POLICY & PRACTICE

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Court Passes on 'Pay for Delay'

The Supreme Court has refused to consider whether drug companies violate antitrust laws when they pay generic competitors to stay out of the marketplace. The high court's rejection of the case in March allowed companies to continue the practice, known as "pay for delay." In this case, Bayer AG, which makes the antibiotic Cipro, paid generic competitor Barr Laboratories $398 million to not make a version of the drug. Before this, such deals have come under increased scrutiny. Last year, the Federal Trade Commission condemned the deals, and estimated that they will cost consumers about $35 billion over the next decade. There is also legislation pending in Congress (S. 27) to ban pay for delay.

Psoriatic Arthritis Awareness

The Arthritis Foundation has joined the National Psoriasis Foundation and drug makers Amgen and Pfizer to educate patients about psoriatic arthritis. The centerpiece of the "Joint Smart Coalition" effort is the new Web site BeJointSmart.org, with information about psoriatic arthritis and related inflammatory conditions, including rheumatoid arthritis. The site drives home the message that people should see a physician if they experience pain, tenderness, or swelling in their joints lasting more than 3 days, or if have such symptoms many times a month. "Early diagnosis and treatment of psoriatic arthritis can help to stop or slow the progression of permanent damage to the joints," Dr. Patience White, vice president of public health at the Arthritis Foundation, said in a statement.

Research Volunteers Sought

Researchers are asking rheumatoid arthritis patients aged 18-75 years to help test the effect of two tumor necrosis factor–blocking agents on memory B lymphocytes. The phase IV, multicenter study is being sponsored by the National Institute of Allergy and Infectious Diseases. Participants will be randomized to receive subcutaneous injections of either etanercept (weekly) or adalimumab (every 2 weeks). The study is slated to last 24 weeks. The research centers are located in Birmingham, Ala.; San Francisco; Chicago; Manhasset, N.Y.; Rochester, N.Y.; and Charleston, S.C. More information about the study is available at www.clinicaltrials.gov (search Anti-TNF Agents).

HIT Benefits Emerging

Both small physician practices and large health care organizations that quickly adopted health information technology (HIT) are already benefiting, according to Health and Human Services officials reporting in the journal Health Affairs. They reviewed recent peer-reviewed literature on HIT and found that nearly two-thirds of studies showed improvements in at least one aspect of care, ranging from patient mortality to practice efficiency, with none deemed worse because of HIT. Another 30% of the literature indicated some positive effects but also at least one negative to HIT, mainly related to transitioning to electronic records. Dissatisfied providers generally blamed problems with the technology or inadequate support for the obstruction of care improvements with HIT, according to the review from the Office of the National Coordinator for Health Information Technology.

Doctors' Tweets Could Improve

Physicians are using the social networking service Twitter to share medical information with the public, which could have a positive effect on people's health, according to a letter published in JAMA. Few of the 5,156 physicians' tweets studied exhibited ethical breaches, reported researchers led by Dr. Katherine C. Chretien of the Washington DC VA Medical Center. They analyzed tweets sent by self-identified physicians in May 2010. About half of the tweets were health related, 12% were considered "self-promotional," and 1% recommended a medical product or proprietary service. The researchers reported that just 3% of the total were "unprofessional," mainly because of patient-privacy violations, profanity, sexually explicit material, inaccurate medical information, or discriminatory statements.

Tobacco Firms Sue Over Bias

Two large tobacco firms have sued the Food and Drug Administration to remove from a tobacco advisory committee three members who have ties to antitobacco litigation. Lorillard and R.J. Reynolds Tobacco asked the U.S. District Court in Washington to bar the FDA from heeding advisory committee recommendations until Dr. Neal Benowitz, Dr. Jonathan Samet, and Jack Henningfield, Ph.D., have been replaced by members that the companies deem to be unbiased. The suit also asked the court to prevent the FDA from providing any confidential document to the committee until then. The three committee members "have made tens of thousands of dollars as paid expert witnesses in litigation against tobacco products manufacturers" and have "continuing financial relationships with pharmaceutical companies that make smoking-cessation products," the two companies said in a statement.

