2015 Conference Abstracts

The Real Risks of Rx Drugs

PharmedOUT.ORG

Day 1: June 11th

Hormones and the fountain of youth
Adriane Fugh-Berman MD, Georgetown University Medical Center
Tony Scialli MD, George Washington University
Hormonal therapies as a youth-preserving treatment began in men and dates to the late nineteenth century. Menopausal hormone therapy was widely promoted as a youth-preserving treatment for women from the 1960s until the Women's Health Initiative found that risks outweighed benefits. In the 21st century, the marketing of testosterone to aging men has paralleled the marketing of hormone "replacement" therapy to menopausal women. The marketing of hormones to both men and women will be explored.

The endangered normal: Does anyone escape a diagnosis?
Adriane Fugh-Berman MD, Georgetown University Medical Center
The medicalization of daily life has become endemic. A child who spits up may be diagnosed with infant GERD. A shy child may be diagnosed with social anxiety disorder. Someone who urinates more than four times a day is diagnosed with overactive bladder syndrome. A young woman who is less interested in sex than her partner may be diagnosed with Hypoactive Sexual Desire Disorder. Diagnoses such as these have a clear advantage to the pharmaceutical companies that invented them: a huge market exists for treatment of common human conditions. In this talk, Dr. Fugh-Berman will examine how pharmaceutical companies create or exaggerate "disease states" and address the potential public health impact of pathologizing normalcy.

Demented patients and difficult behaviors
Tom Finucane MD, Johns Hopkins School of Medicine
In elderly patients with dementia, drug treatment of behavior problems is toxic, largely ineffective, and very expensive. When drugs are used, physicians should be clear that the goal of drug treatment is generally to neutralize the patient, often for the benefit of those around her.

When to hold 'em, when to fold 'em: Effective medication management in advanced illness
Mary Lynn McPherson PharmD MA BCPS, University of Maryland
Older adults with advanced illnesses are frequently receiving a plethora of medications. Whether due to clinical inertia, an inability to weigh the benefits and burdens of drug therapy, or patient/family preference, these patients often remain on medications that have long outlived their therapeutic usefulness. This presentation will present a critical thinking process that can be used to determine the appropriateness of continuing medications in advanced illness.

The impact of pricing of specialty drugs on care, coverage… and just about everything else
Sharon Levine MD, Kaiser-Permanente
For the better part of the last decade there has been growing concern about the pricing and the cost, of specialty pharmaceuticals—5, 6 and 7 figure price tags for rheumatologics, oncology drugs and enzyme replacement factors. 2014 and 2015 saw the introduction of Direct Acting Antivirals to treat Hepatitis C, with an estimated 3 to 5 million potential US beneficiaries of these likely far-superior therapies, at a launch price of $1000 and $1200 respectively for sofosbuvir and the combination sofosbuvir/ledepisvir.
With "orphan drug pricing" for therapies to treat a communicable disease impacting a large population, concern has become "high anxiety" about the ability of public and private payers to provide access to these therapies, without eviscerating state budgets, and driving significant increases in health car expenditures. The presentation will describe the limitations of existing public policy and market-based approaches to addressing the challenge of specialty drug pricing, and make the case that we need a different conversation about value, and a much broader group of stakeholders engaged in that conversation.

The high price of a "free" market: Medicines pricing in the US and beyond
Ruth Lopert MD, George Washington University
This talk will examine the current controversies surrounding the pricing of medicines in the US, with particular reference to new therapies for cancer and hepatitis C, and to the rhetoric around the cost of drug development. Dr. Lopert will then discuss alternative approaches to drug pricing, drawing on the example of the "fourth hurdle" process in Australia in which prices of new medicines are inextricably linked to evidence of comparative benefit.

Getting better in light of political realities
Louis Jacques MD, ADVI
Critics of the current research paradigm in the US complain that clinical trials are too big, last too long, and cost too much. This argument has gained some traction in health policy circles and often used to support efforts to lower the evidentiary requirements of FDA and CMS among others. This premise is reflected in discussions about the causes of the perceived decline of American investment and innovation.

Fundamentally clinical trial design is a math problem rather than a signal of unreasonable expectations of payers and regulators. Clinical trial designs are driven by absolute effect sizes and outcome event rates. The reliance on surrogate outcomes or composite endpoints can make trials more efficient but creates downstream challenges for those who seek persuasive evidence of improved meaningful outcomes for patients in real world settings. Has available medical technology reached the point that the absolute clinical differences are small between new technologies and the status quo? Metaphorically, are we stuck on the upper plateau of the hemoglobin oxygen dissociation curve, when ever larger inputs return ever smaller gains?

What are the rules of the road? FDA law and regulations for reviews of drug and biological products
John Powers MD, George Washington University
This talk will spell out the legally defined criteria for evaluating "safety" of drugs and biologics reviewed by the US Food and Drug Administration. Law spells out that "safety" is a balance of benefits and harms on how patients feel, function and/or survive, so this talk will enumerate the requirements for evaluation of both effectiveness and harms, and the similarities and differences in the scientific criteria for their evaluation, including the history behind how these law and regulations came into being.

