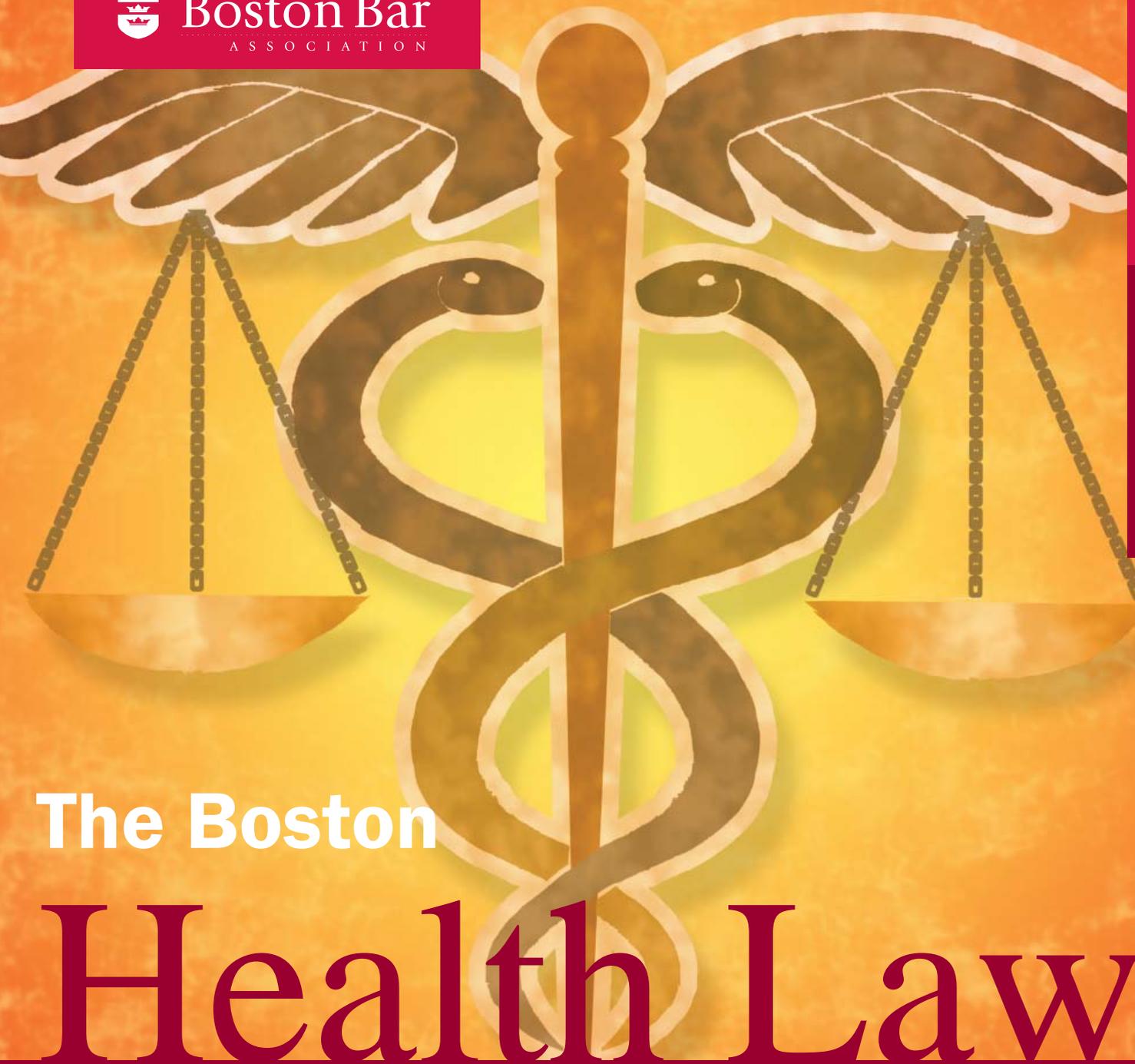




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Section Co-Chairs' Corner

Winter 2009

Happy 2009! With a new year, comes a new edition of Health Law Reporter. Once again, the Health Law Section's Communications Committee has assembled an outstanding collection of articles on a range of topics, including an overview of litigation affecting the pharmaceutical industry by Tom Barker, Josh Greenberg's article on legislation clarifying the legal and ethical permissibility of research on human fetuses and neonates, and an overview of proposed DPH regulations implementing the "gift ban" legislation that regulates financial interactions between pharmaceutical and medical device manufacturers and health care practitioners by Melissa Lopes. As always, we are grateful to the authors, peer reviewers, and editors who make the Reporter possible.

We recently had the pleasure of meeting with Gerry Cahill and other members of the pro bono committee of the Civil Rights & Civil Liberties Section, with the goal of trying to find opportunities for collaboration between the Pro Bono Committee and the Health Law Section. We heard a number of compelling proposals and have made it a priority to find ways for the Health Law Section to support the pro bono work of the Association. If you have specific suggestions, we welcome them; please feel free to contact either of us with your thoughts.

The Health Law Section has been active in scheduling both continuing education and brownbag lunch programs on a wide variety of health law topics, including elder care issues, the impact of the gift ban regulations on continuing medical education, antitrust, the legislative process, advocacy, and our recent Legislative Update. Upcoming programs include a session on health fraud. Please take advantage of these opportunities for education and professional development.

Matt Herndon and Dave Szabo

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Section Co-Chairs



Matthew Herndon, Esq.

Harvard Pilgrim Health Care
93 Worcester Street
Wellesley, MA 02481
(617) 509-3077

Matthew_Herndon@harvardpilgrim.org



David S. Szabo, Esq.

Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
(617) 439-2000

dszabo@nutter.com

Washington Word: Recent Litigation Affecting the Pharmaceutical Industry

By Thomas Barker, Esq.

Two pieces of litigation – one recently argued before the Supreme Court of the United States, the other recently decided by the U.S. District Court for the District of Columbia – should be of great interest to practitioners in the life sciences industry. *Wyeth v. Levine*, argued before the Supreme Court on November 3, 2008, raises the question of whether the Federal Food, Drug and Cosmetic Act (FDCA) impliedly pre-empts state common law tort claims. *Hays v. Leavitt*, decided by the district court in October 2008, enjoins the Centers for Medicare & Medicaid Services (CMS) from utilizing an alternative reimbursement methodology for outpatient prescription drugs paid under part B of the Medicare program, even where the drug is, in the view of CMS's contractors, clinically identical to a less costly drug. This article considers both cases.

The Wyeth Pre-Emption Case

Last Term, in *Riegel v. Medtronic*, 552 U.S. ___, 128 S. Ct. 999 (2008), the Supreme Court held, in an 8 – 1 decision, that the Medical Device Act Amendments of 1976 expressly pre-empted a state common law tort claim brought against the manufacturer of a medical device. At issue was 21 U.S.C. § 360k(a), which provides that a state shall not “establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the

device” After concluding that the federal government had established requirements applicable to the medical device at issue in the case, the Supreme Court analyzed whether the common law tort claim was based on state requirements that are “different from, or in addition to” the federal requirements and that relate to safety and effectiveness. Concluding that the tort claim indeed relied on state requirements that differed from the federal requirements, the Court found the claim expressly pre-empted based on the clear words of the statute.

