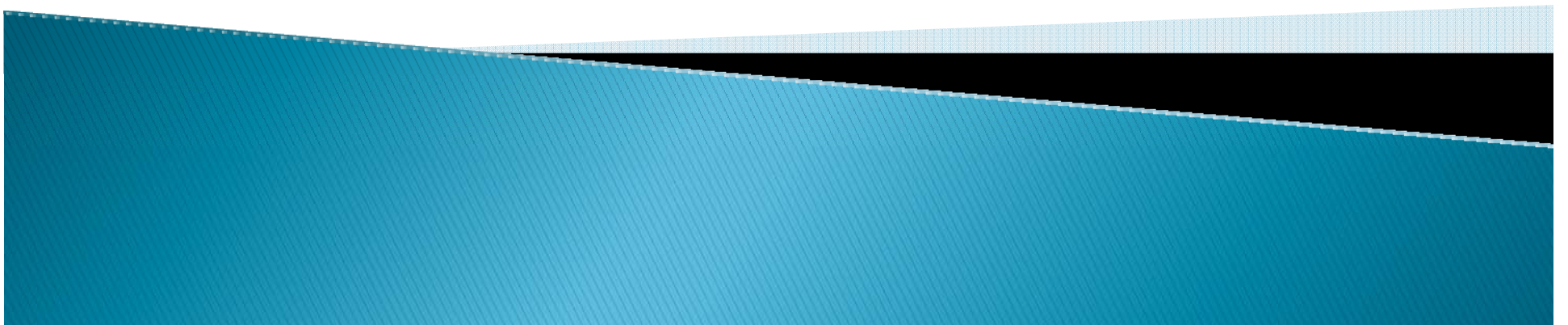


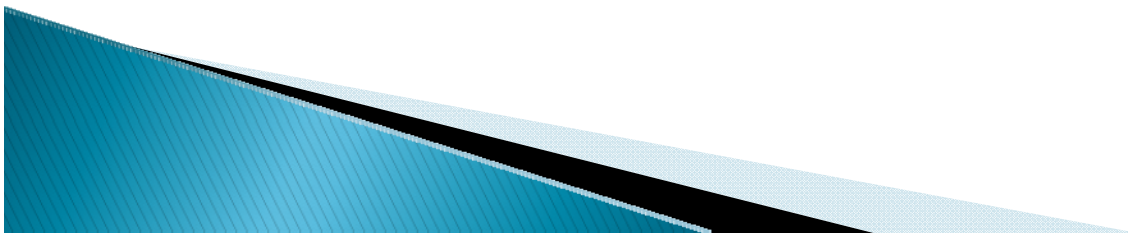
Informed Consent for Off-Label Uses

Margaret Z. Johns
School of Law
University of California, Davis



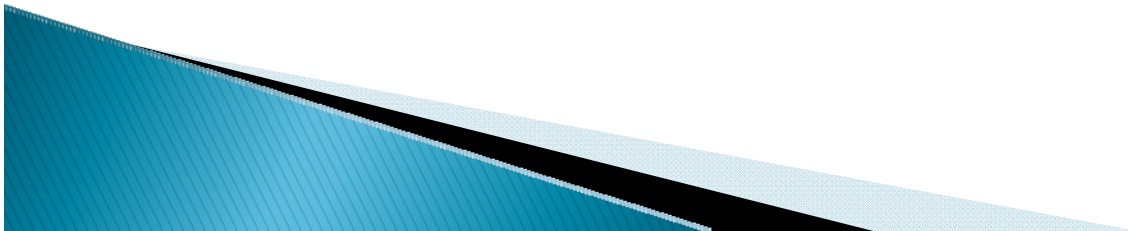
Why should off-label prescribing be disclosed for informed consent?

