Symposium Articles

173
Introduction
Kevin Outterson

I. PATENTS, INNOVATION & PUBLIC HEALTH

176
Using Patent Data to Assess the Value of Pharmaceutical Innovation
Aaron S. Kesselheim and Jerry Avorn

Though many more patents emerge from industry sources, drug-related patents generated in the non-profit setting appear to have greater importance than patents arising from the commercial sector, which helps demonstrate the value non-profit research institutions can have in driving drug development.

184
An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries
Sean Flynn, Aidan Hollis, and Mike Palmedo

This paper offers an economic rationale for compulsory licensing of needed medicines in developing countries. The patent system is based on a trade-off between the “deadweight losses” caused by market power and the incentive to innovate created by increased profits from monopoly pricing during the period of the patent. However, markets for essential medicines under patent in developing countries with high income inequality are characterized by highly convex demand curves, producing large deadweight losses relative to potential profits when monopoly firms exercise profit-maximizing pricing strategies. As a result, these markets are systematically ill-suited to exclusive marketing rights, a problem which can be corrected through compulsory licensing. Open licenses that permit any qualified firm to supply the market on the same terms, such as may be available under licenses of right or essential facility legal standards, can be used to mitigate the negative effects of government-granted patents, thereby increasing overall social welfare.

209
Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines While Minimizing Investment Side Effects
Robert C. Bird

This manuscript addresses how developing countries can maximize access to essential medicines and minimize unwanted side-effects within the legal environment of a compulsory license regime. While compulsory licensing can play a role in improving public health, external social and political conditions must be considered in order to make licensing an effective practice.

222
Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules
Kristina M. Lybecker and Elisabeth Fowler

This paper examines two recent examples of compulsory licensing legislation: one globally embraced regime and one internationally controversial regime operating under the same WTO rules. In particular, we consider Canadian legislation and the use of compulsory licensing for HIV/AIDS drugs destined for a developing country. This is then contrasted with the conditions under which Thai authorities are pursuing compulsory licenses, the outcomes of their compulsory licenses, as well as the likely impact of the Thai policy. Finally, we construct a rubric to evaluate characteristics of a successful regime. This is then used to analyze the Canadian and Thai regimes and frame the expected implications of each national policy. It is hoped that the assessment will guide changes to compulsory licensing design to ensure that legitimate regimes are embraced while illegitimate ones are disallowed.

240
Wild-Card Patent Extensions as a Means to Incentivize Research and Development of Antibiotics
Jorn Sonderholm

Antibiotic resistance is a serious public health problem on a global scale. In both developed and developing countries, the unpleasant consequences of the phenomenon are being felt. This paper discusses wild-card patent extensions as a means to incentivize research and development of new antibiotics. The thesis defended in the paper is that the implementation of such patent extensions is an appropriate legislative response to the problem of antibiotic resistance. The general idea of wild-card patent extensions is presented in the first part of the paper. A number of objections to the idea are thereafter discussed and rejected.
II. INVITED REVIEWS

247

Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options
Jerome H. Reichman

In this Comment, the author traces the relevant legislative history pertaining to compulsory licensing of patented pharmaceuticals from the TRIPS Agreement of 1994 to the 2003 waiver to, and later proposed amendment of, article 31, which enables poor countries to obtain needed medicines from other countries that possess manufacturing capacity. The Comment then evaluates recent, controversial uses of the relevant legislative machinery as viewed from different critical perspectives. The Comment shows how developing countries seeking access to essential medicines can collaborate in ways that would avoid undermining incentives to innovation and other social costs attributed to compulsory licensing. It ends by defending the legality of recent measures taken to promote public health in developing countries, and by reminding developed countries that unilateral retaliation against such measures is demonstrably illegal under WTO foundational law and jurisprudence.

264

Commentary: Innovation Policy for a New Era
Amy Kapczynski

This commentary offers a response to the Sonderholm, Bird, and Flynn et al. articles, and argues that the current innovation crisis requires more ambitious approaches, as well as a serious consideration of alternative mechanisms for R&D such as prizes.