In contrast to *Riegel*, *Wyeth* involves a case of implied pre-emption. Under traditional implied pre-emption analysis, a state law can be pre-empted by federal law where it is “‘impossible’ for private parties to comply with both state and federal law,” *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000), or where the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Because Congress has not specifically spoken to the question of whether state law tort claims against pharmaceutical manufacturers are pre-empted, the Supreme Court must use implied pre-emption analysis to decide the *Wyeth* case.

The facts of *Wyeth* are tragic. Mrs. Levine was a concert guitarist and was a chronic migraine headache sufferer. Her physician had

prescribed Phenergan® to treat nausea associated with her medical condition. The Food and Drug Administration (FDA) approved the drug in 1955. It was approved as safe and effective when administered by either deep intramuscular (IM) or intravenous (IV) injection. The FDA-approved label indicated that IV injection produced clinical effects four times faster; however, Wyeth and the FDA had long been aware since the 1960s that there was risk when the drug was administered by IV injection. In particular, reports indicated that some patients receiving the drug through IV administration had developed gangrene requiring amputation of a limb when blood in a patient's arteries came into contact with Phenergan®. That is precisely what happened to Mrs. Levine. Notably, however, and despite the fact that similar clinical events had occurred with other patients, the FDA never required Wyeth to eliminate IV administration from the drug's labeling.

A pharmaceutical manufacturer may not introduce for sale into interstate commerce any product that does not contain an FDA-approved label, and may not market a new drug unless it has submitted a New Drug Application to the FDA and received the agency's approval. 21 U.S.C. § 355(a). Often, every word on the label is negotiated carefully with the FDA and the manufacturer. As a result of this painstaking negotiation, a manufacturer generally cannot change the label without submitting a supplemental

application subject to the approval of the FDA. A manufacturer must submit such a supplemental application when it becomes aware of a substantial hazard associated with use of the drug. 21 C.F.R. § 314.70(b)(4).

FDA approval aside, however, a manufacturer may change a drug's labeling without awaiting FDA approval, if the change "add[s] or strengthen[s]" a warning. 21 C.F.R. § 314.70(c)(6)(iii)(A) and (C). Nevertheless, the FDA interprets this regulatory provision as permitting a change in labeling without FDA approval only where it addresses "newly-discovered risks" - *i.e.*, those that were not known at the time of FDA approval.¹ If a manufacturer changes a label without obtaining FDA approval, the agency may disapprove the change and could order the manufacturer to cease distribution of the product. 21 C.F.R. § 314.70(c)(7).

After her injury, Mrs. Levine sued Wyeth, the manufacturer of Phenergan®, in Vermont State court under a state common law negligence theory. In particular, Mrs. Levine alleged that Wyeth failed to adequately warn physicians of the risks of IV administration of Phenergan®, even though it had a duty to do so. She prevailed in the trial court and the Vermont Supreme Court affirmed. The Supreme Court of the United States granted a writ of *certiorari* to review the Vermont decision.

In light of the foregoing, it is easy to see the specter of implied conflict pre-emption brewing. Wyeth's argument is that it is impossible to comply with federal law - which permits changes to a drug's approved labeling without FDA approval only in very narrow circumstances not applicable here - and the rule an-

nounced by the Vermont Supreme Court, which seems to impose a duty on a manufacturer to revise the label when a manufacturer becomes aware of previously-un-disclosed risks of a product. Thus, according to Wyeth, because it is impossible for it to comply with both federal law (generally prohibiting a labeling change) and the state law (requiring a labeling change), the state law must yield and Mrs. Levine's claim is impliedly pre-empted.

The U.S. Supreme Court asked for the FDA's views on the pre-emption question. The FDA, in an amicus brief submitted to the Court, agreed with Wyeth and argued that Mrs. Levine's claim was impliedly pre-empted. The FDA brief focused, in part, on the policy reasons for this position. These policy considerations relate to the balancing that the FDA must conduct when assessing the safety and efficacy of a pharmaceutical or biological product or medical device. On the one hand, the FDA cannot permit for sale in interstate commerce a product that is ineffective or, even worse, dangerous. On the other hand, being overly restrictive risks limiting the availability of curative or palliative treatment for patients.

In the FDA's judgment, this balancing test is best conducted by scientists and clinicians at the FDA and not juries composed of laypersons in the trial courts of the 50 states. The jury in Mrs. Wyeth's case heard evidence of how Wyeth's product harmed her, but the jury was not in a position to conduct a balancing test of the attenuated risks of harm to a small number of patients vs. the large number of patients whose medical condition would improve when given Phenergan®. Only the FDA - in its nationwide administration of the FDCA - is able to con-

duct such an assessment. Hence, the FDA argued, Mrs. Levine's claim should be pre-empted.

Handicapping the Supreme Court's decision - which will be handed down before the Court adjourns for the Term in June - is very difficult. Press coverage of the oral arguments indicate that the justices were split, and partially unpredictably.² It does seem clear that the decision will not be as decisive as the decision in *Riegel* in the prior term.

If Mrs. Levine prevails, it seems likely that state tort claims against pharmaceutical manufacturers will explode. The downside of this explosion, of course, is that research and development on promising new medical treatments will decline as manufacturers delay introducing these new treatments into interstate commerce as they await more data on rare, adverse medical events in order to warn consumers. In addition, manufacturers will over-warn consumers and physicians, making it increasingly likely that consumers and physicians will not pay due heed to the warnings. As noted above, the FDA approval process is a tricky balancing test; that balancing test will become more complicated if state common law tort claims are not pre-empted.

If Wyeth prevails, the manufacturer may be celebrating a Pyrrhic victory. That is because Congress has made clear that if the Supreme Court finds implied pre-emption in these common law claims, Congress will amend the FDCA to make clear that such claims are not pre-empted. While it is at it, Congress will quite likely overturn the *Riegel* decision as well, repealing the express pre-emption provision of the FDCA applicable to approval of medical devices. This is, of course,

a policy decision for Congress to make involving the same balancing test that the FDA conducts: the safety of consumers vs. the need of those consumers for palliative medical treatments.

Medicare Reimbursement for Pharmaceutical Products: *Hays v. Leavitt*

One might be excused for forgetting, in light of Medicare's part D prescription drug benefit, that Medicare has long provided coverage for some outpatient prescription drugs. These drugs, covered under part B of the program, are generally drugs that must be administered in a physician's office and incident to a physician's service. 42 U.S.C. § 1395x(s)(2)(A).³ Since 2006, part B drugs are generally reimbursed by Medicare at 106% of the average sales price of the drug. 42 U.S.C. § 1395w-3a(b)(1)(A).