1. Most off-label uses are not supported by scientific evidence
2. Doctors prescribe off-label therapies based on biased drug-company-sponsored research and education
3. Patients mistakenly believe their prescriptions have been approved by the FDA as safe and effective to treat their conditions



Archives of Internal Medicine

- ▶ 73% of off-label uses lacked scientific support
- ▶ Only 27% of off-label uses were supported by scientific evidence
- ▶ Off-label uses without scientific support “jeopardize patient safety or represent economically wasteful prescribing practices.”



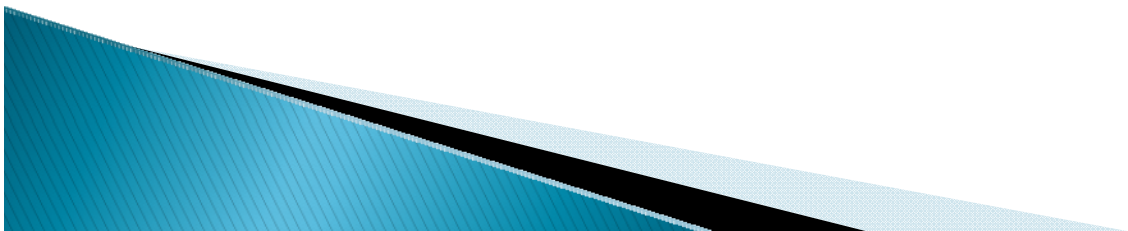
Drug Company Marketing

- ▶ Drug companies increase sales by convincing doctors to prescribe off-label drugs.
- ▶ They get around the ban on promotion of off-label uses by calling it education.
- ▶ “They sponsor make-believe education, and often buttress it by reference to flimsy research studies they sponsor.”

Marcia Angell, M.D.

Harvard Medical School

Former Editor of the New England Journal of Medicine



- ▶ “Unfortunately, very troubling questions have been raised regarding pharmaceutical companies’ manipulation of the peer–review medical journal process to promote their products.”

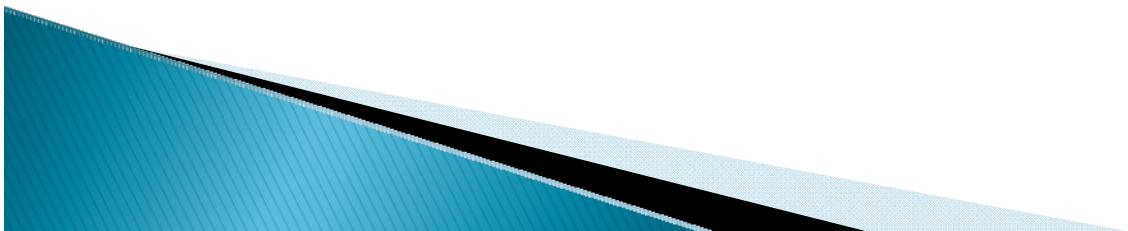
Michael Maves, M.D.

Executive Vice President, American Medical Association

- ▶ “What does it mean to be peer–reviewed if the company has essentially conceived the article, composed the draft and written the paper?”

Joseph S. Ross, M.D.

Mount Sinai School of Medicine

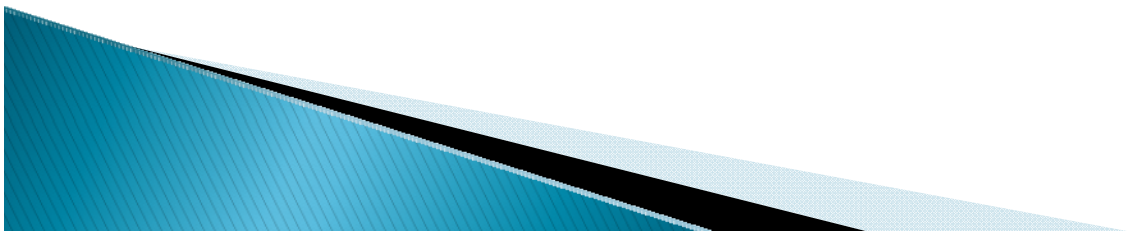


- ▶ “[J]ournals have devolved into information laundering operations for the pharmaceutical industry.”

