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# Section Co-Chairs' Corner

## Summer 2008

It is already starting out as an exciting summer for the health care bar and the BBA's Health Law Section! Several significant pieces of legislation with meaningful impact on the health care community are in the works. As this issue is going to press, the Governor is signing a \$1 billion Life Sciences bill. Major changes to regulation of ambulatory surgery centers and imaging ventures are in the works in another bill pending in the General Court. The Department of Public Health is finalizing new Determination of Need regulations with far-reaching significance. Minute clinics are challenging traditional provider markets. The Commonwealth's largest payor is proposing to return to a payment model that looks like capitation. The most recent figures released show that our Health Reform Initiative has cut almost in half the number of uninsured persons in the Commonwealth. And these are just a few of the major changes that health lawyers need to keep up with.

Among all the resources available to you to keep up with these developments, we hope the Health Law Section is providing valuable content and perspective to help your practice, clients, and you. This issue of The Boston Health Law Reporter alone covers a number of other pressing issues for the health care industry and consumers, including legislation on gifts from pharmaceutical companies, Medicaid cuts, stem cell legislation, and medical malpractice premiums. We are also including a review of a new book on physician-industry relationships, and hope to provide other book reviews in the future. Our editors, writers, and peer reviewers all contribute substantial time and judgment to select topics and points of view that present you with a unique resource - I hope you find it as essential as I do.

This is my last Co-Chairs' Corner, as my term as Co-Chair shortly will be over. It has been an honor to work with an unbelievably dedicated and talented group of professionals from the HLS Steering Committee, committee members, BBA staff, and, most important, you the members of the Health Law Section. Over the past two years, you participated in meetings, lunches, and receptions. You submitted articles to our Reporter. You volunteered to speak at brown bag lunches or CLEs. You called and offered your time to our committees and service projects. In each of these encounters with the Health Law Section, you broadened the experience for us all, and you demonstrated what it means to be a professional in a very small family of lawyers - truly members of the bar. Thank you for your many contributions - and please stay involved. It's what keeps the Health Law Section a vibrant community of colleagues and friends.

**Larry Vernaglia, Co-Chair**  
**Health Law Section**

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We would like to extend our congratulations to Health Law Section member Tom Barker, who was named Acting General Counsel for the Department of Health and Human Services by Secretary Mike Leavitt on May 8, 2008.

Study of Note: Rodwin MA, Chang HJ, Ozaeta MM, Omar RJ. Malpractice Premiums in Massachusetts, A High-Risk State: 1975-2005. Health Affairs, 27, no. 3 (2008): 835-844.

# Massachusetts Senate Passes Biotech Industry Gift Ban Bill

By Robert Driscoll, Esq.

## Introduction

On March 3, 2008, Massachusetts Senate President Therese Murray (D-Plymouth) introduced into the Massachusetts Senate the Health Care Cost Control Bill (the "Bill"). The Bill contains dramatic health care reform legislation intended to control rising health care costs. Perhaps the most dramatic legislative reform contained within the Bill is a provision which would make Massachusetts the first state to ban gifts to health care providers from pharmaceutical or medical device manufacturing companies.<sup>1</sup> The gift ban provision, contained in Section 26 of the bill, was added by Senator Mark Montigny (D-New Bedford). The Bill was passed unanimously by the Senate and is currently being considered by the House Ways and Means Committee. The Bill has spurred debate on whether physicians require such drastic legislation to ensure that patients are not damaged by undue influence of pharmaceutical or medical device manufacturing companies. A summary of the Bill and its potential impact follows.

## Section 26 of Senate Bill 2660 – Chapter 268C

The apparent intent of the Bill is to prevent undue influence on the prescribing pattern of physicians by pharmaceutical or medical device manufacturing companies.<sup>2</sup> In its original form<sup>3</sup>, the Bill would have proscribed both the giving of gifts by pharmaceutical or medical device manufacturers and the acceptance of gifts by physicians, and provided for punishment by fines of up to \$5,000 and up to two years in

prison for each offense. In debate on the floor of the Massachusetts Senate, the Bill was amended and resubmitted as Massachusetts Senate Bill 2660. The amendments removed the criminal provision of the Bill and added a section requiring reporting to the Massachusetts Department of Public Health ("DPH") by pharmaceutical or medical device manufacturers of all payments or benefits given to health care providers, including research, scientific discovery, stock payments, and investigator expenses. On April 17, the amended Bill passed the Senate by a vote of 36-0, and the House of Representatives referred the Bill to the House Ways and Means Committee on April 24.

Section 26(1) of the Bill broadly defines the term "gift" as a payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value, unless consideration of equal or greater value is received and for which there is a contract with specific deliverables which are not related to marketing and are restricted to medical or scientific issues. The Bill carves out from the definition anything of value received by inheritance, a gift received from a member of the health care practitioner's immediate family or from a relative within the third degree of consanguinity of the health care practitioner or of the health care practitioner's spouse or from the spouse of any such relative, or prescription drugs provided to a health care practitioner solely and exclusively for use by the health care practitioner's patients.