Before Medicare will pay for any covered benefit, however, the program must analyze whether expenses incurred by a beneficiary are "reasonable and necessary for the diagnosis or treatment" of a medical condition. 42 U.S.C. § 1395y(a)(1)(A). In particular, the statute provides that "no payment may be made ... for any expenses incurred for items or services - which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury." *Id.* CMS or its contractors rely on national or local coverage decisions to determine whether or not expenses meet the statutory standard. CMS has long taken the position that where expenses are incurred for two covered benefits that offer clinically identical therapeutic outcomes, the program will only pay for the "least costly alternative" product under the theory that expenses for the more expensive product are not

"reasonable and necessary" within the meaning of the statute.⁴

In *Hays v. Leavitt*, a Medicare beneficiary and the manufacturer of a part B drug successfully challenged this "least costly alternative" policy. Patients with chronic obstructive pulmonary disease (COPD) are often prescribed albuterol for their medical condition. Dey manufactures DuoNeb®, an inhalation drug that combines albuterol and ipratropium in one dose. In the view of CMS's contractors, articulated through a local coverage determination, DuoNeb®, although more expensive, is clinically indistinguishable from albuterol. To that end, they invoked CMS's least costly alternative policy and announced that payment for DuoNeb® would be at the albuterol rate. The manufacturer and a beneficiary challenged the policy.

The U.S. District Court for the District of Columbia invalidated the policy. The court reasoned that the statute specified only one rate of payment for part B drugs: 106% of the average sales price for the drug. According to the court, CMS or its contractors lacked authority under the statute to specify a different payment rate. The court rejected CMS's position that the phrase "reasonable and necessary" in 42 U.S.C. § 1395y(a)(1)(A) modified the word "expenses" in that section; in CMS's view, such a construction would permit it to adjust the "expenses" that it determined were "reasonable and necessary" and pay at a lower rate. Rather, the court held that the phrase "reasonable and necessary" instead modified the phrase "items or services." Under that construction, once CMS determined that an item or service was "reasonable and necessary," it could not alter the statutorily-prescribed payment rate.

It is worth briefly noting the issue of standing. CMS argued that the manufacturer lacked standing to bring the challenge, as it was not negatively affected by the reimbursement decision since CMS does not reimburse the manufacturer directly. Rather, CMS reimburses the physician who purchases the drug. The court agreed with CMS's position here that the manufacturer lacked standing. Ultimately, however, the case went forward because of the presence of a Medicare beneficiary who, in the court's view, clearly did have standing to bring the claim. As a result, future challenges to CMS policies articulated through a coverage decision will likely be brought by beneficiaries rather than manufacturers.

Affirmation of the District Court's decision in *Hays v. Leavitt* by the U.S. Court of Appeals for the District of Columbia will seriously hinder the ability of CMS to control spending on part B drugs nationwide, given that a decision in the D.C. Circuit is essentially a nationally-effective decision. The recent interest in "comparative effectiveness," in which a body of medical experts determines whether a particular medical treatment is worth the reimbursement assigned to it, could also be impacted by this decision. Certainly, under the *Hays* decision, it would be far more difficult for CMS to take action once it has assessed the comparative effectiveness of two clinically similar part B drugs. If a future Congress and Administration intend to introduce the comparative effectiveness model in publicly-funded health care, the *Hays* decision will need to be addressed.

Conclusion

Practitioners in the life sciences industry will be interested in the

outcome of the *Wyeth* case and interested in the government's next steps in *Hays v. Leavitt*. The decision in *Wyeth* will obviously have nationwide impact. Given that *Hays* was filed in the D.C. Circuit, an adverse decision for the government at the appellate level would effectively have nationwide impact. Such nationwide decisions could also invite Congress to legislate in both areas.

1 See 47 Fed. Reg. 46,623 (Oct. 19, 1982); 73 Fed. Reg. 49,603 - 10 (Aug. 22, 2008); and 21 C.F.R. § 601.12 (codifying that interpretation). The 2008 codification merely reflected FDA's longstanding - dating back to 1982 - interpretation of the regulation.

2 See, e.g., Jerry Markon, "High Court Case Looms Large for Drugmakers," *The Washington Post* at D-01 (Nov. 4, 2008) (citing "divisions within the conservative bloc of the court" as exemplified by questions by Justice Alito). See also Adam Liptak, "Justices Weigh Effect of F.D.A. Approval of Drug Labels on Suits in State Courts," *The New York Times* at A-20 (Nov. 3, 2008) (also highlighting Justice Alito's skepticism of the manufacturer's claim).

3 Incredibly, in light of the historically abysmal job the Medicare program has done setting prices for part B drugs, some in Congress have actually advocated extending this price-fixing regime to the part D program - a sure way to drive up the costs and politicization of the part D benefit.

4 CMS has never codified this interpretation in its regulations. Rather, it appears in the Medicare Benefit Policy Manual.

Targeting and Eliminating Potential Conflicts of Interest in the Industry/Practitioner Relationship: The Massachusetts Approach

By Melissa Lopes, Esq.

Introduction

On August 10, 2008, Governor Deval Patrick signed into law Chapter 305 of the Acts of 2008, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Healthcare (the "Act"). Part of this Act, Chapter 111N, directs the Massachusetts Department of Public Health ("Department") to regulate financial interactions between pharmaceutical and medical device manufacturers and health care practitioners.¹ Chapter 111N grew out of a desire to make information relating to certain financial relationships between industry and health care practitioners publicly available and to identify and minimize potential conflicts of interest in such relationships. According to the Prescription Project, an advocacy group dedicated to advancing medical practice and policy, 94% of physicians nationally have received food, drug samples, or other reimbursements or payments from the drug industry.² Pharmaceutical companies employ about 90,000 detailers and spend over \$7 billion annually to market their products to physicians.³ Pervasive industry interactions with health care practitioners raise questions of bias in medical decision-making,⁴ and may potentially influence prescribing patterns.

Evolving Policy Solutions

Conflicts of interest, both real and perceived, in the industry-practitioner relationship have motivated

medical organizations such as the American Medical Association ("AMA") and the American College of Physicians to endorse adherence to voluntary guidelines. Guidelines outlining ethical conduct have been established by the AMA,⁵ the federal Office of the Inspector General,⁶ and industry groups such as the Pharmaceutical Researchers and Manufacturers of America ("PhRMA")⁷ and the Advanced Medical Technology Association ("AdvaMed")⁸. Both the PhRMA and AdvaMed Codes of Conduct address the myriad of interactions between pharmaceutical and medical device manufacturers and practitioners, providing guidance on sponsorship of continuing medical education and other scientific and professional meetings, the conduct of informational presentations and trainings, and the provision of gifts, educational materials, meals, travel and lodging, and other benefits to practitioners. All of these voluntary guidelines, however, lack mechanisms for monitoring and ensuring compliance, making them inadequate to the task of minimizing potential conflicts of interest.

