



# Off-label Publication Issues: A Defense Lawyer's Perspective

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# Damned if You Do-- Damned if You Don't

- Did and Damned--Parke Davis
- Didn't and Damned--GSK
- Industry Faced Again with Conflicting and/or Incomplete Guidance

# Reasons for Discomfort

- To the extent that this is part of the “lessons” of Parke Davis, can you really punish a company for publishing an accurate?
  - Significant First Amendment issues
  - Should government even want to do this?
- Should Parke Davis really be understood as a case about the distribution of published material and statements made in connection with those distribution efforts?

# More Concerns

- Is a “consistent” policy of publication the “lesson” of GSK?
- Is this another triumph for “transparency”?
- Will transparency achieve the desired result?
- Is this kind of consistency even desirable?
- Aren’t there legitimate reasons to at least wait on publication decision?
- If consistency is the requirement, does that mean that the same peer-reviewed publications have to be used?

# Aren't These the Kinds of Issues that Should Be Weighed by the FDA?

- And yet it is the DOJ, State AGs and others who are, de facto, setting the standards.
- Does this make sense?

# Other Forces Will Be Pushing Early Publication

- The Looming Coverage Attack on part B Coverage
  - Revisiting Dr. Tunis' Comments
- Part D and the P&T Standards
  - Publish or perish given new meaning