The broad language of the Bill would not only ban continuing medical education ("CME") payments, honoraria, consulting, and travel payments, but would also bar focus groups, consulting, dinner meetings, board fees, stock options, promotional events, journal reprints, and medical books. There is concern in the health care community that the wide ban of Section 26(1) would lead to such a hostile regulatory environment in Massachusetts that both pharmaceutical and medical device manufacturing companies as well as physicians would seek more favorable conditions in other states, substantially impairing the Massachusetts biotech industry.

Section 26(2) of the Bill would forbid agents of pharmaceutical and medical device manufacturing companies from offering or giving a gift of any value to a health care practitioner, a member of a health care practitioner's immediate family, a health care practitioner's employee or agent, a health care facility or an employee or agent of a health care facility. As stated above, the definition of gift is so broad as to include everything from de minimis gifts of pens and coffee to the provision of CME programs by pharmaceutical and medical device manufacturers. There are certain exemptions in Section 26(2) including an exemption for the provision, distribution, dissemination, or receipt of peer reviewed academic, scientific or clinical information and for the purchase of advertising in such journals.

The amended form of the Bill added

public disclosure and licensing requirements to all transactions between health care providers and representatives of pharmaceutical and medical device manufacturing companies. By July 1 of each year, every pharmaceutical or medical device manufacturing company would have to disclose to DPH the value, nature, purpose and recipient of any fee, payment, subsidy or other economic benefit which the company provided to any health care provider. For each expenditure, the company would have to report the provider, his or her address, credentials, institutional affiliation, and state board or Drug Enforcement Administration numbers. Each pharmaceutical or medical device company must also have an individual responsible for the company's compliance. DPH would then report to the Massachusetts Office of the Attorney General ("OAG") any expenditure in violation of these provisions.

Section 26(4) of the Bill would require licensing by DPH of all agents of pharmaceutical and medical device manufacturers. The original Bill was amended to include that as a condition to licensing, agents must complete training developed by DPH. Further, to renew a license, each agent would have to complete continuing education through DPH. Fees generated by the licensing requirements would be divided by DPH (75%) and OAG (25%).

Although the Senate dropped the criminal provision of the Bill, it retained stiff penalties on the order of a fine of not more than \$5,000 for each transaction, occurrence or event that violates this chapter.

### **Legislation Welcomed by Patient Advocacy Groups**

The Bill has been applauded by non-profit advocacy groups such as the Massachusetts Prescription Reform

Coalition ("MPRC")<sup>4</sup>. MPRC cites the cost of prescription drugs as among the fastest growing segments of health care spending. According to MPRC, between 2000 and 2007 the price of many of the most commonly prescribed brand name drugs rose in excess of inflation, creating a significant hurdle to individual access to medications.<sup>5</sup> The group has also expressed concern that gifts from pharmaceutical and medical device manufacturing companies to prescribers impact prescribing decisions.<sup>6</sup> MPRC claims that "pharmaceutical gifts undermine quality of care and unnecessarily increase prescribing of the most expensive drugs," and that "the costs are passed on to consumers, employers, and the state in inflated prescription drug prices – prices that threaten access to needed medications and strain individuals' and the Commonwealth's budgets."<sup>7</sup>

Adriane Fugh-Berman, MD, the principal investigator of PharmedOut, an advocacy group formed to disseminate information to physicians about how pharmaceutical companies influence prescribing behavior, stated in *BusinessWeek* magazine that a doctor who spends just one minute with a sales representative "typically ends up prescribing 16 percent more of that rep's product than he or she was prescribing before. And a four-minute encounter is likely to prompt a 52 percent jump in prescriptions."<sup>8</sup>

### **"Unintended Consequences"**

The Massachusetts Medical Society ("MMS")<sup>9</sup> has stated that while it supports the intent of the Bill – preventing undue influence on the prescribing pattern of physicians by pharmaceutical and medical device manufacturers -- it feels the legislation is overbroad. MMS warns that the Bill would "have the

unintended consequence of limiting support for legitimate physician continuing medical education programs and potentially even the distribution of scientifically accurate information in medical and scientific publications."<sup>10</sup> MMS advocates for a more measured approach tailored closely to the American Medical Association's ethical guidelines, such as the language of Massachusetts House Bill 2251 instituting "sunshine provisions" which would "accomplish the same goal without the negative consequences, and also allow the state to review the current level of gifts and incentives provided by the industry throughout the health care system and craft an appropriate response to the issue."<sup>11</sup>

MMS is especially sensitive to the repercussions the Bill would have on CME programs, many of which are sponsored by the pharmaceutical industry. MMS points out that the Accreditation Council for Continuing Medical Education ("ACCME"), which sets nationwide CME quality standards, recently strengthened guidelines for commercial support of CME programs.<sup>12</sup> The MMS policy in this regard states that "subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible."<sup>13</sup> However, MMS claims that its policy advocates against individual doctors being paid by commercial interests for travel expenses or time spent at educational conferences.<sup>14</sup>

There have been complaints from the biotech industry that the Bill would place significant restrictions on the ability of researchers to obtain funding, recruit patients for clinical trials, and compete with researchers in other states not subject to the same restrictive prohibitions. Chris Andersen, President of the Massachusetts



High Technology Council, has stated that the legislation sends a contradictory message to pharmaceutical companies when compared with Governor Patrick's economic development plan.

