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Fifty FDAs:

The Expanding Role of State Attorneys General in Drug and Device Regulation and Prosecution

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Overview

- The increase in state actions against FDA-regulated industry
  - A brief history
  - The decision to go solo
  - Outsourcing legal work
- How states regulate the pharmaceutical industry
  - Regulation through settlement
  - New uses of warning letters
- Explaining increased state attorney general activity
- Implications for FDA-regulated companies

A Brief History

- States indirectly benefited from the spike in federal enforcement in the 1990s and early 2000s
  - States got $106 million from $430 million Neurontin settlement (2004)
- States more directly involved beginning in the mid-2000s
- First major state-only pharma settlement was GSK's 2004 settlement with New York AG Eliot Spitzer
- By 2008, states were routinely taking the lead on enforcement actions
  - Examples: Merck (29 states & D.C., $58 million), Eli Lilly (32 states, $62 million)
  - State actions preceded federal actions in these cases

The Decision to Go Solo

- States have traditionally proceeded in multi-state consortiums
- Increasingly, the trend has been for states to proceed solo
- States tend to receive more favorable settlements when they proceed alone
  - However, they are responsible for litigation costs/burdens
  - Also, to the extent they use outside counsel, their net settlement is likely to be even more dramatically reduced
    - W.V. reportedly paid $6 million of its $25 million Zyprexa settlement to outside counsel

Outsourcing Legal Work

- AGs have shown an increasing willingness to use private counsel for enforcement actions
- Plaintiffs' law firms are making themselves available
  - One major plaintiffs' law firm recently established a public client practice group for exactly this type of case
- Examples: Alaska and West Virginia in Zyprexa litigation
- Not seamless relationships: Different missions and audiences can result in clashes
  - Clashes can go public: "The settlement was done exclusively by the attorney general without our input…. As a lawyer, I feel we really have not been treated well." – Alaska's outside counsel in Zyprexa case, to The New York Times
  - Risk to companies: States may proceed unpredictably

Outsourcing Legal Work (cont'd)

- Constitutional arguments against AGs outsourcing legal work
  - Due process (government attorneys must look to the public interest, while outside counsel are not similarly bound)
  - Separation of powers (appropriating funds should be left to the legislature)
- Challenges to outsourcing have been brought in many states, but results have been limited
- President Bush issued an executive order in 2004 forbidding contingency arrangements at the federal level

Regulation Through Settlement

- States now have a role in regulating the industry through settlements
- Today's settlement requirement can become tomorrow's law
  - In 2004, New York required GSK to disclose clinical trials. In 2007, a similar requirement was incorporated into the FDA Amendments Act.
- FDA shows no signs of resisting states' "entrepreneurial" settlements

Regulation Through Settlement (cont'd)

- All three of the major state-only settlements in the watershed year of 2008 required companies to:
  - Clearly indicate FDA-approved uses for drugs in any marketing promotions
  - Make medical departments, not sales and marketing personnel, ultimately responsible for the content of medical letters and references
  - Refrain from using grants or CME for promotion
  - Disclose payments to providers who were promotional speakers or consultants
  - Distribute drug samples only to providers whose practice is consistent with FDA-approved indications
  - Publicly issue accurate, objective, and balanced research reports
  - Submit all future direct-to-consumer television commercials to FDA for prior approval

Regulation Through Settlement (cont'd)

- States regulate more than marketing. Guidant's 2007 settlement, focused on product safety, required company to:
  - Establish a patient safety advisory board consisting of independent experts to evaluate data concerning device performance
  - Establish a patient safety officer position, staffed by a physician whose primary responsibility is to advance the safety of patients using the device
  - Clearly disclose to the public specific information on a quarterly basis, including worldwide failure data, survival probability estimates, and current information in the event of an FDA recall of any device
  - Post a notice on its website within 30 days of any modification to any of its devices to correct a failure pattern
  - Solicit the return of out-of-service devices
  - Maintain a data system to track the serial numbers, implant dates and explant dates of all devices distributed by Guidant in the United States

New Uses of Warning Letters

- Warning letters are informal, advisory FDA communications issued for violations of regulatory significance
- States have used FDA warning letters in enforcement actions
- Two uses:
  - As a catalyst for states to launch actions
  - As substantive evidence against companies
- FDA welcomes the “collaboration” with states, per DDMAC Director Tom Abrams
- The practice is already widespread, affecting major companies in states including Florida, Connecticut, and West Virginia