III. PHARMACEUTICAL INNOVATION & SPECIAL POPULATIONS

269

Right to Experimental Treatment: FDA New Drug Approval, Constitutional Rights, and the Public’s Health
Elizabeth Weeks Leonard

On May 2, 2006, a divided panel of the U.S. Court of Appeals for the District of Columbia, in a startling opinion, Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach, held that terminally ill patients who have exhausted all other available options have a constitutional right to experimental treatment that FDA has not yet approved. Although ultimately overturned by the full court, Abigail Alliance generated considerable interest from various constituencies. Meanwhile, FDA proposed similar regulatory amendments, as have lawmakers on both sides of the aisle in Congress. But proponents of expanded access fail to consider public health and consumer safety concerns. In particular, allowing patients to try unproven treatments, outside of controlled clinical trials risks both the study’s outcome and the health of patients who might benefit from the deliberate, careful process of new drug approval as it currently operates under FDA’s auspices.

280

Just a Spoonful of Sugar: Drug Safety for Pediatric Populations
Barbara A. Noah

Children deserve optimal medical care. Although prescription drugs play a prominent and essential role in pediatric health care delivery, health care providers often must make prescribing decisions for their young patients based on imperfect or absent safety and efficacy data for pediatric populations. The safe and effective use of prescription drugs in children depends on a thorough understanding of the physiologic differences between children and adults. Currently, only one-third of drugs prescribed to children have been studied for safety and efficacy in pediatric populations. Until relatively recently, the Food and Drug Administration (FDA) made surprisingly little effort to improve the quality or quantity of clinical research data for this patient group. Recent agency efforts to encourage pediatric drug research have generated mixed results and created unintended consequences. The development, prescribing, and safety evaluation of prescription drugs for children will require that the FDA and health care providers examine current practices, acknowledge their shortcomings, and consider creative solutions to the challenges associated with gathering additional data through pediatric drug research.

292

Prizes and Parasites: Incentive Models for Addressing Chagas Disease
Sara E. Crager and Matt Price

Recent advances in immunology have provided a foundation of knowledge to understand many of the intricacies involved in manipulating the human response to fight parasitic infections, and a great deal has been learned from malaria vaccine efforts regarding strategies for developing parasite vaccines. There has been some encouraging progress in the development of a Chagas vaccine in animal models. A prize fund for Chagas could be instrumental in ensuring that these efforts are translated into products that benefit patients.

305

Riegel v. Medtronic, Inc.: Revisiting Pre-emption for Medical Devices
Bruce Patsner

The recent United States Supreme Court decision in Riegel v. Medtronic, Inc. affirmed the doctrine of pre-emption protection only for those medical devices reaching U.S. markets via the PMA (premarketing approval) process and preserved the previous Lohr v. Medtronic decision’s lack of preemption protection for those medical devices marketed via the generally more abbreviated 510(k) clearance mechanism. This paper reviews the logic and faults of the Riegel decision and discusses the implications of the Riegel decision for pre-emption protection for other classes of FDA-approved medical products.
Independent Articles

318
Collaborated Death: An Exploration of the Swiss Model of Assisted Suicide for Its Potential to Enhance Oversight and Demedicalize the Dying Process
Stephen J. Ziegler

Death, like many social problems, has become medicalized. In response to this medicalization, physician-assisted suicide (PAS) has emerged as one alternative among many at the end of life. And although the practice is currently legal in the states of Oregon and Washington, opponents still argue that PAS is unethical, is inconsistent with a physician’s role, and cannot be effectively regulated. In comparison, Switzerland, like Oregon, permits PAS, but unlike Oregon, non-physicians and private organizations play a significant role in assisted death. Could the Swiss model be the answer? The following essay explores the Swiss model of assisted suicide for its potential to enhance the regulation of PAS, reduce physician involvement, and perhaps demedicalize the way we die.