Pharmaceutical and medical device manufacturing companies have taken it a step further, calling the gift ban an anti-business policy that would impede efforts to deliver cutting-edge drugs to patients.<sup>15</sup> In a letter to the chairs of the Massachusetts Legislature's Economic Development and Emerging Technologies Committee, executives from Pfizer, Amgen, Abbott Bioresearch Center, Genentech, all of which have facilities in Massachusetts, criticized the gift ban as paradoxical to the government's efforts to lure the life sciences industry.<sup>16</sup> The letter, signed by Pfizer COO W. Stephen Faraci, Amgen Executive Director Mark Duggan, Genentech State Government Affairs Director Todd Kaufman, and Abbott Divisional Vice President Peter Isakson, states, "[t]he proposal to restrict the ability of biopharma companies to interact with physicians ... will send the message loud and clear to biopharma CEO's considering expansion or new investment: Go elsewhere."<sup>17</sup>

Thomas Sullivan, President of the Rockpointe Corporation, a medical communications company, stated that "[t]he bill, if passed, would be a disaster to the biotech industry of Massachusetts, and have devastating effects on the research institutions that make Boston the largest healthcare economy in the country."<sup>18</sup> Sullivan added that at least one state - North Carolina - is planning an advertising campaign to attract biotech companies and academic group practices in the Boston area, should they decide to relocate if the Bill passes.<sup>19</sup>

## Other States' Laws

The Massachusetts gift ban would restrict marketing and sales practices to an unprecedented degree in comparison with other state laws. Maine, Minnesota, Vermont, West Virginia, and the District of Columbia are the only jurisdictions with mandatory physician gift reporting laws. In Minnesota, gifts in excess of \$50 have been banned. The District of Columbia, Maine, and Vermont all have "sunshine provision" laws, which require pharmaceutical and medical device manufacturing company representatives to disclose the dollar value of gifts over \$25. West Virginia requires reporting of payments over \$100, but there is no enforcement mechanism.<sup>20</sup>

## Conclusion

The coming weeks will be a crucial period for the gift ban provisions of the Massachusetts Health Care Cost Control Bill. While the intent of the Bill is to prevent undue influence on the prescribing pattern of physicians by pharmaceutical and medical device manufacturers, the broad language of the legislation may negatively impact CME and biotech investment in Massachusetts.

## Endnotes

<sup>1</sup>Section 26 of Massachusetts Senate Bill 2660 proposes to add a new Chapter (268C) to the General Laws of the Commonwealth.

<sup>2</sup>"Ban on gifts to doctors sought: Murray targets firms' freebies", The Boston Globe, March 4, 2008 ([http://www.boston.com/news/health/articles/2008/03/04/ban\\_on\\_gifts\\_to\\_doctors\\_sought/](http://www.boston.com/news/health/articles/2008/03/04/ban_on_gifts_to_doctors_sought/) [last accessed on May 30, 2008]).

<sup>3</sup>Originally filed as Massachusetts Senate Bill 2526.

<sup>4</sup>MPRC members include: AARP Massachusetts, AIDS Action Committee, Blue Cross Blue Shield of Massachusetts, Commonwealth Care Alliance, Commonwealth of Massachusetts Group Insurance Commission, Community Partners, Health Care For All, Massachusetts Senior Action Council, MASSPIRG, National Physicians Alliance, Neighborhood Health Plan, The Prescription Project, and the United Auto

Workers, Massachusetts State Community Action Program Council.

<sup>5</sup><http://www.hcfama.org/index.fm?fuseaction=Page.viewPage&pageId=846&parentID=531> [last accessed on May 30, 2008].

<sup>6</sup>*Id.* (claiming that 94% of physicians receive meals, medication samples, and other payments from pharmaceutical companies).

<sup>7</sup>"The Massachusetts Prescription Reform Coalition Praises Senate President Murray for Taking on Prescription Drug Costs", March 3, 2008 (<http://www.hcfama.org/index.cfm?fuseaction=Feature.showFeature&CategoryId=11&FeatureID=617> [last accessed on May 30, 2008]).

<sup>8</sup>"Building Up Docs' Marketing Resistance: Educational programs are training medical students on how to deal with drug company sales pitches", Business Week, January 18, 2008.

<sup>9</sup>MMS is a statewide professional association of physicians and medical students whose stated mission is to educate and advocate on behalf of physicians and patients throughout the Commonwealth, to advance medical knowledge, and promote a better health care system. MMS publishes the New England Journal of Medicine; the Journal Watch family of professional newsletters covering 11 specialties; and AIDS Clinical Care.

