

## **ETHICS GRAND ROUNDS**

Tuesday, April 14, 2015 South Campus  
D1.602, Noon–1:00, McDermott Plaza Lecture Hall

### **INSTITUTIONAL CORRUPTION & OFF-LABEL DRUG USE**

**MARC A. RODWIN, JD, PhD**

*Professor of Law  
Suffolk University Law School*

Although sometimes reasonable, off-label drug use typically is unsupported by substantial evidence of effectiveness and safety. At the root of inappropriate off-label drug use lies institutional corruption of pharmaceutical practice. Institutional corruption involves perverse incentives for pharmaceutical firms, the lack of evaluation of off-label prescribing and conflicts of interest in the design, oversight, and reporting of clinical trials. Typical reform proposals such as increased sanctions for manufacturers, education for physicians, registration of clinical trials, and disclosure of conflicts of interest do not remove the source of the problem. I explore alternative reform options. These include: 1) tracking off-label prescriptions to monitor the risks and benefits of off-label uses and the manufacturers' conduct; 2) changing pharmaceutical firm reimbursement to remove incentives to encourage off-label prescribing; and 3) independent clinical trials to evaluate drugs.

Ethics Grand Rounds Videos are available a few days after the lecture at:  
<http://repositories.tdl.org/utswmed-ir/handle/2152.5/1292>

**John Z. Sadler, M.D., Course Director**  
**Program in Ethics in Science & Medicine**  
**For Information Contact**  
**Linda Muncy, 214-648-4959**  
**Linda.Muncy@UTSouthwestern.edu**  
[www.utsouthwestern.edu/ethics](http://www.utsouthwestern.edu/ethics)

**Target Audience:** Physicians, faculty, residents, fellows, trainees, students, health care professionals. **Educational Objectives:** At the conclusion of this activity, the participant should be able to: 1) Recognize perennial and emerging bioethical problems in clinical practice, research, public health, and health policy arenas. 2) Describe competing/contrasting viewpoints concerning these bioethical problems. 3) Demonstrate increased skills in analyzing and practically handling bioethical problems in the clinical, research, public health, and health policy arenas. **Educational Method:** Lecture and question-and-answer period. **Accreditation:** The University of Texas Southwestern Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. **Credit Designation:** The University of Texas Southwestern Medical Center designates this live activity for a maximum of **1 AMA PRA Category 1 Credit(s)**<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity. The University of Texas Southwestern Medical Center designates this activity for **1 hour(s)** in medical ethics and/or professional responsibility. **Conflict of Interest:** All persons in the position to control the content of an education activity are required to disclose all relevant financial relationships in any amount occurring within the past 12 months with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on patients. A primary mechanism to resolve identified conflicts of interest is a content review that is prior to the activity. **Off-Label Uses:** Because this course is meant to educate physicians with what is currently in use and what may be available in the future, there may be "off-label" use discussed in the presentation. Speakers have been requested to inform the audience when off-label use is discussed.