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# ANNALS OF HEALTH LAW

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### ARTICLES

**Financial Conflicts of Interest in Science**..... JOANNA K. SAX 291

*This Article proposes a new direction for addressing financial conflicts of interest, which plague biomedical research and threaten scientific integrity. This Article descriptively states the controversy surrounding financial conflicts of interest by explaining how these conflicts arise and the damage that can be created as a result. By describing the scientific process, the Article explains that changes to the academic environment may allow the public-private interaction to proceed, without creating the problems associated with financial conflicts of interest.*

*Financial conflicts of interest are created when the profit-seeking motive of a private funding source unduly influences an academic scientist's primary responsibilities. The problem with financial conflicts of interest has grown since the passage of the Bayh-Dole Act in 1980. The cornerstone of current policies to address financial conflicts of interest is disclosure, which is inadequate and unsatisfying.*

*The analysis herein changes the trajectory of current approaches in this area by proposing that an analysis of the underlying environment and behavior leading to conflicts of interest must be considered. This Article proposes the use of behavioral economics to craft a policy that effectively addresses conflicts of interest. To this end, this Article applies research from the field of psychology to understand both the environment of academic scientists as well as to begin to understand how academic scientists make decisions. Drawing on psychology literature, this article proposes that academic scientists may experience cognitive dissonance when faced with a situation in which a conflict of interest may arise. This helps to understand why an academic scientist may make a decision that creates a conflict of interest. In addition, this Article utilizes the results of an empirical study conducted by myself and a colleague. In this study, we asked faculty at five medical schools to respond to an anonymous survey containing hypothetical situations in which a conflict may arise. The combination of the psychology literature and our empirical study can provide support to the creation of new policies.*

*Policy proposals include implementation of default rules, education, and changes to academic requirements. Furthermore, this Article considers ways to incentivize medical centers to implement effective policies as well as changes to intellectual property law.*

**Beyond “Safe and Effective”: The Role of the Federal Government in Supporting and Disseminating**

**Comparative-Effectiveness Research . . . . . MAGGIE H. FRANCIS 329**

*Over the past century, medical advancements have resulted in tremendous health gains for Americans. Although the federal government has played a prominent role in ensuring that new treatments are safe and effective, questions about which medical treatments work best under which circumstances have largely remained unanswered. Thus, the federal government’s recent major investments in comparative-effectiveness research have potential to play a significant role in helping both patients and health care providers navigate the vast array of available treatment options, as well as in improving the quality, efficiency, and delivery of health care system-wide. Yet, the controversial nature of the government’s foray into comparative-effectiveness research also suggests that the path toward realizing these goals may be treacherous. This Article describes the rationales for federal support of comparative-effectiveness research and potential models for that involvement, analyzes the federal government’s recent investments in the research, and concludes with predictions about the probable outcomes of these investments. While increased federal support for comparative-effectiveness research is unlikely to achieve all of the benefits anticipated by its supporters, it is a crucial step toward ensuring that Americans are able to take full advantage of the benefits of medical innovation*

**Putting Together the Pieces: Recent Proposals To Fill in the Genetic Testing Regulatory Puzzle . . . . .**

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*The idea that genetic information is different from other medical information and therefore needs special protection has led to a regulatory puzzle where genetic testing is currently regulated under three separate schemes. Although genetic tests for over 2,000 diseases are available, less than 10% of these tests have been reviewed for clinical validity or utility. Recent action by some genetic testing companies has prompted the federal government to propose changes to the current regulatory scheme. This article discusses the current framework and the recent developments before examining some of the concerns and challenges that face the implementation of these proposed changes. The author evaluates the proposals and competing interests in order to suggest how genetic testing may best be regulated to meet the needs of the industry, clinicians, researchers, patients, and consumers.*

**Options for State and Local Governments to Regulate Non-Cigarette Tobacco Products . . . . .**

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*Most tobacco control laws were written to address the scourge of smoking – particularly smoking cigarettes. As a result, these laws frequently exclude non-cigarette tobacco products, which are becoming more prevalent on the market. These regulatory gaps jeopardize public health by increasing the possibility that these products will be used – particularly by minors and young adults. This article examines gaps in regulation using five products as case studies: dissolvable tobacco products, electronic cigarettes, little cigars, snus, and water pipes. In addition, this article presents policy options that state and local governments can adopt to regulate these products more effectively, including regulations relating to price, flavors, youth access, use in public places, point-of-sale warnings, and marketing. Furthermore, this article contains extensive discussion of the recently adopted federal Family Smoking Prevention and Tobacco Control Act, which both limits and expands the power of state and local governments.*

**Prescription Data Mining, Medical  
Privacy and the First Amendment:  
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KAITLYN DUNN

NANCY RYAN

KATRINA CLEARWATER

*In 2011, the United States Supreme Court in Sorrell v. IMS Health Inc. struck down a Vermont law that would restrict the ability of pharmaceutical companies to purchase certain physician-identifiable prescription data without the consent of the prescriber. The law's stated purpose was threefold: to protect the privacy of medical information, to protect the public health and to contain healthcare costs by promoting Vermont's preference in having physicians prescribe more generic drugs. The issue before the Supreme Court was whether the Vermont law represented a legitimate, common sense regulatory program or a bold attempt to suppress commercial speech when the "message" is disfavored by the state. Striking down the law, the Supreme Court applied a heightened level of First Amendment scrutiny to this commercial transaction and held that the Vermont law was not narrowly tailored to protect legitimate privacy interests.*

**Can the FDA Improve Oversight of Foreign  
Clinical Trials?: Closing the Information Gap  
and Moving Towards a Globalized  
Regulatory Scheme .....**

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*Currently, pharmaceutical companies' utilization of foreign clinical trial data is a ubiquitous and indispensable aspect of gaining approval to market drugs in the United States. Cost benefits, a larger pool of ready volunteer subjects, and greater efficiency in clinical testing are some of the reasons for conducting clinical trials overseas. Despite these advantages, lack of proper oversight may have serious public health implications regarding the integrity of clinical research, ethical treatment of human subjects, and drug safety. Due to the expansive global nature of foreign clinical trials, there are concerns with the FDA's ability to monitor and regulate these trials. This article examines the FDA's oversight of foreign clinical trials and the agency's limitations regulating these trials. In addition to looking at steps the FDA is taking to address these limitations, the article examines other potential regulatory and cooperative actions that can be taken to effectively monitor foreign clinical trials and to ensure data integrity and patient safety.*