<sup>10</sup>"Testimony of the Massachusetts Medical Society Before the Joint Committee on Health Care Financing Regarding Senate Bill 2526, 'An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care'", March 12, 2008 (<http://www.massmed.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=21281> [last accessed May 30, 2008]).

<sup>11</sup>*Id.*

<sup>12</sup>"Redefining Physician-Pharmaceutical Company Relationships", Vital Signs, April 2008.

<sup>13</sup>*Id.*

<sup>14</sup>*Id.*

<sup>15</sup>"Biopharma Firms Slam Murray's Gift Ban Proposal" (State House News), Jim O'Sullivan, State House News Service, April 14, 2008.

<sup>16</sup>*Id.*

<sup>17</sup>*Id.*

<sup>18</sup>"State Senate approves ban on gifts to physicians", Ben Corner, Boston Herald, April 21, 2008.

<sup>19</sup>*Id.*

<sup>20</sup>*Id.*; see also [http://www.prescriptionproject.org/tools/solutions\\_factsheets/files/0006.pdf](http://www.prescriptionproject.org/tools/solutions_factsheets/files/0006.pdf) [last accessed on May 30, 2008].

# The *Stark* Reality of Physician-Industry Relationships

By Barbara E. Bierer, MD

**Book Review of *Managing Relationships with Industry: A Physicians' Compliance Manual* by Steven C. Schachter, William Mandell, Scott Harshbarger, and Randall Grometstein**

An interventional cardiologist is approached by a major biotechnology company to test a catheter that had been recently approved for use by the Food and Drug Administration (FDA). Apparently there is little experience in the hospital with the new device, and the biotech company offered to send one of its own technical experts to assist in the catheterization laboratory. In addition, for the next ten patients, the company proposed that the physician earn \$2500 per patient to complete a "post-use questionnaire," a one-page form that seeks to survey ease of use, clarity of instructional material, and physician satisfaction. The company representative explained that the questionnaire would take 15-20 minutes to complete and is optional. Further, no institutional review board review and approval is required, since this study is considered a quality improvement initiative for "post-marketing surveillance" of a new product. Finally, the company offered an additional \$10,000 if all ten surveillance questionnaires were completed and returned within three months, arguing that rapid collection of the data was important for patient safety.

Should the cardiologist participate in this activity? What if the physician declined the assistance of the company technical expert? What if he declined the 'bonus payment' for rapid accrual of the patient cohort? What if, in the absence of bonus payments or technical expert

assistance, the questionnaire took three hours to complete? What if the hospital, not the physician, agreed to receive the company payments through a "service agreement," not a consulting arrangement? What if the physician was participating in a multi-site, randomized clinical trial in which he was enrolling patients to test outcome of this specific treatment?

In this timely publication, *Managing Relationships with Industry: A Physicians' Compliance Manual*, authors Schachter, Mandell, Harshbarger, and Grometstein review the legal, ethical, and professional framework by which physicians interact with, and contract with, industry and the context in which such relationships are reviewed, managed, permitted or judged. The book itself is a sobering and cautionary introduction to the potential risks for both physicians and their institutions; a range of potential relationships is explored. The contribution makes a compelling case for careful consideration, for thoughtful oversight, and for disciplined management, and it argues that there are times, albeit rarely, when one should just say "no."

Gone are the days when physicians could casually enter into a consulting or other relationship with industry. The media has publicized a number of physician payments from industry, some in the setting of undisclosed but apparent conflicts of interest;

the public is intolerant of lucrative payments most particularly if patient care or safety is of concern. Recently, Congressional leaders have initiated a penetrating review of the National Institutes of Health oversight of grantee institutions that allow—and fail to adequately monitor—federally-funded investigators that have received industry payments, again in the setting of potential conflict of interests. And huge financial settlements have encouraged perspicacious "whistleblowers" to monitor the activities of industry ever more closely.

This book rests on the premise that physicians are fundamentally ethical people trying to take care of their patients, contribute to education, and direct both basic and clinical research toward understanding pathobiology of disease, advancing therapeutic interventions, and relieving suffering. These ethical principles are, however, personal beliefs and may be questioned, reasonably, by colleagues or in litigation. Because physician interactions with industry are under scrutiny, any individual considering such a relationship should thoughtfully approach and document the terms of the agreement, including payments, deliverables, and other expectations, in a responsible and compliant manner such that review of the interaction, as well as the agreement, would survive public scrutiny. This book sets out the legal and ethical principles upon which

such legitimate relationships should rest. The presumed audience is the individual physician at the outset of the industry interaction. Appropriate consideration of the issues at play for group practices, for medical centers, and for academic institutions would have been welcome.

