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Symposium Articles

SYMPOSIUM

Developing
Oversight
Approaches to
Nanobiotechnology:
The Lessons of
History

Guest Edited by
Susan M. Wolf,
Gurumurthy
Ramachandran,
Jennifer Kuzma, and
Jordan Paradise

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Letter from
the Editor

Cover image ©Corbis

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**Introduction: The Challenge of
Developing Oversight Approaches to
Nanobiotechnology**

*Jordan Paradise, Susan M. Wolf,
Jennifer Kuzma, Gurumurthy
Ramachandran, and Efrosini Kokkoli*

I. CASE STUDIES OF OVERSIGHT
SYSTEMS

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**Evaluating Oversight Systems for
Emerging Technologies: A Case Study
of Genetically Engineered Organisms**

*Jennifer Kuzma, Pouya Najmaie, and
Joel Larson*

The U.S. oversight system for genetically engineered organisms (GEOs) was evaluated to develop hypotheses and derive lessons for oversight of other emerging technologies, such as nanotechnology. Evaluation was based upon quantitative expert elicitation, semi-standardized interviews, and historical literature analysis. Through an interdisciplinary policy analysis approach, blending legal, ethical, risk analysis, and policy sciences viewpoints, criteria were used to identify strengths and weaknesses of GEOs oversight and explore correlations among its attributes and outcomes. From the three sources of data, hypotheses and broader conclusions for oversight were developed. Our analysis suggests several lessons for oversight of emerging technologies: the importance of reducing complexity and uncertainty in oversight for minimizing financial burdens on small product developers; consolidating multi-agency jurisdictions to avoid gaps and redundancies in safety reviews; consumer benefits for advancing acceptance of GEO products; rigorous and independent pre- and post-market assessment for environmental safety; early public input and transparency for ensuring public confidence; and the positive role of public input in system development, informed consent, capacity, compliance, incentives, and data requirements and stringency in promoting health and environmental safety outcomes, as well as the equitable distribution of health impacts. Our integrated approach is instructive for more comprehensive analyses of oversight systems, developing hypotheses for how features of oversight systems affect outcomes, and formulating policy options for oversight of future technological products, especially nanotechnology products.

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**Commentary: Emerging Technologies
Oversight: Research, Regulation, and
Commercialization**

Robbin Johnson

This paper reviews the paper by Kuzma, Najmaie, and Larson that looks at what can be learned from the experience with genetically engineered organisms for oversight of emerging technologies more generally. That paper identifies key attributes of a good oversight system: promoting innovation, ensuring safety, identifying benefits, assessing costs, and doing so all while building public confidence. In commenting on that analysis, this paper suggests that looking at “oversight” in three phases — research and development, regulatory review, and market acceptance — can help to determine when certain of these attributes should take precedence over others and how to structure remedies when an error occurs. The result is an approach that is precautionary with respect to research and development, prudent and open to public input in the regulatory review stage, and purposefully persuasive once market acceptability is at stake, with remedies that are risk-containing in the first phase, risk-managing in the second, and risk-assuaging in the third. Combining the key attributes with the idea of three phases can help attune oversight to society’s needs.

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**Commentary: Is It Possible to
Determine the Extent to Which
Informational Asymmetries and
Prejudice Bias Responses?**

Terrance Hurley

This commentary provides a brief overview of the methods and results presented by Jennifer Kuzma, Pouya Najmaie, and Joel Larson in “Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms.” It offers suggestions regarding how supplemental information might be used to gain additional insights into the authors’ results and how future research could further enhance our understanding of the attributes and outcomes of regulatory oversight for genetically engineered organisms.

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**Evaluating Oversight of Human
Drugs and Medical Devices: A Case
Study of the FDA and Implications for
Nanobiotechnology**

*Jordan Paradise, Alison W. Tisdale,
Ralph F. Hall, and Efrosini Kokkoli*

This article evaluates the oversight of drugs and medical devices by the U.S. Food and Drug Administration (FDA) using an integration of public policy, law, and bioethics approaches and employing multiple assessment criteria, including economic, social, safety, and technological. Criteria assessment and expert elicitation are combined with existing literature, case law, and regulations in an integrative historical case studies approach. We then use our findings as a tool to explore possibilities for effective oversight and regulatory mechanisms for nanobiotechnology. Section I describes oversight mechanisms for human drugs and medical devices and presents current nanotechnology products. Section II describes the results of expert elicitation research. Section III highlights key criteria and relates them to the literature and larger debate. We conclude with broad lessons for the oversight of nanobiotechnology informed by Sections I-III in order to provide useful analysis from multiple disciplines and perspectives to guide discussions regarding appropriate FDA oversight.

