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Foreword

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Foreword

In this Winter Issue of Volume 16, we are pleased to present our readers with a selection of articles covering a variety of ethical and legal issues in the health care industry. Each article discusses a timely debate in the area of health law and offers insightful and interesting suggestions to advance these debates.

Accessibility to diagnostic imaging technology is an essential tool for the diagnosis and treatment of patients, especially in the case of medical ultrasound. In an article to which all purveyors of pop culture can relate, Dr. Archie A. Alexander describes the emerging market for these services in "Just Scanning Around' with Diagnostic Medical Ultrasound: Should States Regulate the Non-Diagnostic Uses of this Technology?" Because such practices may violate the prudent use of this technology, as intended by its manufacturers, state-based legislative efforts may be needed to protect consumers from abuse. The author identifies the potential health risks to consumers and reviews the existing federal and state regulations, ultimately recommending increased legislation and mandated control of this technology.

In another article also related to diagnostic imaging, Dr. Charles Caldwell and Evan Seamone explore the treatment of missed diagnoses by the courts in "Excusable Neglect in Malpractice Suits Against Radiologists: A Proposed Jury Instruction to Recognize the Human Condition." Radiology is a practice area that creates great confusion in the courts, as evidenced by the varying results when complaints against radiologists are brought. Dr. Caldwell and Mr. Seamone present a formula for calculating liability to address the debate surrounding the characterization of errors as culpable or merely "human." The authors explore the human factor as it applies to radiology practice and recommend a jury instruction that discusses appropriate levels of culpability for excusably negligent acts.

Just as patient safety is at the forefront of treatment standards and the calculation of liability formulas, the regulation of drug trials in pediatric patients must be conducted with safety as a foremost concern. In "Give Them What They Want? The Permissibility of Pediatric Placebo-Controlled Trials Under the Best Pharmaceuticals for Children Act," Holly F. Lynch reviews the steps taken by the FDA and Congress to improve the level of information available to pediatric prescribers. As part of a new model, the FDA has requested pediatric placebo-controlled trials of drugs used to treat depression and obsessive-compulsive disorder. Ms. Lynch explores the legal and ethical issues surrounding such trials in light of safety concerns, most especially suicidality in the pediatric population. Once there is a safe and effective alternative treatment available, the requested placebo controls will no longer be acceptable based on the current language of the regulations. As a result, the author suggests that, while clinical trials of these drugs must still be conducted in children, these tests must use an active-control design to satisfy both legal and ethical standards.

The next article, "Releasing Managed Care's Chokehold on Healthcare Providers," is authored by Kristin Jensen. We selected Ms. Jensen's article from the top twenty percent of articles submitted to the Eighth Annual Epstein Becker & Green Health Law Writing Competition. Ms. Jensen addresses the power of managed care organizations (MCOs) to affect physician practice and patient care. The article examines the interplay between informed consent and physician-patient communications, disparity in bargaining power between physicians and MCOs, and MCOs' strategic use of termination-without-cause clauses. Ms. Jensen advocates methods to protect patients' rights to treatment information and provide physicians with greater power, such as allowing physicians to bargain collectively, providing physicians a private right of action, and creating an impartial appeals system to challenge terminations.

Finally, Stacy Cook examines a cutting edge issue in the area of quality assurance and cost control, in "Will Pay For Performance Be Worth The Price to Medical Providers? A Look at Pay for Performance and Its Legal Implications For Providers." Ms. Cook gives guidance to attorneys who represent physicians or hospitals that participate in, or are evaluating participating in, a pay for performance program. The author provides the history of such programs and examines the components of pay for performance to show how it will affect the practice of medicine and impact provider liability and rights. The article demonstrates how healthcare providers can minimize the more detrimental effects of pay for performance and take advantage of these programs' potential benefits. Furthermore, this article previews many of the issues central to the Sixth Annual Health Law and Policy Colloquium, which will be thoroughly covered in our Summer Issue of Volume 16.

In conclusion, we hope you will enjoy the variety of perspectives and health law topics that these articles provide. The staff welcomed the opportunity to work with these authors and publish their contributions to this issue of the *Annals of Health Law*, and we would like to thank them for their assistance. We also would like to thank the Beazley Institute for Health Law and Policy, Kelley Yaccino, John Blum, and Larry Singer for their support. We wish you the best for the New Year!

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