



SIDLEY AUSTIN BROWN & WOOD LLP
AND AFFILIATED PARTNERSHIPS

BEIJING
CHICAGO
DALLAS
GENEVA
HONG KONG
LONDON
LOS ANGELES
NEW YORK
SAN FRANCISCO
SHANGHAI
SINGAPORE
TOKYO
WASHINGTON D.C.

Off-Label Promotion: Not Just an FDA Issue

Paul E. Kalb, M.D., J.D. - (202) 736-8050

Pharma Congress National Audioconference

October 2, 2003

Off-Label Promotion: Statutory and Constitutional Issues

FDCA:

- No specific prohibition on off-label promotion
- Statutory theories
 - Misbranding
 - Marketing new drug for unapproved use

Off-Label Promotion: Statutory and Constitutional Issues

First Amendment:

- “Scientific” vs. “Commercial” speech
- In either event, FDA’s prohibitions not appropriately tailored
- Result: Confusion? Creative tension?
- Doctrine of constitutional avoidance

Alternative Grounds for Attack

False Claims Act:

- Theory: Promotion for unapproved use causes submission of “false” claims
 - Extent to which federal programs do not cover for unapproved uses is far from clear
 - Very significant issues of proof
 - Policy considerations: Will DOJ cut off funding for oncology patients?

Alternative Grounds for Attack

Unfair or Deceptive Trade Practice Statutes:

- Preemption/Primary jurisdiction
- Problems of proof
 - Where is the deception?
 - Professional judgment
- First Amendment: Trumps conflicting state laws