Recognizing the need for enforcement mechanisms, a number of states have enacted legislation aimed at regulating potential conflicts of interest in industry-practitioner interactions. Prior to the passage of Chapter 111N, state regulation of the industry-practitioner relationship took the form of either compliance requirements or disclosure requirements. Current-

ly, seven states and the District of Columbia have laws that regulate marketing conduct by pharmaceutical and/or medical device manufacturers.⁹ Three states, including Massachusetts, require compliance programs and regulate conduct by both pharmaceutical and medical device manufacturers.¹⁰ Of these three states, Massachusetts is the only state to establish and require compliance with a state-authored Marketing Code of Conduct for both pharmaceutical and medical device manufacturers and also to require disclosure of industry payments to practitioners. Five states, including Massachusetts, and the District of Columbia require disclosure of industry payments to practitioners.¹¹ Three of these states, including Massachusetts, make such disclosures publicly available, to varying degrees.¹² Of these three states, Massachusetts is the only state to call for the creation of a publicly searchable database of payments and to require disclosure of industry payments by medical device manufacturers. In September 2007, U.S. Senator Charles Grassley introduced the Physician Payments Sunshine Act, requiring disclosure of payments to physicians by both pharmaceutical and medical device manufacturers. Revisions to the text of this bill were made public in May 2008 and expand the number of exemptions to disclosure. If the revised bill is re-introduced in the new Congress and becomes law, it would exempt state law with respect to disclosure requirements.

The Department's Proposed Regulatory Approach

Pursuant to Chapter 111N, the Department issued proposed industry sales and marketing regulations on December 10, 2008.¹³ Although a number of consumer groups have raised concerns that the Department's proposed regulations do not go far enough, Chapter 111N and the Department's proposed regulations represent the most comprehensive state approach to the conflict-of-interest issue in industry-practitioner interactions.

The proposed regulations approach the conflict-of-interest issue from three angles: (i) mandating a state-authored marketing code of conduct that regulates certain activities by pharmaceutical and medical device manufacturers, (ii) requiring adoption of and adherence to compliance and training standards by pharmaceutical and medical device manufacturers, and (iii) requiring disclosure of certain industry-practitioner financial relationships. Under the Department's proposed regulations, compliance with the state's Marketing Code of Conduct would be required as of July 1, 2009, and the first disclosure reports required under the statute and regulations would be due on July 1, 2010.

Massachusetts Marketing Code of Conduct

Massachusetts is the only state to mandate industry adoption of and adherence to a state-authored Marketing Code of Conduct. Similar to California and Nevada, Massachusetts law applies to both the pharmaceutical and medical device manufacturing industries and requires the establishment of compliance programs anchored in the PhRMA and AdvaMed guidelines.

However, Chapter 111N goes beyond the PhRMA and AdvaMed Codes by specifically restricting certain activities in a state-authored and state-imposed Marketing Code of Conduct. Neither California nor Nevada specifically restricts activities. Also, both California and Nevada allow pharmaceutical and medical device manufacturers the freedom to develop their own Codes of Conduct.

Chapter 111N recognizes that some industry-practitioner interaction is beneficial by including a number of specifically allowable activities in Section 2.¹⁴ Thus, Chapter 111N seeks to prohibit certain activities likely to influence prescribing patterns without inhibiting productive and legitimate industry interactions with practitioners. As a result, the Department's proposed Marketing Code of Conduct specifically prohibits activities likely to raise conflict of interest concerns, rather than simply banning all interactions. The Marketing Code of Conduct specifically prohibits entertainment or recreational items of any value, meals associated with entertainment, the provision of complimentary items such as pens, coffee mugs, gift cards or flowers, and the provision of grants, scholarships, subsidies, consulting contracts, or educational items in exchange for prescribing or disbursing prescription drugs or medical devices. Consumer advocates suggest that Minnesota law is stronger in that it imposes a gift ban on all gifts over \$50.00. However, the Minnesota law fails to target and to minimize potentially troublesome industry-practitioner interactions. Minnesota law provides exceptions for items less than \$50, educational materials, certain consulting agreements, and reasonable honoraria, among others, without a catchall provision requir-

ing that such payments not be provided in exchange for prescribing prescription drugs or medical devices. Further, the Minnesota gift ban only applies to pharmaceutical companies¹⁵ whereas the Massachusetts marketing prohibitions apply to both pharmaceutical and medical device manufacturers.

Massachusetts Disclosure Requirements

Another state approach to addressing conflicts of interest is to require disclosure of industry payments. Apart from Massachusetts, four states and the District of Columbia require disclosure of industry payments to practitioners. However, as stated earlier, Massachusetts is the only state that requires disclosure of industry payments by both pharmaceutical and medical device manufacturers. Massachusetts will also be one of only three states to make such disclosures public.¹⁶ The Department will make all reportable payments publicly available via a searchable database. Neither Vermont nor Minnesota provides for the level of detail and accessibility proposed under Massachusetts law. According to one study, both the Minnesota and Vermont disclosure laws are "insufficient for revealing the true patterns of payments" and "fail to provide the public with easy access to information about these payments."¹⁷ For example, Vermont has an exemption from publication for trade secrets, which shielded 61% of all payments reported to the state from public view.¹⁸

Massachusetts' proposed regulations also call for the broadest state definition of "sales and marketing activities" subject to disclosure. The Department's proposed regulations acknowledge that a number of pharmaceutical or med-

ical device manufacturer interactions with health care practitioners may influence sales or the market share of a prescription drug, biologic or medical device, or influence the prescribing behavior of an individual health care professional. The Massachusetts definition goes beyond those activities traditionally considered to be pure “sales and marketing activities,” to include activities such as the following: product education, training, and the provision of any fee, payment, subsidy or other economic benefit with a value of at least \$50 to a health care practitioner for any purpose other than reasonable compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or clinical trial.

The proposed regulations call for broad public disclosure of all industry-practitioner interactions apart from professional consulting services in conjunction with genuine research or clinical trials. Under the proposed regulations, Massachusetts will be the only state to require public disclosure of prescription drug samples and medical device demonstration units. Vermont law also specifically exempts payments in conjunction with clinical trials from its public reporting requirements.¹⁹ Minnesota law specifically requires disclosure of the “substantial professional or consulting services of a practitioner in connection with a genuine research project,” but the law is silent on whether payments in conjunction with clinical trials must be reported.²⁰ Additionally, the lack of enforcement provisions in the Minnesota law makes it unclear as to the level of disclosure on such interactions.²¹ Access to clinical trials and new drug and device discoveries provide Massachu-

sets healthcare consumers with immeasurable benefits. The proposed regulations strike a balance to protect such benefits.

Conclusion

In essence, the Department’s proposed regulations seek to minimize potential conflicts of interest, increase transparency, and encourage disclosure with respect to industry/practitioner relationships without compromising companies’ and researchers’ legitimate confidentiality interests in protecting trade secrets and other intellectual property rights associated with genuine medical research, clinical trials, and the discovery of new treatments and medical devices.

