



*“Off-Label” Communications at
Risk: Changes and Challenges
to Reimbursement for
Prescription Drugs*

Stephen Paul Mahinka
Morgan Lewis
C O U N S E L O R S A T L A W
Washington, D.C.

*Washington Legal Foundation
Media Seminar
February 3, 2004
Washington, DC*

smahinka@morganlewis.com



Expanding Challenges to Off-Label Promotion

- Original concerns
 - restrictive FDA prescription drug promotion regulations
 - challenged successfully in Washington Legal Foundation v. Friedman (D.D.C. 1998)
 - but see United States v. Caputo (N.D.Ill. 2003) (medical devices)
- Challenges increasingly focused on reimbursement



Challenges to Reimbursement for Off-Label Promotion of Drugs

- Prosecutions under False Claims Act and/or Anti-Kickback Statute by HHS OIG and DOJ
 - allege manufacturers “cause” a healthcare provider to submit a claim for reimbursement of off-label uses
 - also may allege violation of Anti-Kickback Statute, by “inducing” the reimbursement claim for an off-label use




Challenges to Reimbursement for Off-Label Promotion of Drugs

- Several recent prosecutions on these theories:
 - United States ex rel. Franklin v. Parke-Davis (D.Mass.)
 - allegation that manufacturer liable under False Claims Act and Anti-Kickback Statute for inducing physician's use by providing off-label information for Neurontin
 - substantial settlement reportedly imminent
 - Other reported investigations:
 - Schering-Plough
 - Serono
 - Eli Lilly
 - See also United States ex rel. Neel v. Orthofix, Inc. (N.D.Texas 2003)
 - \$1.6 million settlement regarding off-label use reimbursement for medical devices



Challenges to Reimbursement for Off-Label Promotion of Drugs

- Prosecutors attempt to avoid First Amendment concerns by focusing on:
 - size of detail force relative to approved uses
 - bonuses to retail force for off-label sales
 - targeting physicians who treat only unapproved indications



Following Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Changes Reported in CMS' Off-Label Reimbursement Policy

- Centers for Medicare and Medicaid Services (CMS) reportedly intends to reimburse for oncology products (and eventually others) for off-label uses only when such uses:
 - are listed in an official compendium, or
 - when the scientific data is published in qualified peer-reviewed journals identified by HHS



Following Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Changes Reported in CMS' Off-Label Reimbursement Policy

- CMS' reported change would focus on cost restrictions, by:
 - following the Medicare statute, which sets out these requirements at 42 U.S.C. § 1395x (t)(2)(B).
 - resulting in restricting the current scope of reimbursement for off-label uses of drugs, by both the government and private insurers.



Enforcement and Regulatory Trends Present Serious Concerns

- Circumventing First Amendment protection of truthful off-label promotion of prescription drugs
- Restricting proper practice of medicine and adversely affecting public health, in view of the predominance of off-label prescription of many drugs by physicians
- Illustrates likely development of administrative cost restriction mechanisms following introduction of the new Medicare Act's prescription drug benefit