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# ANNALS OF HEALTH LAW AND LIFE SCIENCES

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### ARTICLES

#### **Off-Label Drug Risks: Toward a New FDA Regulatory Approach**

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*Most off-label uses of prescription drugs are not supported by strong clinical evidence, leading to millions of patients being exposed to poorly understood risks without well-established benefits. The FDA's approach to limiting these risks has been to bar manufacturers from promoting their drugs for off-label uses. But this strategy has had only limited success and is threatened by courts' increasing willingness to extend First Amendment protections to drug makers' speech.*

*This Article proposes that the FDA should shift its focus from off-label promotion toward off-label prescribing. The Agency should provide information on drug labels about the strength of the evidence that supports common off-label drug uses. Leveraging the FDA's unique ability to gather and analyze information and physicians' role as learned intermediaries could alter prescriber practices to reduce the rate of unsupported off-label drug uses.*

#### **Regulatory De-Arbitrage in Twenty-First Century Cures' Health Information Regulation**

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*The 21st Century Cures Act (Cures), passed in 2016, seeks to regulate health data at two levels. It targets the micro-level by preventing information blocking in electronic health record regulation, penalizing, for the most part, those who participate in a voluntary certification program. At the macro level, it creates a national health data network, in which participation is voluntary. To the extent both programs are voluntary, regulatory arbitrage is easy. Firms can just choose not to participate in more robust regulation, thereby escaping regulation. However, in promulgating regulations, the Department of Health and Human Services (HHS)*

*has taken steps to incent providers and other healthcare entities to participate both in the certification program and in the national network. I conclude that HHS incentives for participation in the certification program—which involve stimulating market demand for certified, as opposed to non-certified EHRs—will be effective. However, those for participating in the national network are less so. I make recommendations to make such participation highly desirable.*

**Can Clinical Genetics Laboratories be Sued for Medical Malpractice?**

Jessica L. Roberts, JD, Alexandra L. Foulkes, MS, JD, Paul S. Appelbaum, MD, Wendy K. Chung, MD, PhD, Ellen Wright Clayton, JD, MD, Barbara Evans, JD, PhD, LLM, Gary E. Marchant, JD, PhD ..... 153

*Clinical genetics laboratories are handling more patient information than ever before, including genetic data that has no established clinical significance. Those labs could face legal liability if that previously uncertain information gains clinical significance and a laboratory fails to notify the impacted patients. Should patients choose to sue clinical genetics labs, what body of law will govern: medical malpractice or ordinary negligence? We conducted a fifty-state survey assessing whether clinical laboratories are “health care providers” for the purposes of medical malpractice to answer this question. We found that six states expressly include laboratories or laboratory personnel in their statutory definition of health care provider, fifteen states have judicial opinions that treat laboratories as health care providers, and four states have caselaw concluding that laboratories are not health care providers. Thus, twenty-five states have yet to decide this important threshold matter. We therefore conclude that the legislatures in these states should provide clarity regarding the potential medical malpractice liability of clinical genetics laboratories.*

**Disentangling Dicta: Prince v. Massachusetts, Police Power and Childhood Vaccine Policy**

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*Each year communicable disease outbreaks such as measles, mumps, and pertussis occur, spurring debates in the media, among public health professionals, and in the legislature about what constitutes the appropriate response. Some stakeholders assert the state should enact strict mandates because it is unreasonable to decline vaccination, that non-medical exemptions should be abolished, and that state health officials should intervene when parents decline vaccination for their children. This article builds upon legal scholar Wendy Mariner and colleagues’ observation that courts following Jacobson v. Massachusetts “expanded, superseded, or even ignored” portions of Jacobson’s limitations on police power. Decades of jurisprudence have upheld compulsory vaccination laws as they expanded in scope and rejected challenges to both compulsory vaccination laws and removal of nonmedical exemptions based on Prince v. Massachusetts. A closer examination of Prince v. Massachusetts; however, reveals core quotes adopted by multiple subsequent courts distorted dicta into binding law. Neither Prince’s*

*holding, nor its citing authority People v. Pierson ever addressed disease prevention or vaccination.*

*At a critical juncture when numerous legislatures are considering bills to remove nonmedical vaccine exemptions, this article analyzes how imprecision in applying dicta set forth in Prince v. Massachusetts dramatically altered the development of vaccine jurisprudence. Recalling the forgotten limits on police power, this article describes significant implications for balancing Constitutional rights and proposes a solution that incorporates public health values of accountability, transparency, and trust.*

### **Reference Pricing in Health Care: An Inventory of Techniques, and Practical and Policy Implications**

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*Reference-based pricing is a new innovation in health care payment. Reference-based pricing (RBP) is defined here as any announced policy by a payer to place a firm limit on its payment for a service or product based upon some reference point. With high prices considered the culprit in high US health care costs, some payers are reconsidering the network contracting model, through which payers offer patient referrals in exchange for an ostensibly discounted price. Over this decade, RBP has evolved from a fairly simple beginning (shoppable services) to iterations involving more complex legal and market leverage considerations, including imposition of reference prices for state employee benefits, and “Medicare-Plus” pricing by small employers. Recently CVS Caremark announced that it will marshal its clients to place a limit on prices of new drugs, pegged to ICER cost effectiveness analyses. This raises the prospect of payers acting collectively to impose a reference pricing regime, which may come to include purchasing of services.*

*This paper taxonomizes RBP techniques and discusses the negotiating/leverage dynamics and practical and legal implications of each. The principal promise of this innovation is price reductions through payer self-help rather than through politically-fraught rate-setting legislation. But perils come from: (1) the game-of-chicken dynamic inherent in some techniques—if providers do not capitulate, consumers may be left with narrower networks or balance bills; (2) without contracting, accountable care organizations and other payment reforms could be supplanted by arrangements devoted solely to addressing prices; (3) possible cost-shifting from self-insured payers onto fully insured payers, whose ability to impose reference prices is restricted by network adequacy regulations; (4) legal uncertainty about antitrust implications when payers act in concert. Nevertheless, the paper concludes that further experimentation, including demonstration of a Local Healthcare Markets Payment Advisory Commission, would be worthwhile.*