The book consists of six well-conceived chapters. The first chapter reviews the history of physician-industry interactions and the motivations behind these interactions. Industry is big business in the United States: big profits, driven by new drugs and devices, and prescribed by physicians often influenced by marketing (direct or insidious) and potentially by personal financial gain. The methods for such influence range from provision of free sample medications, gifts, and dinners, to lucrative arrangements such as speakers bureaus, continuing medical education courses, consultation, and payment for services including physician-to-physician marketing and enrolling patients in clinical trials. The second chapter outlines the legal framework upon which these relationships are founded and explains, in clear language, anti-kickback laws (prohibiting payment or gifts in which the remuneration is directly tied to or intended to influence physician prescribing behavior) and attendant safe harbors protections, the Stark Law (prohibiting certain physician referrals to entities in which they or their immediate family members have a financial interest) and permissible indirect and direct financial relationships (e.g., fair market value compensation) under Stark, and the federal False Claims Act (prohibiting any party knowingly submitting a false claim for payment from a federal agency) and whistleblower protections and payments. The authors explain the range of penalties and sanctions

that can result from legal action, including financial penalties, reputational risk, and sanctions. The third chapter reviews recent investigations and prosecutions, focusing on interpretations of the law. There is no question that this is serious business, with serious consequences, not an intellectual exercise.

Chapter 4 reviews the standards set by a variety of responsible agencies (Office of the Inspector General, Center for Medicare and Medicaid Services) and organizations (including the Advanced Medical Technology Association, Pharmaceutical Research and Manufacturers of America, the International Federation of Pharmaceutical Manufacturers and Associations, the Utilization Review Accreditation Commission, the American Medical Association, FDA, Accreditation Council for Continuing Medical Education, and others) to provide guidance for interactions between pharmaceutical and device companies and health care professionals. There is greater similarity than differences between these different guidance documents, but the subtle differences exist. The medical community would be well served by a single harmonized, clear guidance policy that delineates acceptable – and clearly unacceptable – interactions, and how to evaluate and review the many situations that fall between.

Chapter 5 details the types of relationships that may exist and the considerations that would inform an approach for each. Finally, Chapter 6 outlines a compliance approach and plan for each interaction and situation. The language is not proscriptive but rather advisory; the range of engagement activities is broad and the considerations numerous. Delineation of a series of practical examples, starting with

common situations and advancing to more subtle variations, would have been welcome.

While each concept is presented with clarity without requiring technical sophistication, in the end one can't help but feel overwhelmed. For the mere professional without legal training, one finishes with a sense that there are so many details, the relationship(s) so nuanced, and the risks and consequences so grave, that no interaction should proceed without the benefit of legal review and a documented contract. The stakes are high. It better be worth it. And your best friend is your lawyer.

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# Medicaid: Focus on Cost Growth Can Obscure the Growing Role of the Program and Divert Attention from an Imminent Federal Assault

By Anya Rader Wallack, Ph.D. and Jarrett Barrios, Esq.

Scrutiny of Medicaid spending by the state often ignores the significant role the program plays in delivering health care to residents of the Commonwealth. It also obscures a much greater danger to the state's fiscal health than the actual cost of Medicaid: Attempts by federal lawmakers to rollback Medicaid programs. The purpose of this article is to explain the central role Medicaid plays in the Massachusetts health care system, and to highlight the most recent federal threats to the program.

Half of all the state spending on Medicaid is paid by the federal government. It is not an insignificant sum. In fiscal year 2007, Medicaid accounted for 19.3%, or \$7.6 billion, of total state spending. If this funding is squeezed by the federal government, it will devastate the patchwork of services available to the state's most vulnerable residents. In 2007, more than 30% of all children and nearly 6% of all adults under 65 received their health insurance through MassHealth, the Medicaid program for Massachusetts. In addition, almost 220,000 disabled adults and children in the Commonwealth received Medicaid-financed long-term care services, ranging from employment support to personal care in the home to institutional services for individuals with serious mental disabilities. More than 100,000 low-income elderly residents of the state also received Medicaid coverage in 2007, either to supplement their Medicare health

insurance or to pay for long-term care either in a nursing home or in the community. In total, nearly 1.1 million Massachusetts residents currently are covered by Medicaid.

Medicaid is the source of an estimated 41% of revenues for safety net hospitals nationally. Examples of such providers in Massachusetts include Cambridge Hospital and Boston Medical Center. Medicaid also accounts for 34 percent of revenues for Community Health Centers. These providers have been the backbone of services for the poor and underserved in the past, and now play a critical role in assuring access to services under the new Massachusetts Health Reform law.

But recently, federal administrators have moved to curtail severely the dollars available to state Medicaid programs. Last October, and again in December, President Bush vetoed a reauthorization of the State Children's Health Insurance Program (SCHIP), created in 1996 to supplement Medicaid in providing health insurance coverage to low-income children. Congress, through a veto override, was able to extend the program through March of next year, but its long-term viability — not to mention the health insurance of millions of American children who have benefited from the program — are in question.

In August of 2007, the Centers for Medicare and Medicaid Services (CMS), which administers Medicaid

at the federal level, issued a directive that severely limits the ability of states to use SCHIP funds to cover children in families with incomes between 250 - 300% of the federal poverty level. States like Massachusetts that already cover children in that income range will have to meet strict new federal tests to continue to receive federal matching funds for this population, and will be required to impose waiting periods and new cost-sharing requirements on children and their families. Other states like Louisiana and Oklahoma that were planning coverage expansions for children have abandoned those plans.

