PhRMA's Policy Perspective on Compliance Issues

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Premises

- Disease should be the enemy.
- Rules should be clear.
- Enforcement should be fair.
- Rule development, interpretation, and enforcement should advance the public health.

Concerns

- Industry is perceived as the enemy.
- Regulation through litigation is proliferating.
- As a result:
  - Norms are being developed through litigation and settlement rather than legislation and rulemaking.
  - Rules have become less clear.
  - Enforcement of unclear rules raises fundamental fairness concerns.
  - Interpretation and enforcement are divorced from public health policy.

"Clinical Trial Conduct May Be Subject To DOJ Enforcement" – Pink Sheet 2/7

- DOJ reportedly is examining the adequacy of informed consent, protocol design, etc.
- Government acknowledges that these concerns do not fit the classic fraud model, but is crafting a theory under the FCA.
- Questions:
  - What are the rules? Are they the same as FDA's, or different?
  - Who decides whether the rules have been violated and, if so, what to do about it?
  - What is a company to do?

Who Makes the Rules?

- FDA and CMS pursuant to authority delegated by Congress
- Or:
  - The Department of Justice
  - State Attorneys General
  - Private plaintiffs' bar
  - Judges and juries

What Are the Rules?

- Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations
- Or:
  - False Claims Act
  - State consumer protection and unfair practices laws
  - Complaints, settlements, and verdicts

"What Is To Be Done?"

- Companies need to devote systematic and sophisticated attention to compliance.
- The FDA and other public health agencies need to reassert their primacy.
- Courts need to deal decisively with meritless claims and fairly with defendants accused of violating uncertain and evolving standards.