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Commentary: Public Outreach by the FDA
Mark S. Frankel

As nanotechnology emerges as an important public policy issue, the FDA's relationship with society is about to be tested. Most would agree that fostering public input will be critical to developing effective public policy for nanotechnology. Yet, it will not be easy. Low public confidence in the FDA, the general lack of knowledge about nanotechnology among ordinary Americans, and the way in which the "average" citizen obtains and evaluates knowledge about a public policy issue all pose serious challenges to any public outreach by the FDA. It will be necessary for the FDA to be attentive to not only its own public messages, but also to who is listening and how those messages are being perceived.

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**Commentary: Evaluating Oversight of
Human Drugs and Medical Devices**
Susan Bartlett Foote

This article seeks to provide insights into appropriate FDA oversight of nanotechnology. This commentary identifies limitations in the methodology employed and concludes that the analysis would be stronger with a more in-depth institutional dimension based on administrative law and political science research.

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**Review of the OSHA Framework for
Oversight of Occupational Environments**

*Jae-Young Choi and
Gurumurthy Ramachandran*

The OSHA system for oversight of chemicals in the workplace was evaluated to derive lessons for oversight of nanotechnology. Criteria relating to the development, attributes, evolution, and outcomes of the system were used for evaluation that was based upon quantitative expert elicitation and historical literature analysis. The oversight system had inadequate resources in terms of finances, expertise, and personnel, and insufficient incentive for compliance. The system showed a lack of flexibility in novel situations. There were minimal requirements on companies for data on health and safety of their products. These factors have a strong influence on public confidence and health and safety. The oversight system also scored low on attributes such as public input, transparency, empirical basis, conflict of interest, and informed consent. The experts in our sample tend to believe that the current oversight system for chemicals in the workplace is neither adequate nor effective. It is very likely that the performance of the OSHA oversight system for nanomaterials will be equally inadequate.

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**Commentary: Oversight of Engineered
Nanomaterials in the Workplace**

Andrew D. Maynard

Research and business investment in emerging nanotechnologies is leading to a diverse range of new substances and products. As workers are faced with handling new materials, often with novel properties, the robustness of current workplace health and safety regulatory frameworks is being brought into question. Here, 12 characteristics of the U.S. occupational safety regulatory framework identified by Choi and Ramachandran are considered in the context of emerging nanotechnologies. The assessment suggests that, as the number of new materials entering the workplace continues to increase, OSHA will need to develop flexible approaches to identifying and reducing potential risks. Relying on conventional approaches in the face of unconventional challenges will increase the probability of otherwise avoidable health impacts. If the potential for engineered nanomaterials to cause harm is to be understood and managed, the agency will need to look at new approaches to generating, sharing, and using information.

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**Gene Therapy Oversight: Lessons for
Nanobiotechnology**

*Susan M. Wolf, Rishi Gupta, and
Peter Kohlhepp*

Oversight of human gene transfer research ("gene therapy") presents an important model with potential application to oversight of nanobiology research on human participants. Gene therapy oversight adds centralized federal review at the National Institutes of Health's Office of Biotechnology Activities and its Recombinant DNA Advisory Committee to standard oversight of human subjects research at the researcher's institution (by the Institutional Review Board and, for some research, the Institutional Biosafety Committee) and at the federal level by the Office for Human Research

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Protections. The Food and Drug Administration's Center for Biologics Evaluation and Research oversees human gene transfer research in parallel, including approval of protocols and regulation of products. This article traces the evolution of this dual oversight system; describes how the system is already addressing nanobiotechnology in gene transfer; evaluates gene therapy oversight based on public opinion, the literature, and preliminary expert elicitation; and offers lessons of the gene therapy oversight experience for oversight of nanobiotechnology.

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Commentary: Who's Afraid of the RAC? Lessons from the Oversight of Controversial Science

Jeffrey P. Kahn

This commentary asks what we can learn from our oversight of controversial science and how can we do better in the future? After briefly examining the history of gene transfer research oversight, some observations are offered for the oversight of nanobiotechnology and other emerging areas of science.