More recently, CMS issued seven new regulations designed to dramatically reduce federal reimbursement under Medicaid. The regulations will cut the availability of funds — or eliminate them entirely — for such items as graduate medical education, certain safety net hospital reimbursements, rehabilitation and school-based services. All told, an estimated \$1 billion in costs will be shifted over the next five years from the federal government to the state of Massachusetts. That will devastate the state budget and put needed services for our most vulnerable populations in jeopardy.

It is true that Medicaid — and its costs — have grown dramatically since its inception some 40 years ago. But it is not just Medicaid that has grown — our expectations



of the program have been raised significantly. As health policy expert Alan Weil once observed: “Medicaid has become the work horse of the U.S. health care system. When the nation has identified a new problem – from a population that needs health coverage to a provider or health system in need of financial support – Medicaid has gotten the call.”

Perhaps the clearest example of this was when the Massachusetts Legislature passed health reform two years ago. Chapter 58 expanded Medicaid coverage to include children, pregnant women, and some other adults in families with incomes between 200 - 300% of the federal poverty level. Nearly 100,000 residents of Massachusetts, who were previously uninsured, have enrolled in MassHealth since July 1, 2006. These individuals now have access to regular sources of primary care, are more likely to be healthy over the long term, and have the peace of mind of knowing that they have health insurance coverage. In addition, MassHealth has expanded the range of services provided to some who are covered by the program, particularly children with mental health needs.

Meanwhile, it is important to remember three aspects of Medicaid spending that are often lost in discussions around its costs. First, there is no real benchmark for the costs borne by Medicaid for the care of the disabled and low-income elderly, who have wide-ranging needs and require relatively expensive services. Commercial insurers typically do not finance the types of services covered by Medicaid for these populations. Second, the state has deliberately used Medicaid to fund programs, such as portions of special education programs, which were previously funded entirely with

state and/or local expenditures. These are not new expenditures, but simply attempts by the state to maximize the extent to which we avail ourselves of federal matching funds. Last, despite the fiscal burden placed on Medicaid by elderly and disabled populations, the program has grown in recent years at a rate that roughly mirrors overall economic growth. From 1994-2005, the average annual growth rate in Medicaid was 5.6%. Over the same period, personal income within Massachusetts, a proxy for the level of economic activity and taxable resources available, grew at an average annual rate of 5.3 percent. By this measure, Medicaid was growing at what many would consider a sustainable rate.

The Patrick Administration is currently engaged in negotiations with CMS regarding renewal of the state’s Section 1115 Medicaid waiver. This waiver, which expires at the end of June, has allowed the Commonwealth to support the Medicaid expansions described above, to continue to support essential community providers, and to maintain the fabric of Medicaid services on which so many residents rely. The stakes for health care in Massachusetts have never been higher. The success of the reform effort rests on the federal government’s approval of the waiver renewal. These negotiations will undoubtedly be tough. We suggest that the outcome of these negotiations, which could have a devastating impact on the advances that have been supported by Medicaid, are a more appropriate focus for concerned policy-makers than is growth in Medicaid costs.

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# Policymaker Profile: Daniel Bosley, Massachusetts State Representative (D-North Adams)

Interviewed by Melissa J. Lopes, Esq.

Inspired by his grandfather, who developed a great love for this country, its history, and system of laws while studying to become a naturalized citizen, Massachusetts State Representative Daniel Bosley entered public service and has remained for over 22 years. Proving the maxim that “all politics is local,” the condition of a neighborhood bus shelter prompted Bosley’s entree into the public arena. While out with friends one rainy evening, he commented on the fact that a local bus stop was without a bus shelter to shield passengers from the rain. To address this and other issues affecting local citizens, he ran for city councilor of North Adams. After three years in that role, Bosley ran for state representative, where he has remained to the present.

Representative Bosley serves as House Chair of the Economic Development and Emerging Technologies Committee. Throughout his years of service, Representative Bosley has co-authored bills on stem cell research, electric deregulation, and unemployment insurance and has authored five economic stimulus bills, including the 10-year, \$1 billion Life Sciences Bill recently signed into law by Governor Patrick. This historic economic stimulus package focuses on the fertile life sciences industry in Massachusetts. Core provisions include \$500 million for new research facilities and labs, \$250 million for research grants, and \$250 million in tax credits to private companies involved in the life sciences industry. Representative Bosley suggests this stimulus package will create a significant amount of job growth and economic development

within Massachusetts and will secure Massachusetts’ place as a global leader in life sciences.

Representative Bosley holds a B.A. (cum laude) from North Adams State College and M.S. in Public Affairs from the University of Massachusetts Boston.