The Department held two well-attended hearings in Boston and Worcester during the month of January. Further, the Department allowed for a written comment period beyond the dates of the public hearings to provide interested parties ample opportunity to comment on the proposed regulations. Over a hundred pieces of written testimony, reflecting the perspectives of industry, the consumer, the practitioner, and various other indirectly impacted businesses, were submitted within the comment period. The Department will carefully review and consider the comments received as part of the formal notice and comment period, revisit the language set forth in the proposed regulations, and return to the Public Health Council with a final set of regulations for approval and final promulgation.

ics of the Relationship, Society of General Internal Medicine, January 17, 2007.

- 4 Wazana, Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *Journal of the American Medical Association*, January 19, 2000; http://www.prescriptionproject.org/tools/solutions_factsheets/files/0006.pdf.
- 5 <http://www.ama-assn.org/ama/pub/category/11910.html>.
- 6 <http://www.ama-assn.org/ama/pub/category/11910.html>.
- 7 http://www.phrma.org/code_on_interactions_with_healthcare_professionals/.
- 8 <http://www.advamed.org/MemberPortal/About/code/>.
- 9 California, Maine, Massachusetts, Minnesota, Nevada, Vermont, West Virginia, District of Columbia.
- 10 California and Nevada also have compliance requirements.
- 11 Maine, Massachusetts, Minnesota, Vermont, West Virginia, and the District of Columbia.
- 12 Vermont and Minnesota also make disclosures of industry payments public.
- 13 105 CMR 970.000.
- 14 Section 2 specifically allows:
 - (1) the provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;
 - (2) the purchase of advertising in peer reviewed academic, scientific or clinical journals;
 - (3) prescription drugs provided to a health care practitioners solely and exclusively for use by the health care practitioner’s patients;
 - (4) compensation for the substantial professional or consulting services of a health care practitioner in connection with genuine research project or a clinical trial;
 - (5) payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor’s purchase contract for the device.
- 15 MINN. STAT. . §151.461.
- 16 Minnesota and Vermont also make disclosures publicly available.
- 17 Ross, Lackner and Lurie, Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota, *Journal of the American Medical Association*, March 21, 2007.
- 18 *Id.*
- 19 VT. STAT. tit. 18 §4632(a)(4)(B).
- 20 MINN. STAT. §151.47(f).
- 21 MINN. STAT. §151.461, 151.47.

1 M.G.L. c. 111N.
 2 The Prescription Project Fact Sheet, Regulating Industry Payments to Physicians: Identifying and Minimizing Conflicts of Interest, http://www.prescriptionproject.org/tools/solutions_factsheets/files/0006.pdf.
 3 Chimonas, Brennan, and Rothman, Physicians and Drug Representatives, Exploring the Dynam-

Chapter 333 of the Acts of 2008: Clarifying the Legal and Ethical Permissibility of Research on Human Fetuses and Neonates

By Joshua Greenberg, Esq.

Chapter 333 of the Acts of 2008, “An Act Relative to Biomedical Research,” clarifies the legal and ethical standards that should be applied when a Massachusetts researcher seeks to undertake studies involving neonates or fetuses. (For the non-researchers among us, a neonate is generally understood to be a newborn, e.g., an infant of less than 28-30 days of age.) The new law modifies Chapter 112, Section 12J, which previously contained a general prohibition on such research subject to two poorly defined, and arguably ethically suspect, exceptions. It was and is a criminal statute that subjects violators, potentially including researchers, institutions, and members of institutional review boards (IRBs), to both incarceration and financial penalties. For the purposes of this discussion, I will refer to the “original” statute and the “amended” statute.

It is worth noting at the outset that neonates are not little adults, nor are they physiologically identical to older children. Their bodies are adjusting to their new reliance on their own organ systems and are subject to unique ailments, dangers, and pathologies. For that reason, neonatology is its own clinical and academic specialty. Foregoing neonatal research would mean foregoing cures for the huge numbers of neonates born each year who suffer from lethal conditions that develop in utero but do not manifest themselves until birth,

when dependence on the mother’s body is no longer possible.

The original statute, while subject to diverse interpretations, could be read to prohibit research on neonates unless that research had “therapeutic” benefit.¹ It suffered from poor drafting. For example, it did not define the term “neonate” or the term “experiment,” nor did it indicate in clear terms which research was permissible. It could be read to allow “minimal risk” research on fetuses but not on neonates.² Moreover, it was very inconsistent with federal regulations subsequently developed during the Reagan Administration that set strict national standards for the ethical conduct of fetal and neonatal research.³

While these may seem like technical issues, the context is important. The original statute could and had been interpreted to prohibit research involving neonatal control groups who by definition received no “therapeutic benefit” from the intervention precisely because they were members of a control group.⁴ For neonates (but not for fetuses), this was true even if the intervention caused no significant harm to the infant – for example, in cases involving the collection of small amounts of blood, tissue, mucus, or other genetic material. It also provided criminal penalties for violators, including IRB members who approved such research.

The amended statute does not attempt to correct all defects, but it does make three important changes. First and foremost, it makes explicit the types of research that are permissible, and brings them in line with federal legal and ethical standards in this area, which I would argue are more carefully and thoroughly set out:

“[T]his section shall not prohibit or regulate diagnostic or remedial procedures the purpose of which is to determine the life or health of the fetus or neonate involved or to preserve the life or health of the fetus or neonate involved or the mother involved, or to improve the chances of a viable birth for fetuses with congenital or other fetal conditions that would otherwise substantially impair or jeopardize their health or viability, or research approved by an Institutional Review Board applying federal regulations for the protection of fetuses and neonates, that are conducted for the purpose of developing, comparing or improving diagnostic or therapeutic fetal or neonatal interventions to improve the viability or quality of life of fetuses, neonates and children.” (MGL c. 112, sec. 12J(a)(l) as amended).

Second, it extends the “no jeopardy” exception to neonates in addition to fetuses (“[t]his section shall not prohibit procedures incident to the study of a human fetus while it is in its mother’s womb or a neonate; provided that in the best

medical judgment of the physician, made at the time of the study, the procedures do not substantially jeopardize the life or health of the fetus or neonate...”). Thus, it permits research that causes no significant harm, like drawing a small amount of blood for a population-based study on neonatal physiology. Finally, it allows researchers to seek an advisory opinion from the Attorney General in questionable cases in advance of the IRB making a decision that can serve as an affirmative defense in any subsequent prosecution.⁵ Together, these changes bring some amount of clarity to a generally ambiguous statute and help promote research seeking to improve the health and well-being of vulnerable infants.