II. COMPARING ACROSS CASE STUDIES

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Developing U.S. Oversight Strategies for Nanobiotechnology: Learning from Past Oversight Experiences

Jordan Paradise, Susan M. Wolf, Jennifer Kuzma, Aliya Kuzhabekova, Alison W. Tisdale, Efrosini Kokkoli, and Gurumurthy Ramachandran

The emergence of nanotechnology, and specifically nanobiotechnology, raises major oversight challenges. In the United States, government, industry, and researchers are debating what oversight approaches are most appropriate. Among the federal agencies already embroiled in discussion of oversight approaches are the Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Department of Agriculture (USDA), Occupational Safety and Health Administration (OSHA), and National Institutes of Health (NIH). All can learn from assessment of the successes and failures of past oversight efforts aimed at emerging technologies. This article reports on work funded by the National Science Foundation (NSF) aimed at learning the lessons of past oversight efforts. The article offers insights that emerge from comparing five oversight case studies that examine oversight of genetically engineered organisms (GEOs) in the food supply, pharmaceuticals, medical devices, chemicals in the workplace, and gene therapy. Using quantitative and qualitative analysis, the authors present a new way of evaluating oversight.

III. CROSS-CUTTING IDEAS

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Governance of Nanotechnology and Nanomaterials: Principles, Regulation, and Renegotiating the Social Contract

George A. Kimbrell

Good governance for nanotechnology and nanomaterials is predicated on principles of general good governance. This paper discusses on what lessons we can learn from the oversight of past emerging technologies in formulating these principles. Nanotechnology provides us a valuable opportunity to apply these lessons and a duty to avoid repeating past mistakes. To do that will require mandatory regulation, grounded in precaution, that takes into account the uniqueness of nanomaterials. Moreover, this policy dialogue is not taking place in a vacuum. In applying the lessons of the past, nanotechnology provides a window to renegotiate our public's social contract on chemicals, health, the environment, and risks. Emerging technologies illuminate structural weaknesses, providing a crucial chance to ameliorate lingering regulatory inadequacies and provide much needed updates of existing laws.

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What Does the History of Technology Regulation Teach Us about Nano Oversight?

Gary E. Marchant, Douglas J. Sylvester, and Kenneth W. Abbott

As policy makers struggle to develop regulatory oversight models for nanotechnologies, there are important lessons that can be drawn from previous attempts to govern other emerging technologies. Five such lessons are the following: (1) public confidence and trust in a technology and its regulatory oversight is probably the most important factor for the commercial success of a technology; (2) regulation should avoid discriminating against particular technologies unless there is a scientifically based rationale for the disparate treatment; (3) regulatory systems need to be flexible and adaptive to rapidly changing technologies; (4) ethical and social concerns of the public about emerging technologies need to be expressly acknowledged and addressed in regulatory oversight; and (5) international harmonization of regulation may be beneficial in a rapidly globalizing world.

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Problem Formulation and Option Assessment (PFOA) Linking Governance and Environmental Risk Assessment for Technologies: A Methodology for Problem Analysis of Nanotechnologies and Genetically Engineered Organisms

Kristen C. Nelson, David A. Andow, and Michael J. Banker

Societal evaluation of new technologies, specifically nanotechnology and genetically engineered organisms (GEOs), challenges current practices of governance and science. Employing environmental risk assessment (ERA) for governance and oversight assumes we have a reasonable ability to understand

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consequences and predict adverse effects. However, traditional ERA has come under considerable criticism for its many shortcomings and current governance institutions have demonstrated limitations in transparency, public input, and capacity. Problem Formulation and Options Assessment (PFOA) is a methodology founded on three key concepts in risk assessment (science-based consideration, deliberation, and multi-criteria analysis) and three in governance (participation, transparency, and accountability). Developed through a series of international workshops, the PFOA process emphasizes engagement with stakeholders in iterative stages, from identification of the problem(s) through comparison of multiple technology solutions that could be used in the future with their relative benefits, harms, and risk. It provides “upstream public engagement” in a deliberation informed by science that identifies values for improved decision making.