Richard Horton, M.D.
Editor of Lancet

- ▶ “There is substantial evidence that the pharmaceutical industry has inappropriately influenced the scientific literature through selective publication and ghost authorship.”

Michael Valentino
Chief Consultant, Pharmacy Benefits Management
Department of Veterans Affairs

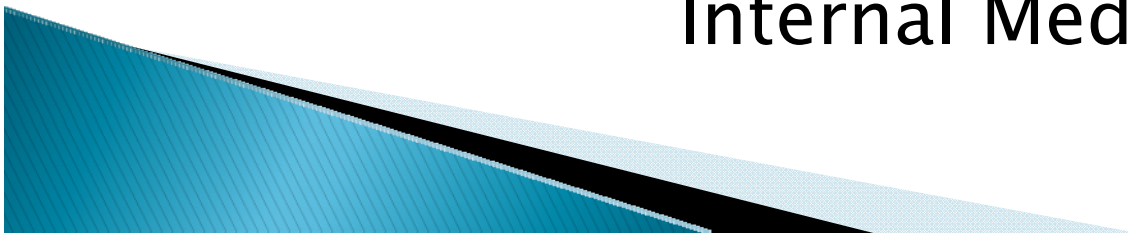


Joint Statement

The 12 most influential medical journals issued a joint statement about commercially-sponsored research:

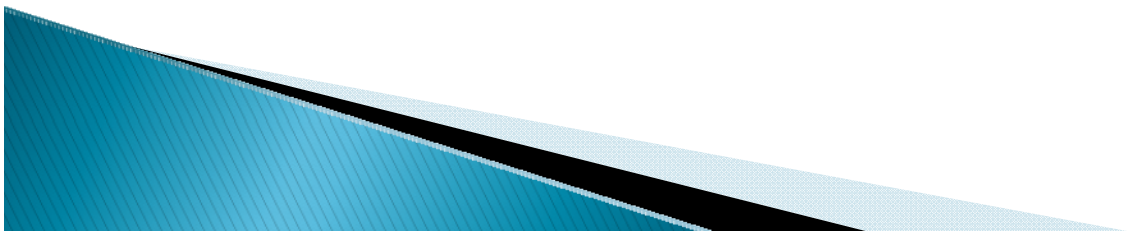
“[Commercially sponsored clinical trials are] primarily for marketing . . . [This] makes a mockery of clinical investigation and is a misuse of a powerful tool.”

JAMA, New England Journal of
Medicine, Lancet, Annals of
Internal Medicine, et al.



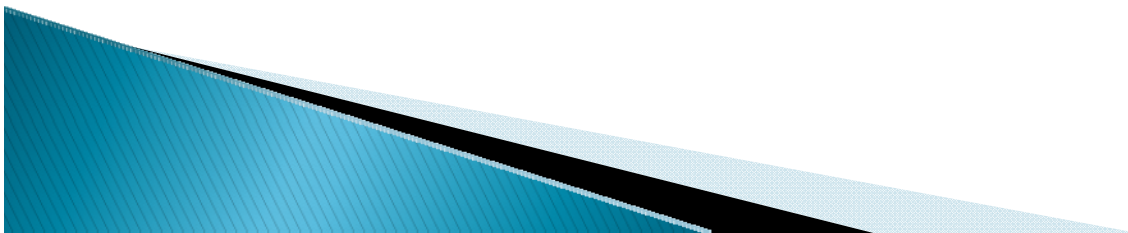
Attorneys General of Illinois and Oregon

“[W]e have found a very disturbing pattern of pharmaceutical companies not only ignoring the limitations on off-label marketing to doctors, but also aggressively building market share based largely on off-label marketing campaigns that rely on widespread distribution of selected articles promoting off-label drug uses.”