–Mary Ellen Schneider

Conflicts of Interest Often Unreported in Meta-Analyses

BY JANE ANDERSON

FROM JAMA

Most meta-analyses of pharmaceutical treatments published in major medical journals fail to include information on financial conflicts of interest in the original trials, even when the trials were funded by the pharmaceutical industry or include authors employed by drug manufacturers, a study showed.

VITALS

Major Finding: Only about 26% of the randomized controlled trials reported author financial disclosures.

Data Source: Analysis of 29 meta-analyses of pharmaceutical treatment trials reported in 'high-impact' medical journals in 2009.

Disclosures: Dr. Joel Lexchin reported being a consultant to a law firm representing Apotex in 2007, the Canadian federal government in a lawsuit challenging the Canadian ban on direct-to-consumer advertising of prescription drugs in 2007-2008, and a law firm representing a plaintiff in a case against Allergan in 2010. The other authors reported no disclosures.

The omission of those data from meta-analyses represents "a major gap in the reporting of conflicts of interest, and suggest[s] that, without a formal reporting policy, [conflicts of interest] from [randomized, controlled trials] are unlikely to be reported when results are synthesized in meta-analyses," wrote Michelle Roseman of the psychiatry department at McGill University, Montreal, and her colleagues.

The authors recommended that the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guidelines, which most researchers follow when reporting data for meta-analyses, be updated to require authors of meta-analyses to report funding sources of included randomized controlled trials.

Authors of meta-analyses also should include information on trials' funding sources and authors' financial ties to industry when evaluating the risk of trial bias, the study authors wrote.

The researchers investigated whether meta-analyses of pharmacological treatments published in "high-impact" biomedical journals included information on the conflicts of interest reported in the original studies. They selected 29 meta-analyses of patented pharmacological treatments, all of which were published in 2009 in major medical journals, including JAMA, the Lancet, Annals of Internal Medicine, and BMJ.

The 29 meta-analyses included 509 randomized clinical trials. Only two meta-analyses reported randomized controlled trial funding sources, and none reported author-industry ties or employment by the pharmaceutical industry (JAMA 2011;305:1008-17).

However, when the study authors evaluated the individual randomized controlled trials included in the meta-analyses, they found that more than 62% included information on the trial's funding source.

Of those, nearly 69% were funded in part or entirely by the pharmaceutical industry, about 30% were funded by non-industry sources, and fewer than 1% received no funding.

Only about 26% of the randomized controlled trials included in the 29 meta-analyses reported author financial disclosures. Of those, nearly 69% reported one or more authors having financial ties to the pharmaceutical industry.

Almost all of the randomized controlled trials included in the 29 meta-analyses – 95% – reported author affiliations, and more than 26% of the trials included at least one author employed by the pharmaceutical industry.

None of the 29 meta-analyses analyzed reported author-industry financial ties or employment associated with the included clinical trials. ■

Fla. Judge Allows Implementation Of Affordable Care Act … for Now

A U.S. District Court judge in Florida ruled that the federal government can continue to implement the Affordable Care Act, despite his own earlier judgment voiding the entire law.

In a 20-page ruling full of twists and turns, Judge Roger Vinson clarified his Jan. 31 decision, in which he ruled as unconstitutional the law's provision requiring individuals to obtain insurance – known as the individual mandate – and threw out the remainder of the law because its provisions could not be severed.

In the clarification, Judge Vinson wrote that he had meant for the Jan. 31 ruling to have the force of an injunction and had expected the federal government to halt its implementation of the law.

However, since implementation has continued, Judge Vinson decided to issue the government a "stay," which would allow officials to continue moving forward with the law.

But the stay was conditional. After Judge Vinson wrote that the government must file an appeal of his original ruling within 7 calendar days and seek an expedited appellate review, the Justice Department sent its request to the 11th Circuit Court of Appeals on March 8.

–Mary Ellen Schneider