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Science, Ethics, and the “Problems” of Governing Nanotechnologies

Linda F. Hogle

Commentators continue to weigh in on whether there are ethical, social, and policy issues unique to nanotechnology, whether new regulatory schemes should be devised, and if so, how. Many of these commentaries fail to take into account the historical and political environment for nanotechnologies. That context affects regulatory and oversight systems as much as any new metrics to measure the effects of nanoscale materials, or organizational changes put in place to facilitate data analysis. What comes to count as a technical or social “problem” says much about the sociotechnical and political-historical networks in which technologies exist. This symposium’s case studies provide insight into procedural successes and failures in the regulation of novel products, and ethical or social analyses that have attended to implications of novel, disruptive technologies. Yet what may be needed is a more fundamental consideration of forms of governance that may not just handle individual products or product types more effectively, but may also be flexible enough to respond to radically new technological systems. Nanotechnology presents an opportunity to think in transdisciplinary terms about both scientific and social concerns, rethink “knowns” about risk and how best to ameliorate or manage it, and consider how to incorporate ethical, social, and legal analyses in the conceptualization, planning, and execution of innovations.

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Risk Communication for Nanobiotechnology: To Whom, About What, and Why?

Susanna Hornig Priest

Regulatory oversight and public communication are intimately intertwined. Oversight failures quickly galvanize media and public attention. In addition, regulations sometimes require that risks and uncertainties be included in communication efforts aimed at non-experts outside of the regulatory and policy communities — whether in obtaining informed consent for novel medical treatments; by including risk information on drug labels, in drug advertisements, or on chemicals used in the workplace; in providing nutritional information on food packages; or by opening environmental impact assessments to public comment. In recent decades, broad public input with respect to new technologies has also been sought “upstream” of hard policy decisions in the hope of ultimately gaining legitimacy for those decisions — and perhaps increas-

ing their quality. When communication fails, oversight may also be seen as failing — rightly or wrongly. As part of a larger project organized by the University of Minnesota, this paper presents six models of public risk communication and uses those models to analyze the communication challenges facing nanotechnology and nanobiotechnology. Reviewing the communication dynamics associated with the historical cases of technology regulation with which this symposium issue is concerned (genetically engineered organisms [GEOs] in the food supply, pharmaceuticals and medical devices, chemicals in the workplace, and gene transfer research or “gene therapy”) helps shed light on the communications challenges facing nanobiotechnology.

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Using Expert Elicitation to Prioritize Resource Allocation for Risk Identification for Nanosilver

Emma Fauss, Michael E. Gorman, and Nathan Swami

This article introduces a method to identify risks through expert elicitation, using silver nanotechnology as a case study. Unique features of the method include supplying experts with a list of silver nanotechnology products, and conducting the elicitation in an extended interview format that captures the experts’ reasoning. The end result is a series of graphical representations of expert thinking from which high-risk scenarios and knowledge gaps can be reliably inferred. This methodology, combined with other approaches to expert elicitation, can help identify knowledge and oversight gaps, and can be used as part of an adaptive management strategy.

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Combining Instrumental and Contextual Approaches: Nanotechnology and Sustainable Development

Nina Liao

Billions of people live in poverty, with no access to safe drinking water or solutions for other critical health and medical needs. Nanotechnology is poised to create workable solutions for large-scale public health needs in developing countries, including improving water quality and providing life-saving pharmaceuticals. There are two views on how emerging technologies such as nanotechnology can influence and affect developing countries. Instrumentalists believe that the international community can transfer nanotechnology from one context to another and use it to assist the poor. Contextualists warn that nanotechnology can increase inequality in underdeveloped regions. Because of inadequacies in both positions, the international community must adopt a mixed strategy. This article argues that this mixed strategy should target the bottom of the pyramid, develop native capability, implement emergency protocols in projects, create accountability, and engage the public. Managed well, this strategy can propel developing countries toward sustainable development.

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**Introduction: Comparative Health Law
and Policy: What, If Anything, Can We
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**Why Patients Sue Doctors: The Japanese
Experience**

Eric A. Feldman

Scholars in the U.S. have shown relatively little interest in the management of legal conflict over health care in other nations. This article examines the Japanese health care system, particularly litigation over medical malpractice, and asks what (if anything) American scholars and policy makers can learn from the Japanese experience.

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**Between Public Opinion and Public
Policy: Human Embryonic Stem-Cell
Research and Path-Dependency**

Stephen R. Latham

In bioethics as in other areas of health policy, historical institutional factors can shape policy independently of interests or public opinion. This article finds policy divergence among countries with similar national moral views of stem cell research, and explains that divergence as the product of path-dependency.