**In 2006, you had the opportunity to take on a new role in public service, as a cabinet member in the Patrick Administration. Why did you decide to remain in the House? Have you received other opportunities to take on different public service roles?**

I was an early supporter of Deval Patrick and was offered the job as economic advisor/coordinator of his economic cabinet. I eventually declined the role, as I determined that I could play a more effective role in formulating policy from my position within the Legislature. Throughout my career, I have been very fortunate to be involved in activities within and beyond the day-to-day issues of my district and state. Trade policy is an area that I am highly interested in, and I received the opportunity to chair a multi-state task force on international trade. Additionally, in 2003, I became national chairman of the Council of State Governments, which deals with all branches of state government. My co-chairman at the time was Mike Huckabee. In this role, I received the opportunity to travel around the country and discuss legislation, common issues, and potential collaborations. Currently, I am a member of the advisory board to the U.S. Trade Representative.

**You recently started a blog. Why did you initiate that, and how has blogging changed the way you approach your work?**

I started blogging about three months ago. When I first started here, it was all newspapers and radio. The way we communicate with our constituents/citizens of Massachusetts has changed dramatically. I originally began posting on a couple of other blogs, then I decided to start my own. It is important for people to understand the thought process behind the things we do as it impacts their lives. I find that blogging is an excellent way of communicating and getting feedback from some of the constituents and also informing constituents of some of the work going on in the Legislature.

**During your career, you have authored a number of economic stimulus plans. How does the \$1 billion Life Sciences Bill compare?**

This is the largest. From that perspective, it is different. I have authored five or six strictly economic development bills and bills that have otherwise helped the economy. This is the first and only one focused on one industry sector. Normally, we try to take a broader approach, trying to help all businesses. Our job base is changing in Massachusetts, and the life sciences industry holds the promise of new jobs and expanded economic growth.

The life sciences industry sector is very unusual for a number of reasons. First, it seems to be growing during what is a recessionary time for most other businesses. Second, it doesn’t

perform like other businesses. If you manufacture widgets, you purchase a machine and within days, you're producing widgets. With life sciences, you approach investors, borrow money, and spend your money down within a five-, ten-, or fifteen-year period before your product comes to fruition. All the money is spent and research is done in the early stages as opposed to the conventional manufacturing-type business. It is important for us to ensure that life sciences businesses survive those formative years so that developments toward treatments and cures might be realized. Many life sciences businesses cannot shoulder the financial burden beyond the pre-proof-of-concept development stage. In essence, they have a concept, and need to prove that the concept is promising, which takes time and money. The Life Sciences Bill seeks to assist life sciences businesses pre-proof of concept and beyond to ensure that potential treatments and cures reach fruition.

**You were involved in the drafting of the Biotechnology Bill authorizing stem cell research, which became law in 2005. How does the \$1 billion Life Sciences Bill intersect with the former bill? Within the sphere of permissible research modalities, will limitations be placed on the types of research eligible for State funds?**

Both bills deal with diseases that previously were thought to be incurable. Therapies are possible today that ten years ago one would have ascribed to faith or science fiction. It is amazing work. The Life Sciences Bill provides the wherewithal to utilize some of the research modalities already authorized by the Biotechnology Bill. However, where the Biotechnology Bill is largely focused on stem cell research, the scope of the Life Sciences Bill is much broader. The life sciences industry sector is composed of four separate but equal industry groups, including: (1) agriculture, (2) medical

devices, (3) research institutions, and (4) broad pharma. Life sciences companies are trying to treat people with pharmaceuticals but also trying to determine the promise of stem cell therapeutics.

We are looking to give researchers more tools to utilize embryonic stem cells. We may go back and enhance some of the provisions of the stem cell bill. For example, the bill doesn't directly address informed consent issues related to abandoned embryos.<sup>1</sup>

Additionally, researchers will be able to collaborate across state and international borders. We also want to develop language addressing the legal intricacies of this industry. If the University of Massachusetts helps to develop a new cure for a particular ailment in collaboration with another entity, who owns the resultant intellectual property? In essence, how can government fund research at our public universities, so that it does not simply inure to the benefit of private companies? How can the gains from such government-funded research benefit future research? These are the questions with which we are grappling. The Life Sciences Bill does not resolve all these issues, but does provide pathways to the resolution.

**What are the goals of the Life Sciences Bill? How do you see it impacting the economic climate in Massachusetts?**

Prospective cures in and of themselves will be worth the money—to say that this bill might play some part in fostering an environment that leads to cures for juvenile diabetes or paralysis is remarkable. But this bill will also provide tremendous job growth and economic activity. The life sciences industry is an important industry sector in Massachusetts, and all the ingredients to grow this sector are here. We have tremendous research institutions; we have a healthy financial industry here

for investment opportunities; we have other technologies, such as information technology, the #2 most requested job set in life sciences, that intersect with life sciences; there is a vibrant community of lawyers who specialize in life sciences; and we have a brain trust of world-class researchers resident in our research institutions and teaching hospitals. The seeds exist here to grow our life sciences sector, which in turn will create a gravitational pull where others feel they need to be here.

One of the initiatives we want to take on in the Life Sciences Bill is developing a collaborative agreement with the city of Haifa, in Israel. Israel has made a strong commitment to the biotechnology and life sciences sector. Rather than duplicating each other's work and competing against each other, we should be collaborating. And we think there are other areas where we can enter into similar collaborations.