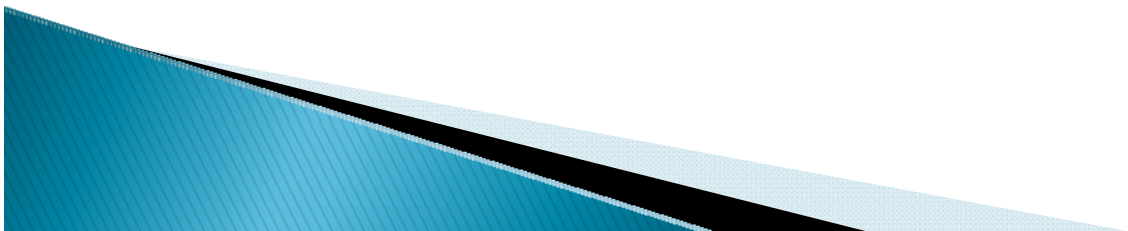
Attorneys General of Illinois and Oregon

“The pharmaceutical industry has taken advantage of the FDA’s lack of resources. . . . and has repeatedly distributed ‘scientific information’ that was biased and/or not balanced in order to increase sales by encouraging off-label uses.”



U.S. Senate Committee on Finance

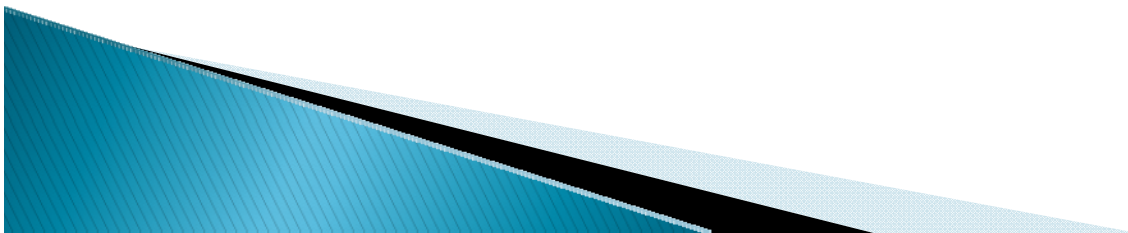
- ▶ “The *off-label promotion risk* of educational grants appears to pose the *greatest threat to Federal health care programs*, but it is also the most difficult to demonstrate conclusively.”
- ▶ “Encouraging doctors to prescribe drugs for unapproved uses exposes patients to heightened risks.”



“You’re taking a medicine because a drug company needs to market it. Who knows if it will work?”

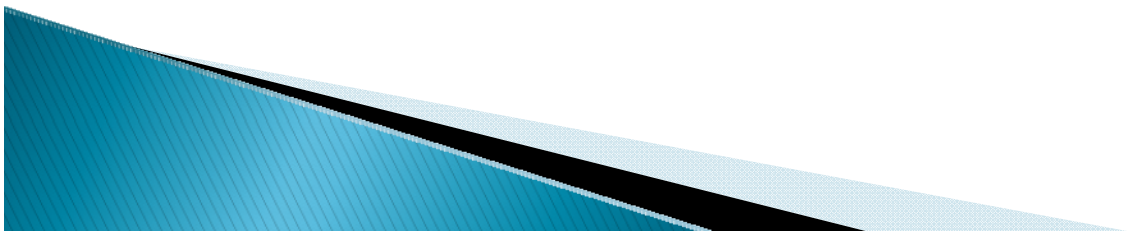
Arnold Relman, M.D.

Former Editor of the New England
Journal of Medicine



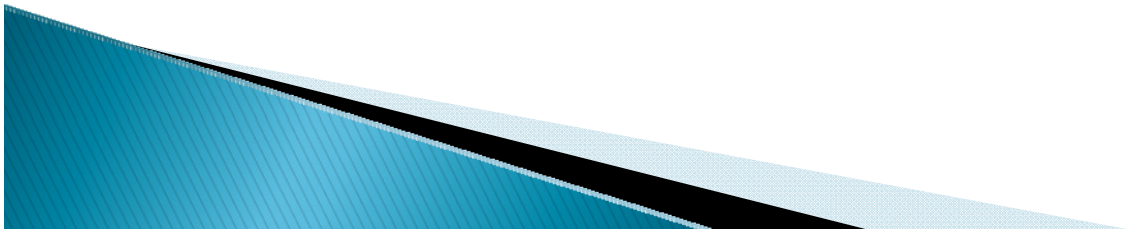
Patients' Mistaken Belief in FDA Approval