331
Pushing the Dead into the Next Reproductive Frontier: Post Mortem Gamete Retrieval under the Uniform Anatomical Gift Act
Bethany Spielman

In re Matter of Daniel Thomas Christy authorized post mortem gamete retrieval under the most recent revision of the Uniform Anatomical Gift Act. This article recommends that the National Conference of Commissioners on Uniform State Laws explicitly address the issue of post mortem gamete retrieval for reproductive purposes; that legislators specify whether their states will follow the Christy ruling; and that ethics committees and consultants prepare for the questions about human identity and self determination that post mortem gamete retrieval raises.

344
When Scientists Deceive: Applying the Federal Regulations
Collin C. O’Neil and Franklin G. Miller

Deception is a useful methodological device for studying attitudes and behavior, but deceptive studies fail to fulfill the informed consent requirements in the U.S. federal regulations. This means that before they can be approved by Institutional Review Boards, they must satisfy the four regulatory conditions for a waiver or alteration of these requirements. To illustrate our interpretation, we apply the conditions to a recent study that used deception to show that subjects judged the same wine as more enjoyable when they believed it had a higher price.

351
Differences in Regulatory Frameworks Governing Genetic Laboratories in Four Countries
Anne Marie Tassé, Élodie Petit and Béatrice Godard

The purpose of this article is to determine how the heterogeneity of the different regulatory frameworks governing genetic laboratories in Australia, France, the United Kingdom, and the United States hinder the international availability of genetic tests. We conclude that a better understanding of the various national standards governing genetic laboratories may help health professionals choose laboratories for referral in an evidence based manner in order to protect the patient’s best interests.

358
The Pharmacist’s Obligations to Patients: Dependent or Independent of the Physician’s Obligations?
Jason V. Altilio

It has been 40 years since the seminal papers on pharmacy’s status as a profession sparked debate about the pharmacist’s role in health care, yet the questions they raised are just as poignant today as they were then. Questions about whether pharmacists are the experts when it comes to drug therapy information can be answered practically by assessing the perception of pharmacists’ obligations to patients as being dependent on or independent of physicians’ responsibilities. Both options have important implications for pharmacy’s status as a profession, the value that pharmacists can add to health care, and a pharmacist’s right to deny a patient emergency contraception.

Columns

369
Currents in Contemporary Ethics
Cynthia Marietta and Amy L. McGuire

375
Teaching Health Law
Jonathan Todres

380
Recent Case Developments in Health Law
Harvard Law and Health Care Society

389
Calendar of Events
Letters to the Editor

To the Editor:
As I read Robert Baker’s response to my essay [Giles Scofield's article “What Is Medical Ethics Consultation?” was published in JLME 36, no. 1; Robert Baker's response, “In Defense of Bioethics” was published in JLME 37, no. 1 – ed.], I thought that this must be one of this instances in which, as Oliver Wendell Holmes once observed, a page of history is worth more than a volume of logic. For one thing, even if the field of ethics consultation has a brief history, I find it hard to believe that anyone familiar with the primary source material connected with that history, i.e. the articles about whether ethics consultation ought to become a profession, would think that I am a died-in-the-wool advocate of professionalization.1 By the same token, I find it hard to believe that anyone familiar with the primary source material written by those who were involved in or reported on ethics consultation could believe that the Task Force concluded that professionalization ought to happen.2 John Fletcher thought that the Core Competencies had put the entire matter to rest – and had proven me wrong to boot.3 Charles Bosk, another Task Force member, has gone so far as to explained that, when the Task Force said that professionalization, certification and accreditation were not advisable “at this time,” the Task Force did not mean that they would be advisable at a later time, but that it was simply not trying to make an absolute and unqualified statement.4 These things being so, when Baker says that he thinks the field ought to take accreditation, professionalization and certification seriously, he confirms the argument I made in my article, and demonstrates that it is he, not I, who needs to bone up on history.

