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Foreword

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Foreword

We are pleased to write an introduction to this second issue of Volume 12 of the *Annals*, an issue of which we are particularly proud for at least two reasons. First, with this issue the *Annals* officially moves to a bi-annual journal, a long contemplated move that we believe is responsive to the sophistication of the health law field, and the rapidity with which new developments occur. By now publishing twice yearly we intend the *Annals* to be more responsive to academic and practitioner needs for a source which critically analyzes some of the most important issues arising in health law.

This issue is also important because it contains papers from the Institute for Health Law's annual Health Law and Policy Colloquium. The Colloquium, now beginning its third year, is an invitation only event designed to attract thought-leaders gathering to dialogue about a health policy issue of national import. The 2002 Colloquium attracted more than one hundred academics, general counsels from health care providers and payers, government officials, consultants, executives, physician leaders, and senior law firm partners to discuss the role of the hospital medical staff and board of directors in assuring high quality medical care. The conversation was energizing, with significant debate occurring in the room regarding the role and responsibility of the board and the medical staff, and where the province of each begins and ends.

The first four papers of this Volume capture much of the debate occurring during the Colloquium. In "The Hospital Board at Risk and the Need to Restructure the Relationship with the Medical Staff: Bylaws, Peer Review and Related Solutions," John Marren and Michael Paddock from Hogan Marren, and Landon Fezell from QualVal Health Systems, Inc., set forth the parameters of the Colloquium debate, arguing that the current quality assurance structure, whereby the hospital board delegates quality assurance to the medical staff—while ultimately remaining legally responsible for its performance—is unworkable. Reviewing the role of Board and medical staff quality activities in the contemporary hospital, the authors argue that

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the traditional independence of the medical staff from the hospital enables medical staffs, potentially, to poorly perform their delegated responsibilities. This then leaves hospital boards, which are typically unskilled in quality matters, with little effective recourse short of drastic measures. The authors challenge the statutory, regulatory, and accreditation schema which establish this framework, and propose changes to address these shortcomings.

Mr. Ronald Spaeth, a senior executive with Evanston Northwestern Healthcare, provided a chief executive officer perspective to the proceedings. He focuses on the administration—physician linkage, and how this relationship must be developed to effectuate high quality medical care. In his article, “Quality Assurance and Hospital Structure: How the Physician-Hospital Relationship Affects Quality Measures,” Mr. Spaeth examines quality in the academic and community hospital settings, and reviews the differences in each due to organizational structure of the quality function. In doing so, he argues that the challenges of community hospitals, which in most cases rely upon the good graces of physicians in order to generate referrals to the institution, provide a unique set of dynamics when it comes to enforcing quality of care standards.

In concert with Mr. Spaeth, Dr. Gerald Eisenberg, Medical Staff President at Lutheran General Hospital provides a “real world” perspective on quality initiatives. In “The Medical Staff Structure—Its Role in the 21st Century,” Dr. Eisenberg focuses on the role of the independent medical staff, its organization and internal workings, and the role that it must play to assure high quality medical care. He provides insights into some of the most prevalent conflicts between hospitals and their physicians, and offers suggestions to ameliorate some of the most significant conflicts between the two.

In our last Colloquium paper Elizabeth Snelson, a medical staff attorney, offers her perspective as an advocate of physician rights in the institutional quality mechanism. She supports the legal framework underlying the medical staff role in quality activities, and reviews case law concerning medical staff bylaws’ protection of physicians’ legitimate role in quality activities. By-law provisions, which in her view denigrate the physicians’ roles

and responsibilities, are discussed with sample language for protective medical staff bylaw provisions posited.

In short, I believe you will find these four papers from the annual Colloquium, which offer insights from four unique perspectives—hospital attorney, executive, medical staff leader, and medical staff attorney—enlightening, and that you will enjoy joining this debate as much as we did.

This issue of the Annals also continues the Journal's tradition of publishing intriguing articles anticipating significant developments in the field of health law. Professor Ross Silverman, in "No More Kidding Around: Restructuring Non-Medical Childhood Immunization Exemptions to Ensure Public Health Protection" enters a particularly significant debate occurring within the health care and health law communities, analyzing childhood immunization programs. The issue has particular relevance given the controversy surrounding the possible rollout of a mass smallpox vaccine program. Prof. Silverman begins his paper by reviewing the history of immunization programs and the inconsistency of state enforcement of immunization laws and exemptions, using situations arising in New York, Wyoming, and Arkansas to illustrate his points. In doing so, Prof. Silverman demonstrates significant weaknesses in our public health systems. He also raises questions about the conflict between public health and individual autonomy. Prof. Silverman concludes by advocating an informed refusal approach as a way to protect autonomy, while assuring that public health programs have the maximum impact possible to protect public welfare and safety.

Professor James O'Reilly and Nancy Hui have authored articles focusing on the pharmaceutical industry, an area of particular import given the current policy discussion on prescription drug coverage. In his article titled "Off-Label or Out of Bounds?: Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs," Prof. O'Reilly studies promotion practices for unapproved uses of prescription drugs, an issue with significant quality and cost implications. He criticizes Congress for moving away from what he believes was a patient protective review framework and towards a more industry friendly, albeit expansive, approach. He argues that the health consequences of off-label drug use were not well understood by Congress when it passed significant changes to the drug review

framework, and that in passing these 1997 amendments Congress sacrificed the public's health while significantly expanding pharmaceutical profits.

Ms. Hui looks at a related issue which also has significant quality and cost ramifications, and that is the generic drug approval process. Specifically, she focuses upon a recent Food and Drug Administration proposal modifying regulations regarding generics, which regulations have been used to delay or defeat generic drug applications. Ms. Hui discusses the contents of the proposed regulations, and analyzes their likely impact on patients and the pharmaceutical industry.

In her article "The Bipartisan Patient Protection Act: Greater Liability on Managed Care Plans," Urura Mayers examines a topic which has been percolating for some time in Congress, patient protection legislation. Specifically, she examines competing House and Senate versions of this legislation, critically examining the protections offered in each. In the course of her analysis Ms. Mayers proposes various amendments to the Employee Retirement Income Security Act ("ERISA"), since the law has a significant impact on the management of health care plans. Ms. Mayers also raises the troubling issue of access to care for those lacking insurance, and the failure of patient protection legislation to address this significant problem.

Finally, Ms. Zabawa picks up on Ms. Mayers challenge, examining access to care in the context of federally funded health care programs, focusing specifically upon the Medicaid waiver process. The paper has special resonance given the Administration's desire to offer more flexibility, with significantly more financial risk, to the states. Ms. Zabawa reviews the history of waivers and the projects it has spawned, and the role of a collaborative, community-oriented approach to health care delivery. She posits that a collaborative process, involving a true partnership between government and the community it desires to serve, holds the best promise for chipping away at the health care access problem.

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With this issue we say farewell to many of the fine editors who served on the Annals staff this year. They have done a fantastic

job, and positioned the Annals well for a bright future. While the contributions of all are significant, we give a special thanks to Jeffrey Kee, the Annals' Editor-in-Chief, for his leadership in converting the Annals to a bi-annual journal, and for providing a framework under which the Annals is surely to grow and prosper.

Finally, with this issue of the Annals, we complete the design makeover intended to visually demonstrate the new direction set for the Annals. We hope you are as pleased by it as we are.

Let us conclude by stating that the Annals represents the best of what the Institute for Health law stands for: a center for serious dialogue and advancement of the field of health law. We are proud to be a leader in this dynamic field, and encourage you to contact us if you would like to become involved in our myriad endeavors.

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