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Foreword

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Foreword

The *Annals of Health Law* Editorial Board is proud to present our Winter Issue 2012. We would like to begin by thanking our predecessors for making this opportunity possible. Without your hard work and dedication, the *Annals of Health Law* could not have developed its reputation as one of the country's foremost health law and policy publications. This year's Board has endeavored to give our readers the same type of distinct and timely analysis for which our journal has come to be known. Coming up with a cohesive theme for this issue was no small task. Dozens of submissions were reviewed, and we were pleased to select the six articles that made it into this publication. In this Issue, each author provides a unique perspective of a particular regulatory gap, discusses how, academia, pharma, biotech, and tobacco manipulate these gaps, and illustrates their effects, not only on individual consumers, but on the system as a whole.

The first article sheds light on the financial conflicts of interest that can threaten the authenticity of biomedical research. Author Joanna Sax sets the stage by discussing the pressures surrounding research investigators that drive them to compromise professional standards. The article then provides a critique of the generally accepted method of addressing conflicts of interest today, disclosure. After walking the reader through the decision making process of the academic scientist, Sax proposes several unique approaches to mitigating any undue influence a private funding source may exert upon study investigators.

In the second article, Maggie Francis explores the use of Comparative-Effectiveness Research ("CER") in assessing which new medical treatments, despite already having been approved for use in the United States, actually deliver the best results under certain circumstances. For example, if CER determines that several therapies are equally effective at treating a certain disease, the one that is the least expensive necessarily represents the best relative value in comparison to the other possible alternatives. Of particular interest in the article is the exact role that the federal government should play in the generation, dissemination, and use of CER. Francis examines the controversy surrounding the government's involvement in CER, and the inherent conflicts that abound as a result of its interest in controlling costs in a post-health reform America. The author ultimately leans in favor of federal involvement in CER, providing readers with an analysis of the government's contribution thus far, and offering suggestions to improve upon the current approach.

The successful sequencing of the human genome in 2003 led to dramatic advances in genetic testing and an explosion of debate as to the

safest and most appropriate use of this burgeoning technology. In our third article, Serra Schlanger begins by outlining the current regulatory structure for genetic testing and genetic information. The author continues with a discussion of proposed changes to the current system, prompted amidst the backdrop of thousands of newly developed genetic tests, most of which have yet to be evaluated for precision and veracity. Schlanger then provides an in-depth analysis of the proposed changes, compares competing interests, and suggests a course of action best suited to satisfy the needs of those principally affected.

Next, Michael Frieberg investigates a massive regulatory gap in existing tobacco control laws. As the author points out, things like electronic cigarettes, water pipes, and snus (rhymes with “moose”), are generally excluded from tobacco laws. As such, Frieberg contends, these and other similar products are increasingly pervading the marketplace which bolsters the odds they will be used and significantly threatens public health. The author discusses, in particular, the recently enacted Family Smoking Prevention and Tobacco Control Act, signed in to law by President Barak Obama in 2009, and its perceived shortfalls in closing this regulatory gap once and for all. Frieberg concludes with several potential options for driving sound policy in order to more effectively regulate these products.

In the issue’s fifth article, Marcia M. Boumil, along with colleagues Kaitlyn Dunn, Nancy Ryan and Katrina Clearwater, examines the aftermath of the United States Supreme Court decision in *Sorrel v. IMS Health Inc.* In *Sorrel*, the Court struck down a Vermont law that would have limited the ability of the pharmaceutical industry to purchase prescribing data of physicians which is used to tailor the marketing efforts of their sales forces. Vermont’s Prescription Confidentiality Law would have required IMS to obtain physician consent before it could legally include a particular prescriber’s information in its data. The article begins with an overview of that data mining process, and is followed by a discussion of various state laws that have been enacted to limit industry access to prescribing data, and the resulting litigation that eventually led all the way to the Supreme Court. The authors conclude with an analysis of the *Sorrels* decision, and suggestions for tailoring state laws in order to comply with the Court’s judgment.

Finally, the issue concludes with an examination of the practice of pharmaceutical companies of using foreign-based clinical trials to support approval of marketing applications in the United States. Author Andre Ourso assesses the Food and Drug Administration’s (“FDA”) ability to effectively monitor clinical trials conducted outside of the United States, specifically focusing on the agency’s ability to ensure

the validity of clinical data, study results, and the ethical treatment of human subjects enrolled in these trials.

The entire *Annals of Health Law* staff would like to thank each of the authors featured in this issue for their hard work, professionalism, and contribution to health law scholarship. We would also like to thank each and every member of the *Annals* team, without whom publication of the journal would not be possible. I would like to personally thank my fellow Executive Board members, Laura Ashpole, Alexandria Ottens, Doriann Cain, April Schweitzer, Seth Knocke, and Cameron Webb for their exceptional work and dedication. Finally, thank you to the friendly staff at the Beazley Institute for Health Law & Policy for giving us the opportunity to learn and grow as individuals and future attorneys.

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