From the perspective of the practicing attorney, the ultimate impact is to better align Massachusetts law with national standards. For those clients contemplating studies involving fetuses and neonates, the best course of action is likely to assure thorough review by an IRB that is familiar with applying federal standards governing research in this area.

such research is regulated, prohibited, authorized by this chapter by or whether it is exempt from this chapter. If in the opinion of the attorney general the research described in the request is exempt from, or authorized by this chapter, the opinion shall constitute an affirmative defense to any criminal prosecution brought pursuant to this section. Opinions issued by the attorney general pursuant to this section shall be maintained in a publicly accessible manner by the attorney general and shall be filed with the commissioner of public health.”

1 The language of the statute prior to amendment read: “[t]his section shall not prohibit or regulate diagnostic or remedial procedures the purpose of which is to determine the life or health of the fetus involved or to preserve the life or health of the fetus involved.”

2 The statute allowed minimal risk research that did not jeopardize the health of a fetus, but did not allow the same kind of research to be conducted on newborns; “[t]his section shall not prohibit procedures incident to the study of a human fetus while it is in its mother’s womb, provided that in the best medical judgment of the physician, made at the time of the study, said procedures do not substantially jeopardize the life or health of the fetus...”

3 The rights of subjects are protected by federal regulations contained at 45 C.F.R. Part 46, including subparts B (fetuses and neonates) and D (children); see also 21 C.F.R. Parts 50, 56, 312, 600, 812 (FDA protections for children).

4 Note that FDA studies typically insist upon the use of a control group.

5 Chapter 112, Section 12J(b)X (as amended). “Upon receipt of a request from an institution conducting, or preparing to conduct, research pursuant to this section, the attorney general shall provide a written advisory opinion concerning whether

Local Health Law Briefs

***Newton-Wellesley Hospital v. Robert Magrini*, 451 Mass. 777, 889 N.E.2d 929 (2008)**

By Aron Boros, Esq.

In *Newton-Wellesley Hospital v. Robert Magrini*, the Massachusetts Supreme Judicial Court (the “SJC”) addressed the scope of the statutory right to an emergency hearing in connection with the temporary involuntary commitment of a person with mental illness. The SJC addressed the standards to be applied in such a hearing previously (in *Superintendent of Worcester State Hosp. v. Hagberg*, 374 Mass. 271 (1978) and *Commonwealth v. Nassar*, 380 Mass. 908 (1980)), but had not considered the minimum showing necessary to require the hearing itself. In *Magrini*, the SJC found that the statute provides a “catch-all provision,” *Id.* at 784, expanding the circumstances that can be alleged to have resulted in a wrongful involuntary admission beyond those specifically enumerated in the statute. Accordingly, a judge must grant a request for an emergency hearing if the patient satisfies the “minimal showing” that the involuntary commitment resulted from a “misuse or abuse” under the statutory process. *Id.*

In 2006, Robert Magrini, who has a schizoaffective disorder, was temporarily committed to Newton-Wellesley Hospital under General Laws c. 123 § 12(b). Four business days after Magrini’s admission, the hospital filed a petition for his continued involuntary commitment for a six-month period, pursuant to General Laws c. 123 §§ 7 and 8. Magrini moved to dismiss this petition, because § 12 requires that the

patient be discharged within three business days of admission if a petition is not filed within that period. Despite the fact that a District Court judge allowed this motion and ordered Magrini discharged, the hospital did not release him from the locked psychiatric unit and proceeded to restrain and admit Magrini a second time pursuant to § 12 (a) and (b). Through counsel, Magrini requested an emergency hearing, alleging unlawful detention due to “misuse of § 12(a) and § 12(b) to effectively countermand a court order [of] discharge.” *Id.* at 782. The District Court judge summarily denied the request for a hearing, and a divided Appellate Division panel dismissed the subsequent appeal. Although the question was rendered moot by subsequent events, the SJC exercised its discretion to address the merits and determine whether an emergency hearing was required.

Section 12 of General Laws c. 123 addresses the emergency restraint and temporary commitment of persons with mental illness. The statute allows the restraint and hospitalization of persons based on the determination of a designated physician that the “failure to hospitalize such person would create a likelihood of serious harm by reason of mental illness.” This initial hospitalization is temporary and limited to three days. At the end of the three-day period, the hospital must discharge the individual, accept the person’s application for a “conditional voluntary admission,” or file a petition for a continued commitment for six or twelve months under §§ 7 and 8. In 2000, the Legislature added certain protections for persons temporarily committed, including ap-

pointment of counsel. *Id.* at 780. The 2000 language provides: “Any person admitted under the provisions of this subsection, who has reason to believe that such admission is the result of an abuse or misuse of the provisions of this subsection, may request . . . an emergency hearing in the district court.”

The hospital argued that the statute only entitled an involuntarily committed person to an emergency hearing when alleging an abuse or misuse of a specific right enumerated in § 12 (including evaluation by a designated physician against specific medical standards, and the appointment of counsel). The Court disagreed, finding that a broader reading of the statute was mandated by the intent of the Legislature to “extend further procedural protections to persons who, by virtue of their temporary involuntary commitment, are experiencing a ‘massive curtailment’ of their liberty.” *Id.* at 783-84 (quoting *Commonwealth v. Nassar*, 380 Mass. 908, 917 (1980)). The Court determined that the hospital’s second § 12(b) commitment rendered the district court’s discharge order “illusory,” because the hospital never complied and caused Magrini to be involuntarily confined for 11 days without a hearing. This situation “clearly satisfied the minimal showing that [Magrini’s] second § 12(b) commitment resulted from a misuse or abuse under the § 12(b) process.” *Id.* at 784. The SJC concluded that once a sufficient basis for an emergency hearing is demonstrated, the district court must hold such a hearing unless the request for an emergency hearing “on its face is patently frivolous.” *Id.* at 785. Moreover, to ensure meaningful review and due process, “the

person temporarily committed has the right to be present at the hearing and may be heard,” although the judge has the discretion to decide whether evidence should be required. *Id.* The SJC also specifically stated that this decision does not necessarily prohibit the recommitment of a person on a temporary basis absent a “misuse or abuse” of the § 12(b) process. *Id.* at 784.

***Romero v. UHS of Westwood Pembroke, Inc.*, 72 Mass. App. Ct. 539 (Sept. 8, 2008)**

By Daniel Navisky, Esq.

The Massachusetts Appeals Court recently limited the scope of the Massachusetts medical provider whistleblower statute, General Laws c. 149, § 187, which provides a cause of action to health care providers who are retaliated against. The statute prohibits health care facilities from taking retaliatory actions against a health care provider for, among other things, objecting to or refusing to participate in any activity, policy, or practice of the health care facility which that health care provider reasonably believes is either in violation of a law, rule, or regulation, or in violation of a professional standard of practice, which the health care provider reasonably believes poses a risk to public health. In *Romero v. UHS of Westwood Pembroke, Inc.*, the Appeals Court addressed the question of when an institutional activity, policy, or practice is sufficiently imminent to trigger protection from retaliation.

