



ASA NEWS: Aug. 17, 2010

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On-site Press Room (Aug. 13-17): Hilton Atlanta, Room 202, (404) 572-6511

EMBARGOED until Tuesday, August 17, 10:30 a.m. EST

Pharmaceuticals: A Market for Producing “Lemons” and Serious Harm

Incentives and protections for industry encourage development of many drugs with few new benefits over existing pharmaceuticals, but with risk of serious harm to users

ATLANTA — The pharmaceutical industry is a “market for lemons,” a market in which the seller knows much more than the buyer about the product and can profit from selling products less effective and less safe than consumers are led to believe, according to an analysis that will be presented at the 105th Annual Meeting of the American Sociological Association.

“Sometimes drug companies hide or downplay information about serious side effects of new drugs and overstate the drugs’ benefits,” said Donald Light, the sociologist who authored the study and who is a professor of comparative health policy at the University of Medicine and Dentistry of New Jersey. “Then, they spend two to three times more on marketing than on research to persuade doctors to prescribe these new drugs. Doctors may get misleading information and then misinform patients about the risks of a new drug. It’s really a two-tier market for lemons.”

Three reasons why the pharmaceutical market produces “lemons” are: Having companies in charge of testing new drugs, providing firewalls of legal protection behind which information about harms or effectiveness can be hidden, and the relatively low bar set for drug efficacy in order for a new drug to be approved, Light said.

According to his study, independent reviewers found that about 85 percent of new drugs offer few if any new benefits. Yet, toxic side effects or misuse of prescription drugs now make prescription drugs a significant cause of death in the United States.

Light’s paper, “Pharmaceuticals: A Two-Tier Market for Producing ‘Lemons’ and Serious Harm,” is an institutional analysis of the pharmaceutical industry and how it works based on a range of independent sources and studies, including the Canadian Patented Medicine Prices Review Board, the Food and Drug Administration, and Prescrire International.

The foundation for the paper is the work Light did for a forthcoming book he edited, titled *The Risk of Prescription Drugs*, which is scheduled for publication this fall by Columbia University Press.

In both his paper and his book, Light describes the “Risk Proliferation Syndrome” that is maximizing the number of patients exposed to new drugs that have relatively low efficacy and effectiveness but have greater risk of adverse side effects. Building on clinical trials designed to minimize evidence of harm and published literature that emphasizes a drug’s advantages, companies launch massive campaigns to sell it, when a controlled, limited launch would allow evidence to be gathered about the drug’s effects. Companies recruit leading clinicians to try using the drug for conditions other than those for which it is approved and to promote such off-label or unapproved uses. Physicians inadvertently become “double agents” — promoters of the new drug, yet trusted stewards of patients’ well-being, said Light. When patients complain of adverse reactions, studies show their doctors are likely to discount or dismiss them, according to Light.

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Despite the extensive requirements for testing the efficacy and safety of each new drug, companies “swamp the regulator” with large numbers of incomplete, partial, substandard clinical trials, Light said. For example, in one study of 111 final applications for approval, 42% lacked adequately randomized trials, 40% had flawed testing of dosages, 39% lacked evidence of clinical efficacy, and 49% raised concerns about serious adverse side effects, said Light.

“Just recently, major reports have come out about biased, poor trials for Avandia and Avastin,” Light said, who noted that orphan drugs are tested even less well.

“The result is that drugs get approved without anyone being able to know how effective they really are or how much serious harm they will cause,” Light said. The companies control the making of scientific knowledge and then control which findings will go to the FDA or be published.

“A few basic changes could improve the quality of trials and evidence about the real risks and benefits of new drugs,” Light said. “We could also increase the percentage of new drugs that are really better for patients.”

The paper, “Pharmaceuticals: A Two-Tier Market for Producing ‘Lemons’ and Serious Harm,” will be presented on Tuesday, Aug. 17, at 10:30 a.m. EST, in the Hilton Atlanta at the American Sociological Association’s 105th Annual Meeting.

To obtain a copy of the paper; for more information on other ASA presentations; or for assistance reaching the study’s author, contact Daniel Fowler at pubinfo@asanet.org or (202) 527-7885. During the Annual Meeting (Aug. 13-17), ASA’s Public Information Office staff can be reached in the press room, located in Room 202 of the Hilton Atlanta, at (404) 572-6511 or (914) 450-4557 (cell).

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