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**Realization of the International Human
Right to Health in an Economically
Integrated North America**

Eleanor D. Kinney

With the North American Free Trade Agreement (NAFTA), the health care sectors of the United States, Canada, and Mexico are becoming more economically integrated. NAFTA poses major challenges to the realization of the international human right. These include: (1) Cross Border Trade in Medical Products, (2) Cross Border Trade in Medical Services, and the attendant investment protections, (3) Portability

and Comparability of Health Insurance Coverage, and (4) Protection of Public Health Insurance Programs. The United States, Mexico, and Canada all provide public health insurance programs either to the entire population as in Canada or to vulnerable groups as in the United States. In none of these countries have private, for-profit providers and insurers been able to provide universal and affordable health coverage and care in a truly free market. Private insurers and for-profit providers should not profit from the care of the healthy and wealthy in ways that compromise the public programs that serve the poor and seriously ill. Nor should they be allowed to use NAFTA processes to compromise public programs. Policy makers must consider implications of NAFTA and move toward assuring access to affordable health care for all people on the North American continent.

Independent Articles

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**Tobacco Industry Use of Corporate
Social Responsibility Tactics as a Sword
and a Shield on Secondhand Smoke
Issues**

Lissy C. Friedman

The tobacco industry has used corporate social responsibility tactics to improve its corporate image with the public, press, and regulators who increasingly have grown to view it as a merchant of death. There is, however, an intractable problem that corporate social responsibility efforts can mask but not resolve: the tobacco industry's products are lethal when used as directed, and no amount of corporate social responsibility activity can reconcile that fundamental contradiction with ethical corporate citizenship. This study's focus is to better understand the tobacco industry's corporate social responsibility efforts and to assess whether there has been any substantive change in the way it does business with regard to the issue of exposure to secondhand smoke. The results show that the industry has made no substantial changes and in fact has continued with business as usual. Although many of the tobacco companies' tactics traditionally had been defensive, they strove for a way to change to a more offensive strategy. Almost without exception, however, their desire to appear to be good corporate citizens clashed with their aversion to further regulation and jeopardizing their legal position, perhaps an irreconcilable conflict. Despite the switch to offense, in 2006 a federal judge found the companies guilty of racketeering.

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**Ethical and Legal Analyses of Policy
Prohibiting Tobacco Smoking in
Enclosed Public Spaces**

Taiwo A. Oriola

A spate of legislations prohibiting cigarette smoking in enclosed public spaces, mainly on grounds of public health protection, recently swept across cities around the world. This is in tandem with a raft of increasingly restrictive national laws that emerged on the back of the ratification of the WHO Framework for Tobacco Control by more than one 168 countries in 2005. The central debate on the increasingly restrictive tobacco laws revolves on the extent to which public health interests justification should ground political intervention in a private right as basic as tobacco smoking, which interestingly

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is often lumped in the food and beverage category. The pertinent legal and ethical questions therefore are the following: Is or should there be a general unrestricted right to tobacco smoking? If there were such a right, should public health or ethical considerations trump private right to smoke in enclosed public spaces? And if public health interests were so paramount, should they go farther and ground tobacco smoking proscription in all private and public spheres? Using ethical principles and rights-based arguments, the paper critically examines the legal and ethical ramifications of public health justification for tobacco smoking proscription in enclosed public spaces.

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Opioid Contracts and Random Drug Testing for People with Chronic Pain — Think Twice

Mark Collen

The use of opioid contracts, which often require patients to submit to random drug screens, have become widespread amongst physicians using opioids to treat chronic pain. The main purpose of the contract is to improve care through better adherence to opioid therapy but there is little evidence as to its efficacy. The author suggests the use of opioid contracts and random drug testing destroys patients' trust which impacts health outcomes, and that physicians' motivation for their use are concerns about prosecution, medication abuse and misuse, and addiction. Statistics are provided to counter fears, and evidence is offered suggesting opioid contracts are unenforceable and lack efficacy; random drug testing is often inconclusive, and a patient's trust improves adherence to treatment.

