What Should Pharmaceutical Companies Do Now?

Governance and Systems for Drug Safety

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A New Paradigm? … or Is Ignorance Not Bliss? … One Line of Thinking on What to Do on Safety

- Has the bar been raised by what has been reported about corporate handling of drug safety?
  - My view – **YES.**
- A key issue on how to react today -- Do you have a duty to investigate even in the absence of any indicia of a problem?
- Answer – Yes … and let me tell you why …

Duties Under the Federal Food, Drug, and Cosmetic Act

- U.S. v. Park –responsible corporate agents in a position to prevent a violation can be criminally liable for FDA violations event w/o intent or knowledge.
  - "Positive" duty to seek out potential violations
  - "Positive" duty to implement measures to ensure violations will not occur

Duties Under General Corporate Law

- Delaware law – must have an adequate compliance program to prevent violations and probe to ensure violations do not occur – Caremark (1996)
  - In considering a board's potential liability for failure to monitor, the court emphasized the importance of a board exercising "a good faith judgment that the corporation's information and reporting system is in concept and design adequate to assure the board that appropriate information will come to its attention in a timely manner as a matter of ordinary operations ."

Duties Under Corporate Law …

- McCall (2001): Columbia/HCA shareholder derivative action against board members;
  - Directors lose protection of "business judgment" rule and are personally liable for failure to detect and correct violations
  - Board's duty of care breached through nonfeasance: failure to investigate items from internal audit
- Abbott – similar result relative to failure to act on GMP problems

Duties Under Sarbanes-Oxley

- No overt duty to investigate corporate problems; ***however***, under SOX, multiple duties on a company to have adequate procedures to ensure accuracy of public reports
- ***Question*** – how can you know if your financial reports are accurate if you don't know the status of the key license – whether an NDA, BLA, PMA, etc. – supporting your key products?
- ***Answer*** – duty to probe into the future of those licenses

So, What Do You Do?

The Product Dossier & Development Audit

- Comprehensive review of applications (pending or approved)
- Goal –
  - What did we know?
  - When did we know it?
  - What did we do about it?
  - Was what we did about it consistent with benefit/risk?
- How to Do It – many ways – FDA RiskMAP Guidance is one model

A Sidebar Issue of Mine – Trial Registries

- Are open trial registries an answer … Or do they create new problems?
  - Subjectively – a noble goal to which I don't object to its implementation; but the devil is in the details
  - Deterioration of the learned intermediary doctrine?
    - Does this satisfy duty to warn the doctor?
    - Scenario – patient sues doctor and drug company; doctor settles; testifies vs. drug company. Guess what he now says … "Not possible to read all that stuff …"

Questions?

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About the speaker …

Michael A. Swit**, **Esq., who is Vice President, Life Sciences at THE WEINBERG GROUP INC., has extensive experience in all aspects of FDA regulation with a particular emphasis on drugs and medical device regulation. In addition to his private legal and consulting experience, Mr. Swit also served for three and a half years as vice president and general counsel of Pharmaceutical Resources, Inc. (PRI) a prominent generic drug company and, thus, brings an industry and commercial perspective to his representation of FDA-regulated companies. While at PRI from 1990 to late 1993, Mr. Swit spearheaded the company's defense of multiple grand jury investigations, other federal and state proceedings, and securities litigation stemming from the acts of prior management. Mr. Swit then served from 1994 to 1998 as CEO of Washington Business Information, Inc. (WBII) a premier publisher of FDA regulatory newsletters and other specialty information products for the FDA publishing company. Before joining THE WEINBERG GROUP, he served in the FDA Regulatory Law Practices at both Heller Ehrman and McKenna & Cuneo, first in that firm's D.C. office and then in its San Diego office. He first practiced FDA regulatory law with the D.C. office of Burditt & Radzius from 1984 to 1988. Mr. Swit has taught and written on a wide variety of subjects relating to FDA law including, since 1989, co-directing a three-day intensive course on the generic drug approval process, serving on the Editorial Board of the *Food & Drug Law Journal*, and editing a guide to the generic drug approval process, *Getting Your Generic Drug Approved*, published by WBII. Mr. Swit holds an A.B., *magna cum laude*, with high honors in history, in 1979, from Bowdoin College, and earned his law degree from Emory University in 1982. He is a member of the California, Virginia and District of Columbia bars.

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