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Off-Label Liability: Legal and Compliance Issues

Statutory Provisions

- Three Theories
 - FDCA § 502(a), 21 U.S.C. § 352(a): A drug shall be deemed to be misbranded if its labeling is false or misleading in any particular
 - FDCA § 502(f)(1), 21 U.S.C. § 352(f)(1): A drug shall be deemed to be misbranded unless its labeling contains adequate directions for use
 - FDCA § 505(a), 21 U.S.C. § 355(a): No new drug may be introduced or delivered for introduction into interstate commerce without a new drug application (NDA) or abbreviated NDA



"Safe Harbors"

- FDA Policies
 - "Scientific exchange" (21 C.F.R. § 312.7)
 - Example: dissemination of scientific findings in scientific or lay media
 - Responses to unsolicited requests
 - Dissemination in accordance with the CME guidance
 - Dissemination in accordance with reprints guidance



• The following major pharmaceutical manufacturers among others have disclosed that they currently are being or have been investigated for alleged off-label promotion of their

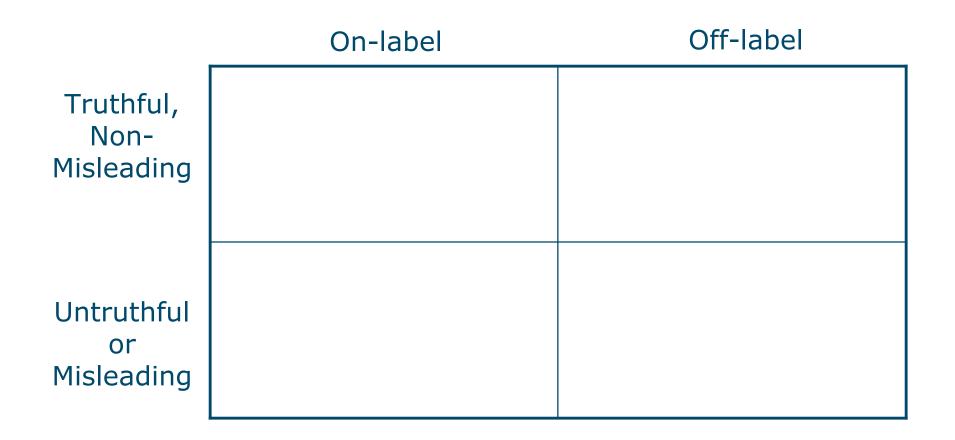
drugs:		
urugs.	Abbott Labs	Johnson & Johnson
	Amgen	Eli Lilly
	AstraZeneca	Novartis
	Cell Therapeutics	Pfizer
	Forest	Sanofi-Aventis
	Genentech	Schering-Plough
	GlaxoSmithKline	Wyeth
	Intermune	

• There are numerous other drugs under investigation.



- In these cases and investigations, the government has pursued criminal off-label charges that do not require a showing of false or misleading representations or other inherently wrongful conduct
- Instead, the government focuses on <u>all</u> off-label dissemination, including conduct that FDA generally permits
 - Scientific exchange
 - Responses to unsolicited requests
 - Dissemination of enduring materials
 - Continuing Medical Education







- Government also pursuing alleged off-label promotion under the civil False Claims Act
 - <u>See</u> United States' Statement of Interest in <u>United</u>
 <u>States</u> v. <u>Rost</u>
- Government's theory cast into doubt by Supreme Court's decision in <u>Allison Engine</u> <u>Co.</u> v. <u>United States</u> ex rel. Sanders (June 9, 2008)



A Few Guiding Principles for Compliance

- FDA is the least of your problems
- One size does not fit all
- All information dissemination has risk
- Consider a portfolio approach to risk
- Be thoughtful about the risks you take



The Future

- Clarity from the courts?
- The future of the reprint guidance and further action by FDA
- Possible clarity from the Department of Justice?
 - Was the communication truthful and not misleading?
 - Were patients harmed?
 - Was FDA approval pursued and\or secured?