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Letters to the Editor

To the Editor:

Jason V. Altilio's interesting article on pharmacists' obligations to patients' touches on the current debate about pharmacists' rights to conscientiously object to filling prescriptions due to the pharmacist's moral or religious convictions. Most of these conscientious objections are related to dispensing emergency contraception, such as Plan B (although there are also reported instances of pharmacists refusing to fill prescriptions for traditional birth control pills). Mr. Altilio claims that regardless of whether the pharmacist's obligation to patients is dependent on, or independent of, the physician's obligation to the patient, pharmacists do not have a right to conscientiously object to "filling prescriptions" for emergency contraception.

The problem with Mr. Altilio's theory as it is applied to emergency contraception is that emergency contraception is supposed to be available to women 17 and older without a physician's prescription. Nevertheless, it is stocked behind the pharmacy counter and must be requested from a pharmacist. Given that no prescription is involved in the provision of emergency contraception, and the pharmacist's role in providing emergency contraception involves merely checking identification of the requester to ensure she is of proper age, pharmacists' professional obligations shouldn't even enter into the picture.

Vickie J. Williams
Associate Professor of Law
Gonzaga University School of Law

1. Jason V. Altilio, "The Pharmacist's Obligations to Patients: Dependent or Independent of the Physician's Obligations," *Journal of Law, Medicine & Ethics* 38, no. 2 (2009): 358-368.

Mr. Altilio Responds

Ms. Williams brings up an important point that bears on a pharmacist's obligations generally and, more specifically, on the argument that pharmacists do not have the foundation

necessary for a right to refrain from dispensing emergency contraception.

On April 22, 2009 the Food and Drug Administration (FDA) released a statement indicating that levonorgestrel, often referred to as the morning after pill, might be sold to women seventeen or older without a prescription after the manufacturer of the medication completed the appropriate applications.¹ Prior to this time the FDA had approved the medication as an over the counter (OTC) drug available to women eighteen and older without a prescription.

However, each state has been free to institute additional regulations regarding emergency contraception. According to the National Conference of State Legislatures twenty-one states, as of May 2009, had statutes relating to emergency contraception.² Of those twenty-one states, nine³ have statutes directly referring to pharmacists' participation in making emergency contraception available to patients. Each of these nine states' statutes refer to the pharmacist as working under a collaborative agreement with a physician and/or necessitate additional training for a pharmacist before allowing him or her to dispense the emergency contraception. Additionally, as Ms. Williams notes, even outside these nine states many pharmacies keep emergency contraception behind the counter making a pharmacist's interaction with a patient who want the emergency contraception more likely.

These facts seem to support several of the points I made in "The Pharmacist's Obligation to Patients: Dependent or Independent of the Physician's Obligations." First, the nine states that specifically mention pharmacists in their statutes regarding emergency contraception further emphasize society's ambiguity about a pharmacist's obligations: even for a drug that does not require a prescription the pharmacist's role is not completely independent of the physician's. Conversely, these same states, as well as those states without such statutes, are likely attempting to increase access to care and a patient's ability to express her autonomy by not requiring direct physician involvement. Again, these are the type of benefits society can expect to reap if pharmacists have independent obligations to their patients.

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Columns are written or edited by leaders in their fields and appear in each issue of *JLME*.

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The Effects of Health Information Technology on the Physician-Patient Relationship

A Symposium Guest Edited by Melissa M. Goldstein and Mark A. Rothstein

Furthermore, even the other twelve states with statutes on emergency contraception that do not specifically mention pharmacists require applicable healthcare providers to inform patients about emergency contraception. Some of the statutes are more ambiguous than others about what information the healthcare provider must pass onto the patient: whether it is simply information about the availability of the drug that must be provided for the patient or more complete information about the drug and its availability. Whichever possibility is implied by these statutes, it would seem inappropriate for any pharmacist asked about a drug, whether prescription or over the counter, not to initiate some conversation with the patient about that drug's potential side effects, contraindications, or/and drug interactions. This is in line with the American Pharmacists Association's claim that "...a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust"⁴ — a statement which does not differentiate between prescription and non-prescription medications. Thus, a pharmacist's professional obligations are not obviated by the fact that the drug is available without a prescription.

1. See <<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149568.htm>>.
2. See <<http://www.ncsl.org/issuesresearch/health/emergencycontraceptionlaws/tabid/14420/default.aspx>>.
3. Those nine are: Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington.
4. Code of Ethics for Pharmacists, available at <<http://www.pharmacist.com/AM/Template.cfm?Section=Search1&template=/CM/HTMLDisplay.cfm&ContentID=2903>> (last visited July 24, 2009).