The plaintiff, formerly the director of a partial hospitalization program of the defendant, UHS of Westwood Pembroke (“UHS”), objected to a proposal to increase the patient-to-staff ratio (“the patient census”). In the face of objections from the plain-

tiff and others, the proposal was not adopted. The plaintiff claimed that her objections led to her reporting to someone new as a result of a 2002 administrative reorganization, and ultimately to her termination three months later as part of a staff reduction.

A claim under the statute requires a plaintiff to establish that (1) she objected to, or refused to participate in, an activity, policy, or practice (2) that she reasonably believed to be in violation of a law, rule, regulation, or professional standard of practice, (3) which she reasonably believed posed a risk to public health (from an objective perspective), and (4) that she was retaliated against as a result, with the objection being a substantial or motivating part of the adverse employment action.

The Appeals Court, affirming summary judgment for UHS on all counts, ruled that the statute does not protect health care providers who object to proposals not actually implemented. “General Laws c. 149, § 187, does not extend to mere proposals. Instead, the plain language of the statute refers only to existing activities, policies, and practices of a health care facility that are (the statute itself using the present tense) in violation of a statute, rule, regulation, or professional standard.” *Id.* at 541.

The Appeals Court regarded this “plain language” reading as consistent with the statute’s underlying policies. Pointing to the law’s notice requirement, the court observed that “a significant purpose of the statute is to ‘afford[] the health care facility a reasonable opportunity to correct the activity, policy or practice.’ In those cases, if the health care facility corrects the problem, the objecting health care provider has no claim.” *Id.* at 542. The court emphasized that, at least in these circumstances, “salutary internal

debate among health care professionals regarding how to handle their medical practice” would not give rise to a claim under the statute. *Id.*

In two other respects, the facts, as understood by the Appeals Court, were insufficient to sustain a medical provider whistleblower claim. First, there was no evidence in the record that the proposal violated any law, rule, regulation, or professional standard of practice as required by the statute. “The plaintiff’s personal views on the proposed patient census increase, unsupported by reference to any statutory, regulatory or professional standard of practice, were not enough to support her claim.” *Id.* Second, the administrative reorganization could not have been a retaliatory action, because it was announced before the plaintiff objected to the proposed patient census increase. As the Appeals Court stated, “It is logically and legally impossible for the claimed retaliatory conduct to have occurred before the plaintiff voiced her objection.” *Id.* at 543.

Lastly, upon analysis, the Appeals Court affirmed summary judgment for UHS on other claims brought by the plaintiff – for pregnancy discrimination under General Laws Chapter 151B, and for intentional interference with advantageous business relations.

Workplace whistleblower protections vary from state to state. While the Appeals Court’s ruling may create a disincentive in Massachusetts for health care providers to voice objections to proposed policies, it is equally likely to encourage health care facilities to promote internal debate on their proposals before implementation without fear of future legal challenges.

Editors

Catherine L. Annas, Esq.

Catherine L. Annas is the Director of the Eastern Massachusetts Health-care Initiative (EMHI), a group of hospitals, health plans, provider groups and universities working together to create a high performance health care system in Eastern Massachusetts. She oversees projects related to patient safety, quality and cost in health care. Prior to joining EMHI, Ms. Annas served for five years as the Director of Patient Safety at the Department of Public Health and the Betsy Lehman Center for Patient Safety and Medical Error Reduction. Before that, Ms. Annas worked for five years on the House staff of the Massachusetts Legislature's Joint Committee on Health Care. Ms. Annas received her J.D. from the Columbus School of Law at the Catholic University of America in 1995, and her Bachelor's Degree in English from the Catholic University of America in 1992.

Mark C. Rogers, Esq.

Mark C. Rogers is an associate at The Rogers Law Firm. He is a member of the Firm's Corporate and Health Care Practice Groups. Although he has extensive experience representing a variety of clients with regard to regulatory, compliance, employment and corporate matters, Mr. Rogers focuses his practice on health care contractual matters, regulatory compliance, and fraud and abuse investigations. He has published and lectured extensively on legal issues in the health care industry and is an adjunct faculty member at New England School of Law where he teaches Health Law. Mr. Rogers earned his undergraduate degree from the College of the Holy Cross and his law degree (cum laude) from Suffolk University Law School, where he served as the Chief Managing Editor of the Suffolk Transnational Law Review.

Susan J. Stayn, Esq.

Susan J. Stayn is Senior University Counsel at Stanford University and Stanford Medical Center, where she advises on health care regulatory and corporate matters and biomedical research. Ms. Stayn has been an advisor to the Interstate Alliance on Stem Cell Research since its inception in 2007, and developed and taught a stem cell research law and policy course at Berkeley Law School in 2008. She previously worked for many years in the Office of the General Counsel of Partners HealthCare System, Inc. Prior to joining Partners, Ms. Stayn worked in the private and non-profit sectors and clerked for the Honorable Levin H. Campbell on the U.S. Court of Appeals for the First Circuit. She is a graduate of Harvard College, magna cum laude, and Columbia Law School, where she was editor-in-chief of the Columbia Law Review.

Contributors To This Issue

Tom Barker, Esq.

Thomas R. Barker recently completed seven years of service in the Administration of President George W. Bush. Most recently, he was acting general counsel of the U.S. Department of Health and Human Services, where he oversaw a staff of 450 attorneys nationwide, attested to the legal sufficiency of every regulation and policy guidance issued by HHS, and oversaw the conduct of all litigation to which the Department was a party.

Áron Boros, Esq.

Áron Boros is a Federal Financing Analyst in the Commonwealth's Office of Medicaid, where he focuses on acute and ambulatory care issues. Previously, Mr. Boros worked as an attorney in the Government Strategies group at Foley Hoag, and in the Office of the General Counsel for St. Joseph Mercy Health System in Ypsilanti, Michigan. Mr. Boros holds a M.P.P. from the Gerald Ford School of Public Policy and a J.D. from the Law School at the University of Michigan, where he taught Benefit-Cost Analysis as a graduate student. Mr. Boros graduated from Amherst College with a B.A. magna cum laude in geology.

Josh Greenberg, Esq.

Josh Greenberg co-chairs the Health Law Section's Legislative Subcommittee, and currently serves as the Director of Government Relations at Children's Hospital Boston. His primary responsibility is oversight of state and federal fiscal and public policy issues, including work on Medicaid, uncompensated care and public health concerns. He previously served as Manager of the Children's Division

at Health Care For All, where he directed the Covering Kids Program for Massachusetts. He also coordinated other children's work, including projects on health quality, teen health and mental health. Prior to joining Covering Kids, Mr. Greenberg founded an innovative legal aid program based at the Boston City Hospital Department of Pediatrics. Mr. Greenberg is a graduate of Dartmouth College and Northeastern University's School of Law.

Melissa J. Lopes, Esq.