- ▶ Most patients mistakenly believe that *all* drugs they are prescribed have passed FDA trials and are safe and effective for treating their condition.
- ▶ Most patients believe that doctors should *not* be allowed to prescribe a drug to treat conditions other than as indicated in the FDA-approved labeling for that drug.



Informed Consent

- ▶ Informed consent ensures patient autonomy and self-determination
- ▶ Informed consent requires doctors to disclose information of material risks either:
 - that a reasonable doctor would disclose; or
 - that a reasonable patient would consider significant

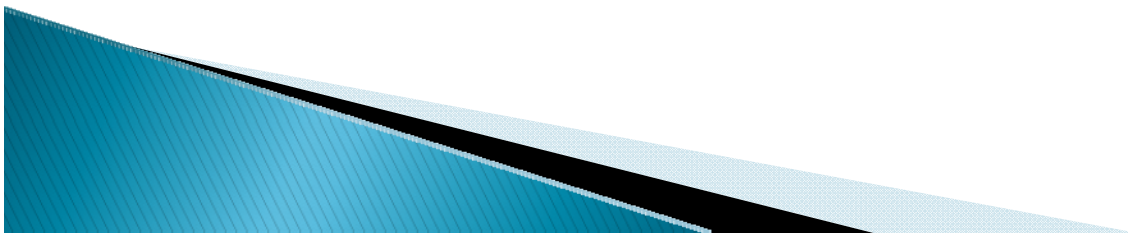


Medical Ethics Require Disclosure

A recent multidisciplinary study concluded that in prescribing off-label therapy where the information is not sufficient to allay concerns about safety and efficacy:

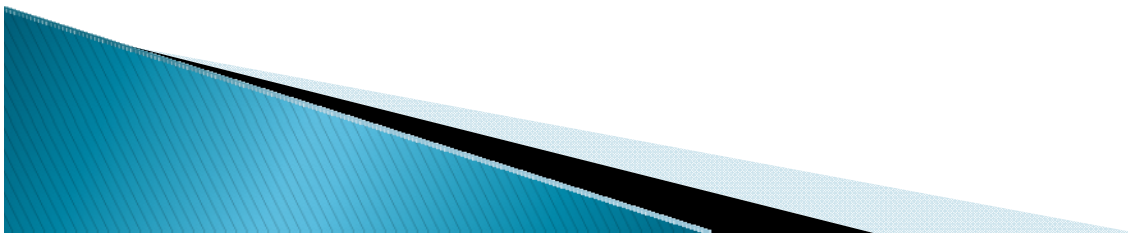
“[P]hysicians . . . must meet their ethical obligations by ensuring that the patient is informed and provides consent prior to administering the drug.”

21 Am. J. Med. Quality 255 (2006)



Misleading Patients

Unless off-label prescribing is disclosed, patients are misled as to the safety and efficacy of the drug. Most patients believe it has been proven safe and effective according to rigorous FDA standards when in fact *73% of the time there is no scientific support for the prescription.*



Don't you want to know?

Drug A

Following rigorous clinical trials, Drug A has been approved by the FDA as safe and effective for treating your specific condition

Drug B

Drug B has been approved for treating an unrelated medical condition; but there is *no scientific evidence* that it is safe and effective for treating your condition

Benefits of Requiring Informed Consent

1. Patients will be better informed about and more cautious in agreeing to off-label uses.
2. Doctors will demand more scientifically reliable information from drug companies to support off-label uses.
3. Drug companies will provide more scientifically reliable information about off-label uses.