New Uses of Warning Letters (cont'd)

- Bayer/Yaz
  - FDA issued warning letter 10/08 regarding two Yaz TV ads that FDA said were misleading
  - 27 states settled with Bayer, arguing that Bayer was in breach of a previous 2007 agreement with states regarding Baycol. The states' leverage rested largely on the warning letter.
  - The assistant AG who worked on the case called the warning letter the "canary in the coal mine"
  - FDA assisted in the state effort but took no further direct action against Bayer
    - However, the Yaz settlement contained numerous quasi-regulatory provisions

New Uses of Warning Letters (cont'd)

- Janssen Pharmaceuticals
  - W.V. sued the company for alleged false and misleading statements in violation of a state consumer protection statute
  - The state used two warning letters and the company's failure to seek administrative appeal as evidence that the company downplayed risks
  - Court said the FDA was "uniquely qualified" to make determinations regarding the truthfulness of statements made by drug manufacturers and that it would "giv[e] deference to the FDA's findings and actions pertaining to the communications at issue."
  - Court granted summary judgment to W.V.
  - W.V. chief deputy AG said about the warning letters: "It's the best evidence I think you can get. That was the crux of our entire case."

Explaining Increased State Attorney General Activity

- States' need for revenue
- States' desire to drive down health care costs
- AGs' need for public support
- Recent changes in state laws
  - State false claims acts
    - 2006 Deficit Reduction Act created incentives for states to reform their false claims acts to resemble the federal version
  - State medical transparency laws
  - 550+ bills that would impact FDA-regulated industry are moving through state legislatures in 41 states and D.C.
- AGs' desire to combat perceived federal laxity on enforcement

Implications for FDA-Regulated Companies

- State cases can be more challenging for companies
  - There may be less favorable laws or unavailable defenses
  - Generally, state AGs are not bound by federal grand jury secrecy rules and are more likely to speak publicly about their investigations on and off the record
- State laws forming the basis for actions
  - Consumer protection statutes
  - False claims statutes
  - Anti-kickback statutes
  - Anti-referral statutes
  - Privacy statutes

Defenses

- In multi-state consumer protection cases, it may be possible to argue no consumer confusion where the company did not put DTC ads in a state
- Defenses often vary by state. For example, some of the federal FCA defenses are not available in all states

Implications for FDA-Regulated Companies (cont'd)

- State investigations sometimes pose fewer challenges
  - State cases are generally civil in nature and do not typically risk criminal prosecution of the company or individuals
  - Some states do not have FCA, AKS, or anti-referral laws
    - Others have favorable variations, e.g., the FCA applies to Medicaid only
  - Historically, state investigations have not been triggered by whistleblower complaints. As a result:
    - The challenge of interacting with Relator's counsel is absent from state cases
    - No whistleblower fees in state civil fines

Implications for FDA-Regulated Companies (cont'd)

- Revisit promotion review procedures
  - In light of states using warning letters as the basis for enforcement actions, companies should carefully assess whether their current internal promotion review procedures are adequate to meet the heightened risk of a state action
  - The procedures must ensure that promotional and other materials for external distribution are both factually accurate and complete
    - This requires a familiarity with the product and the source data underpinning labeling claims that may exceed the knowledge of the standing review committee
- Adjust the personnel involved with warning letter responses
  - Many companies leave warning letter responses to regulatory affairs
  - It may be appropriate to more deeply involve legal personnel, particularly those who handle litigation

Implications for FDA-Regulated Companies (cont'd)

- Document all relevant internal deliberations and external communications with FDA
  - Should include the factual and legal bases for any statements made to FDA
- Implement internal controls to ensure that commitments made to FDA are, in fact, carried out

Implications for FDA-Regulated Companies (cont'd)

- State investigations can result in major settlements and need to be taken seriously
- Notice may come through subpoena, investigative demand or another written request
- Steps following notice:
  - Initiate litigation hold procedures
  - Notify management and other appropriate personnel
  - Assess securities disclosure requirements
  - Dedicate appropriate internal and external personnel
  - Assess what impact the action might have on other government investigations, product liability matters, internal investigations, or CIA notification requirements, as applicable

Questions?

Speaker Biographies

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