As I further pondered the cause of our misunderstanding, I concluded that it boiled down to two words: formal, and new. Baker thinks that I am mistaken in chastising ethics consultation having failed to professionalize, because he thinks that I think it is a new, i.e. relatively young, profession. Regardless of how new the field is – and I don’t think it is as young as Baker does – I also don’t think about it simply in terms of its being a ‘new’ profession.

One of the characteristics of these new occupations is that they claim expertise in areas of life that were previously outside the jurisdiction of any profession, areas that may be loosely described as pertaining to the ‘lifestyles’ of individuals. The new professionals are constantly moving across boundaries, expanding into new territory, disputing jurisdiction with others....The result of this fluidity is what one may call a built-in imperialism[.] ...This imperialistic propensity of the new professions...has a more serious consequence than the self-aggrandizement of this or that occupation group....[T]he new life-style engineering is potentially without limits.5 What this means is that professions may now acquire their ultimate goals, i.e. power, status, etc., in the old, formal way, i.e. visibly and overtly, as did law and medicine, or in a new, informal way, i.e. invisibly and covertly, as ethics consultation seems to be doing.

Whether it’s a new or a “new” profession, at bottom, ethics consultation is about the same thing: the quest for power. I know I clearly said that. And because saying that ethics consultation is new cannot and does not refute the assertion that the field is on a power-trip the gravamen of my “complaint” still stands. Baker’s attempt to change the subject and malign the messenger, which is what those who hold the reins of power always do when they don’t like – but can’t refute – the message, falls flat on its face. Although Baker may like to think that we are on the same page, we could not be further apart. Only time will tell which of us is further from the truth.

Yours sincerely,
Giles R. Scofield, J.D., M.A. (Religion)
Clinical ethicist, Centre for Clinical Ethics;
Clinical ethicist, Joint Centre for Bioethics;
Associate Professor, Department of Family & Community Medicine, Faculty of Medicine, University of Toronto

References
Robert Baker Replies

To The Editor

Giles Scofield appeared to be condemning bioethics for its failure to accredit educational programs, certify the competency of clinical ethics consultants, and develop a code of professional responsibility, when he wrote that clinical ethics consultation “is and can only be what it purports not to be – a moral, if not an ethics, disaster...because...of its failure to do what a profession worthy of the name would do: formally accredit the programs that educate and train its practitioners, formally certify and license its practitioners, and formally establish a meaningful, binding, and enforceable code of professional misconduct.” Scofield now informs us that the “gravamen of [his] ‘complaint’” is that in seeking to accredit training programs and to certify the competency of practitioners “the field is on a power trip.” He buttresses this remark by observing that a decade ago the Core Competencies for Health Care Ethics Consultation report issued by the American Society for Bioethics and Humanities (ASBH) characterized the certification of clinical ethicists and the accreditation of bioethics educational programs, “at this time,” as “premature” because it “could encourage [an] authoritarian approach to ethics consultation,” “undermine disciplinary diversity, or “lead to the institutionalization of a particular substantive view of morality.” Moreover, the report noted continued, “it is unlikely at this time that a sufficiently reliable test could be developed to measure the required competencies.”

Time and experience tend to remedy prematurity; over the past decade the reasons for concern about certification and accreditation noted in the 1998 Core Competencies report have been obviated. Due in no small measure to a consensus inspired by the Core Competencies report itself, clinical ethics consultants today embrace the multidisciplinary nature of their enterprise and reject authoritarian models of the ethics consultation. A new report, soon to be issued by the ASBH, reiterates the earlier report’s rejection of the authoritarian model of consultation, i.e., the notion of the ethics consultant as a moral dictator who authoritatively pronouncing on matters of right and wrong. It endorses instead a version of the “ethics facilitation model” proposed in the 1998 Core Competencies report: a procedural approach to analyzing the sources of ethical conflict by identifying the nature of value uncertainty or conflicts and the communication issues that give rise to requests for consultation. The new report portrays ethics consultants as gathering information, consulting with parties, opening lines of communication, and facilitating the resolution of conflicts in a respectful atmosphere with attention to the interests, rights, and responsibilities of all involved. On this model, ethicists serve to analyze, catalyze, inform, mediate, facilitate, document and review ethical decision-making – not to dictate outcomes.