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Day 2: June 12th

Managing chronic pain: A case study of the potential of comparative effectiveness research

Carolyn Clancy MD, Department of Veterans Affairs

Recent reports from the IOM and other distinguished groups highlight the challenges of managing chronic pain effectively and safely. Approximately 30% of Americans, and 50-60% of Veterans live with chronic pain, and many use opioid medications chronically. Recent efforts to promote the safe, effective use of opioids have yielded some success, but it remains difficult to predict which patients will do well with alternative interventions and which will continue to require opioids. Dr. Clancy will discuss the potential for comparative effectiveness research to address this dilemma, and present selected promising studies in progress.

The opioid addiction epidemic: How marketing and regulatory failure led to a public health crisis

Andrew Kolodny MD, Physicians for Responsible Opioid Prescribing

According to the US Centers for Disease Control (CDC), America's opioid crisis is "the worst drug overdose epidemic in [U.S.] history." Since 1997, rates of addiction to opioid painkillers have increased by 900% and more than 175,000 American have lost their lives to prescription opioid overdoses. This epidemic was caused in large part by a sharp increase in the use of prescription opioids. As prescriptions began increasing, it led to parallel increases in rates of addiction and overdose deaths. Dr. Kolodny will discuss the role played by pharmaceutical companies in promoting aggressive prescribing of opioid analgesics. He will also discuss how pharmaceutical companies have blocked federal and state interventions that would result in more cautious prescribing.

Hyperglycemia, sedentary obesity, and complications of type 2 diabetes

Tom Finucane MD, Johns Hopkins School of Medicine

The Cochrane Review comparing strategies of intensive vs. conventional glycemic control found a risk ratio for death of 1.00. Furthermore they found no significant differences in renal failure, heart failure, or quality of life. For the 28 RCTs, comprising 35,000 subjects, they caution that "all positive effects should be viewed as potentially caused by or influenced by bias," noting that "treatment targets of HbA1c at 7% in the intensive glucose-lowering group have only been used in five trials, involving 542 participants", only one of which lasted longer than a year. The massive enterprise of setting and using drugs to "achieve" glycemic targets is unsupported by data, biologically implausible, and massively profitable to several interests.

Should black box warnings for fluoroquinolones be revised: Is the bar set too high?

Charles Bennett MD PhD, University of South Carolina

The Food and Drug Administration (FDA) has received >150,000 reports of adverse events and 2,400 reports of deaths associated with the generically available levaquin and ciprofloxacin (two of the three FDA-approved fluoroquinolone antibiotics). Almost half of these reports are associated with psychiatric and neurologic toxicity. The current Black Box label warns of tendonitis, tendon rupture risks, and neurotoxicity occurring among persons with myasthenia gravis; Current product labels provide variable information on psychiatric toxicities. The Southern Network on Adverse Reactions (SONAR) has been investigating these questions for four years, using a novel multi-pronged approach that includes animal studies and, in collaboration with persons who have self-reported quinolone toxicity, a review of FDA adverse event reports Is it time for a revision of the Black Box warnings?

The risks of newer anticoagulants: Sales vs. safety

Thomas Moore, Institute for Safe Medication Practices

A major wrong-turn in drug safety began as manufacturers raced to develop replacements for a standard but risky outpatient drug treatment: the anticoagulant warfarin for atrial fibrillation. It was so dangerous that 18% of treated patients experienced bleeding in one year; in 3.5% of all patients the bleed was a life-threatening medical emergency. However, ease of use rather than safety was the priority when manufacturers brought two replacements to market, dabigatran and rivaroxaban. Misjudgments by the FDA made matters worse. This case study outlines what went wrong and why, and describes the needed actions to improve the safety profile of these high-risk treatments.

Researchers behaving badly: Misconduct in clinical trials

Charles Seife, New York University

Sometimes a clinical trial goes wrong—sometimes there's misconduct or a major departure from good clinical practice. When it does, what happens? How does the FDA account for misconduct in clinical trials that are meant to demonstrate the safety and effectiveness of a new drug? How do the peer-review journals handle indications that something has gone awry in a clinical trial? The answers are not what most scientists would assume—and they're certainly not reassuring.

Psychiatry under the influence: Institutional corruption and diagnostic and practice guidelines

Lisa Cosgrove PhD, University of Massachusetts-Boston

The publication of the *DSM-5* in 2013 created a firestorm of controversy because of concerns about industry influence, the integrity of the revision process, and the widening of diagnostic boundaries. Overdiagnosis and the medicalization of lived experience not only results in a financial and public health burden, but has also led to an impoverished sense of self and a belief in a "pill for every ill." Using the conceptual framework of institutional corruption, this presentation will identify some of the changes in the *DSM-5* and show how financial conflicts of interest may function to shift the direction of psychiatric research and practice guidelines, focusing on interventions that are the most commercially attractive but that do not necessarily represent the best science.

Changes in medical students' responses to drug company marketing

Fredrick Sierles MD, Rosalind Franklin University of Medicine and Science

Medical students, like physicians, are exposed to drug company marketing, gifts and interactions. This represents a major national concern as these interactions lead to poorer-quality, more expensive patient care, and create conflicts of interest. Dr. Sierles will discuss whether changes occurred in medical student exposure to and attitudes about drug company interactions between 2003 and 2012, a time period during which various changes where adopted by national organizations and medical schools to keep conflict of interest issues at bay.