least 4 years
  - usually goes hand-in-hand with:
    - criminal prosecution of companies and individuals
    - collateral civil litigation, such as:
      - suits by competitors
      - securities litigation
      - shareholder derivatives action

Questions?

- ***Call, e-mail or write:***

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About Your Speaker

***Michael A. Swit, Esq.*, has been addressing critical FDA legal and regulatory issues for over 30 years. Before returning to his private law practice in late 2017, he served for 3 years as the chief regulatory counsel at Illumina, Inc., the world's leading developer of gene sequencing technologies. Prior to that, Swit was a special counsel in the FDA Law Practice at the global law firm of Duane Morris LLP, in its San Diego office. Before joining Duane Morris in March 2012, Swit served for seven years as a vice president at The Weinberg Group Inc., a preeminent scientific and regulatory consulting firm in the Life Sciences.**

His expertise includes product development, compliance and enforcement, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts for all types of life sciences companies, with a particular emphasis on drugs, biologics, therapeutic biotech products, medical devices, and IVDs.

His FDA legal and regulatory work also has included tenures in private practice with McKenna & Cuneo and Heller Ehrman, and as vice president, general counsel and secretary of Par Pharmaceutical, a top public generic and specialty drug firm, where he helped spearhead the company's emergence from the Generic Drug Scandal. He also was, from 1994 to 1998, CEO of *FDANews.com,* a premier publisher of regulatory newsletters and other specialty information products for FDA-regulated firms.

He has taught and written on many topics relating to FDA regulation and associated commercial activities and is a past member of the *Food & Drug Law Journal* Editorial Board. He earned his A.B., *magna cum laude*, with high honors in history, at Bowdoin College, and his law degree at Emory University.