The facilitation model presupposes a series of specific skills, but in 1998 no reliable method of skills assessment seemed apparent to the authors of the Core Competency report. Ironically, in the very year in which the report was published the Education Commission for Foreign Medical Graduates (ECFMG) became the first accrediting body to formally integrate skills assessment into medical education (Step II, Clinical Skills Assessment). The National Board of Medical Examiners (NBME) and the Medical Council of Canada (MCC) soon followed. Today, skills training and assessment is commonplace in medical education. Moreover, drawing on the expertise of fellow medical educators, leading contemporary bioethics graduate programs integrate skills assessment, including the use of standardized patients, role-plays, and other techniques, into clinical ethics training.

Developments in ethics consultation and bioethics education over the past decade – the dominance of a multi-disciplinary facilitation model, the development of skills assessment methodologies – obviate the concerns about accreditation and certification raised in the 1998 Core Competencies report. Not unreason-
ably, the ASBH is now engaged in a professionalization project: developing standards of professional responsibility for clinical ethics consultants, issuing a new report on core competencies for clinical ethics consultation (due to be published in 2009), and exploring the possibility of credentialing ethics consultants and accrediting clinical ethics education programs.

Scofield characterizes the ASBH’s efforts as a “power trip.” This characterization inverts reality. In fact, clinical ethics consultants are already empowered: fellow healthcare professionals, the institutions that employ ethics consultants, the patients and families who confide in them – society – have already entrusted clinical ethics consultants with enormous advisory authority and influence, “power,” so to speak. The professionalization of clinical ethics consultation is thus not about “power” but about the responsible and accountable use of the authority and influence invested in clinical ethics consultants. Everyone who works in a clinical context should be held accountable to standards of responsible conduct and practice; every program that trains healthcare professionals should also be held to educational standards. Clinical ethics consultation is no exception. As Scofield aptly remarks, bioethicists are obligated to do “what a profession worthy of the name would do: formally accredit the programs that educate and train its practitioners, formally certify and license its practitioners, and formally establish a meaningful, binding, and enforceable code of professional misconduct.”8

To reiterate, ethics consultants have already been deeded “power” in the form of advisory influence and authority, the wisdom of our culture, as parsed over the centuries by apostles (Luke 12:48), poets, presidents and popular culture icons, is that “with great power, comes great responsibility.” For the ASBH to fail to professionalize as the field of clinical ethics consultation matures would be irresponsible. However, in the light of the concerns raised in the 1998 Core Competencies report, it is eminently reasonable for Scofield to question whether those seeking to professionalize have addressed the concerns about certification and accreditation raised a decade ago. As someone directly involved with the ASBH’s professionalization project, and as a member of the society’s Clinical Ethics Consultation Group, I would like to thank Scofield for publicly raising the issue, thereby giving us the opportunity to reassure him and the wider community that we have considered these issues and we have concluded that now is the appropriate time for ethics consultation to professionalize and that failure to do so would be irresponsible.

Robert Baker, PhD
Director & Professor of Bioethics
Union Graduate College-Mount Sinai School
of Medicine Bioethics Program
William D. Williams of Philosophy, Union College

References
4. Id.
5. Id., at 31-32
6. Id., at 31-32
8. Scofield, supra note 1.
9. In response to a request by the ASBH President, Kenneth Kipnis and Robert Baker are working with the members of the ASBH’s Clinical Ethics Consultation Affinity Group to develop a code of professional responsibility for bioethicists involved in clinical ethics consultation.

Errata
In JLME 37, no. 1, in the “Recent Case Developments” Column, the article written by Ching Pin Ang on Michigan’s stem cell developments was incorrectly attributed to Elisha Baron, and the article written by Elisha Barron on HPV was incorrectly attributed to “Chin Pin Ang.” We regret the error.