Melissa Lopes is Deputy General Counsel for the Massachusetts Department of Public Health. In the biotechnology arena, Ms. Lopes provides advisory rulings on egg donation in the research context, promulgates regulations under the Massachusetts Stem Cell bill, and works with the Biomedical Research Advisory Council and the Interstate Alliance on Stem Cell Research. Additionally, Ms. Lopes provides legal advice and guidance to the Determination of Need program, the Clinical Laboratories Program and on matters including blood banking and pharmaceutical marketing in the Commonwealth. Prior to joining the Department of Public Health, Ms. Lopes was a Kellogg Fellow with Community Catalyst, a national healthcare advocacy group. In this capacity, Ms. Lopes worked with grassroots community groups across the country to secure and preserve needed healthcare resources. Ms. Lopes also worked as an associate with the law firm Choate, Hall & Stewart in the corporate and healthcare departments. Ms. Lopes is a graduate of Boston College and Boston University School of Law, where she was an editor of the American Journal of Law and Medicine.

Daniel Navisky, Esq.

Daniel Navisky is an associate in the Government Strategies Group, as well as the Labor & Employment and Litigation Departments at Foley Hoag LLP, where his practice includes advising life sciences and health care clients on legislative and regulatory matters, and representing clients in healthcare investigations and labor and employment disputes. Mr. Navisky worked previously for former U.S. House Democratic Leader Richard A. Gephardt as a Policy Assistant in the House Democratic Policy Committee, and as Assistant Director for Civil Rights and Public Policy for the Anti-Defamation League's New England Region. Mr. Navisky received his J.D. from Boston College Law School where he was Senior Executive Editor of the Boston College International and Comparative Law Review, and graduated with a B.A. in Political Science from the University of Rochester.

Peer Review Coordinator:

Julia Hesse, Esq.

Peer Reviewers:

Karyn Brudnicki, Esq.

Jed Adam Gross, Esq.

Chris Kirby, Esq.

Daniel Lev, Esq.

Emily B. Wood, Esq.

Section Leadership

Section Co-Chairs

Matthew Herndon
Harvard Pilgrim Health Care, Inc.
93 Worcester Street
Wellesley, MA 02481
(617) 509-3077
Matthew_Herndon@harvardpilgrim.org

David Szabo
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
(617) 439-2000
dszabo@nutter.com

Health Law CLE Committee

William Mandell
Pierce & Mandell, P.C.
11 Beacon Street
Suite 800
Boston, MA 02108
(617) 720-2444
bill@piercemandell.com

Alan Einhorn
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 342-4000
aeinhorn@foley.com

Robin Johnson
Johnson & Aceto, LLP
67 Battery March Street
Boston, MA 02110
(617) 728-0888
johnson@johnsonaceto.com

Health Law Communications Committee

Susan Stayn
Stanford University, Office of the
General Counsel
PO Box 20386
Stanford, CA 94305
(650) 724-3132
sstayn@comcast.net

Mark Rogers
The Rogers Law Firm
100 Cambridge Street
20th Floor, Suite 2000
Boston, MA 02114
(617) 723-1100
mrogers@therogerslawfirm.com

Catherine Annas
Eastern Massachusetts Health-
care Initiative
14 Story Street
2nd Floor
Cambridge, MA 02138
(617) 495-2966
catherine_annas@harvard.edu

Health Law Legislative Committee

Joshua Greenberg
Office of Child Advocacy
300 Longwood Avenue, BK120
Boston, MA 02115
(617) 919-3063
Joshua.Greenberg@tch.harvard.edu

Linda Tomaselli
Epstein Becker & Green, P.C. - DC
Office
1227 25th St., NW
Suite 700
Washington, DC 20037
LTomaselli@ebglaw.com

Michael Sroczynski
Massachusetts Hospital Associa-
tion - Boston
101 Arch Street
Suite 1741
Boston, MA 02110
(617) 367-9667
msroczynski@mhalink.org

Health Law Membership Committee

Eve Horwitz
Archstone Law Group P.C.
245 Winter Street
Suite 400
Waltham, MA 02451
(781) 314-0111
ehorwitz@archstonelaw.com

Dianne McCarthy
Joslin Diabetes Center
One Joslin Place
Boston, MA 02215
(617) 667-1894
dianne.mccarthy@joslin.harvard.edu

Leslie Joseph
Mount Auburn Hospital
330 Mount Auburn Street
Cambridge, MA 02138
(617) 499-5752
ljoseph@mah.harvard.edu

Social Action Committee

Sarah Anderson
Greater Boston Legal Services
197 Friend Street
Boston, MA 02114
(617) 371-1234
sanderson@gbls.org

Michael Blau
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 342-4040
mblau@foley.com

Barbara Anthony
Health Law Advocates, Inc.
30 Winter Street
Suite 940
Boston, MA 02108
(617) 338-5241
banthony@hla-inc.org

Health Law Ad Hoc Committee on Health Reform

Christie Hager
Instructor of Public Health Practice
Harvard School of Public Health
chager@hsph.harvard.edu

New Lawyers Liaison

Justin DiBiasio
Appeals Court of Massachusetts
One Pemberton Square
Boston, MA 02108
(774) 254-7413
justin.dibiasio@gmail.com

Health Law At-Large Committee

Lawrence Vernaglia
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 342-4079
lvernaglia@foley.com

Susan Williams
Associate General Counsel
Massachusetts Eye and Ear
Infirmary
243 Charles Street
Boston, MA 02114
(617) 573-3008
Susan_Williams@meei.harvard.edu
Donna Levin
Massachusetts Department of
Public Health

250 Washington Street
2nd Floor
Boston, MA 02108
(617) 624-5220
donna.levin@state.ma.us

Lawrence Litwak
Foley & Lardner LLP
111 Huntington Ave.
Boston, MA 02199
(617) 502-3224
llitwak@foley.com

Clare McGorrian
22 Putnam Avenue
Cambridge, MA 02139
(617) 871-2139
cdmccgcounsel@verizon.net

Diane Moes
Donoghue, Barrett & Singal, P.C.
One Beacon Street
Suite 1320
Boston, MA 02108
(617) 598-6700
dmoes@dbslawfirm.com

Quentin Palfrey
Office of the Attorney General
One Ashburton Place
Boston, MA 02108
(617) 963-2458
quentin.palfrey@state.ma.us

Health Law Education Planning Committee

Sam Senft
Boston Medical Center-Newton-
Medical Legal Partnership for
Children
88 East Newton Street, Vose 5
Boston, MA 02118
sam.senft@bmc.org

Edward Deangelo
Commonwealth Health Insurance
100 City Hall Plaza

Boston, MA 02421
ed.deangelo@state.ma.us

Jesse Caplan
Epstein Becker & Green, P.C.
10 Chestnut Street
9th Floor
Worcester, MA 01608
(508) 368-9571
jcaplan@ebglaw.com

Joel Goloskie
goloskie@comcast.net



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Boston Bar
ASSOCIATION

16 Beacon Street
Boston, MA 02108
Phone (617) 742-0615
Fax (617) 523-0127
www.bostonbar.org