**How does the Massachusetts Life Sciences Bill differ from state-funded research initiatives in states such as California and Connecticut?**

California is obviously the gold standard in the amount of money it is putting into research, due to the large budget available to it. Massachusetts, however, has committed more money to life sciences over the next several years than a majority of its competitor states. But it is not just the money here in Massachusetts that is important—it's creating the attraction by sustaining and strengthening the life sciences cluster. We have the largest single cluster in the United States. The cluster has its own cachet that will draw others here who wish to work in collaboration with world-class researchers and to take advantage of our myriad resources. We line up very well with other states—this is a place where people should want to be.

**Additionally, there are plans to expand the size and the role of the**

**Massachusetts Life Sciences Center pursuant to this bill. What is the current role of this agency and how will it differ under the Massachusetts Life Sciences Bill?**

The Life Sciences Center created in another economic bill passed several years ago will be the focal point for a lot of the grant programs. But, within the Life Sciences Bill, a lot of the money goes into setting up the infrastructure to attract business or to improve the businesses that are already here. We would like to expand the Life Sciences Center's role by including regional centers that report to the Life Sciences Center. This is important for two reasons. First, all life sciences developments can't be done in the Boston/Cambridge corridor, and we must take advantage of other resources and companies around the state. Second, it is also important to create a data system to data-mine from these different regions to determine what resources we do have and how best to maximize these resources.

facility storing these excess embryos may be unable to track down and contact the patient to determine how to dispose of these embryos. At such point, questions abound as to who has legal custody of the embryos and who has the authority to consent to the disposition of such embryos. These issues and whether such embryos may be donated to research may be revisited by the Legislature.

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<sup>1</sup>Under Section 12 of Chapter 111L, the Biomedical Research Advisory Council created pursuant to the statute was tasked with investigating issues of legal custody and informed consent related to pre-implantation embryos remaining after IVF treatment which have been abandoned by the persons contributing the genetic material from which the embryos were created. During IVF treatment, physicians routinely create more embryos than they implant in a woman's uterus. The "excess" or "leftover" embryos are frozen for possible later use. Generally, the IVF patient agrees to pay the storage fees for such embryos. In some instances, many years pass and the IVF patient does not use or arrange for the disposition of these embryos. The patient may also stop paying the storage fees for such embryos. Years later, the IVF



# BBA Presents Three Panels on Health Care Fraud

By Alpana Kumar, Esq.

## Introduction

Practicing law in the highly specialized area of health care fraud means keeping pace with an ever dynamic set of federal and state regulations and case law. As federal and state regulators evaluate and update their enforcement priorities, practitioners must develop their practices to meet client needs accordingly. On April 3, the Boston Bar Association's Health Law and Criminal Law Sections together sponsored a continuing legal education program on current trends in health care fraud enforcement. The program, which brought together practitioners and government regulators<sup>1</sup> in the area of health care fraud, was divided into three panels: "Trends in Health Care Fraud Enforcement," "The Government's Role in Enforcing Health Care Quality," and "Settlement Issues and Ramifications." This article sets forth the highlights of these panel discussions.

## Trends in Health Care Fraud Enforcement

The first panel provided an overview of recent trends in health care fraud and prevention and was moderated by Diana K. Lloyd, Esq., of Choate, Hall & Stewart LLP. The panelists were: Susan G. Winkler, Esq., the Chief of the Health Care Fraud Unit at the United States Attorney's Office; Joshua S. Levy, Esq., of Ropes & Gray LLP; Michael R. Manthei, Esq., of Holland & Knight LLP; Kathy B. Weinman, Esq., of Dwyer & Collora, LLP; and Christopher J. Walsh, Esq., the Chief of the Medicaid Fraud Unit at the Office of the Attorney General of Massachusetts.

Is health care fraud prosecuted overzealously in Massachusetts? Ms. Winkler says "no" and points to the fact that the U.S. Attorney's Office in the District of Massachusetts does not prevent third parties from paying for counsel for defendants in this jurisdiction. She also addressed monitoring and prosecuting quality issues and noted that the United States Attorney's Office for Massachusetts is not as good as the state enforcement agencies in the Commonwealth when it comes to these issues. This is because the Commonwealth has stricter regulations over patient care settings such as nursing facilities. The federal government's tools, on the other hand, are primarily financial, resulting in many of the federal government's fraud enforcement cases being brought by qui tam relators who seek to profit.

On the state side, the Attorney General's Medicaid Fraud Control Unit (MFCU) also has a qui tam team, but 85% of the referrals for it to investigate come directly from MassHealth. Thus, the MFCU division and its 12 investigators have not had the need to seek out cases to prosecute.

The role of counsel in fraud cases was discussed at length. This discussion was sparked by concerns that have arisen since the Department of Justice ("DOJ") filed a complaint<sup>2</sup> against Christi Sulzbach, the former Associate General Counsel and Corporate Integrity Program Director at Tenet Healthcare Corporation, alleging that she was materially involved in the filing of voluminous false claims.<sup>3</sup> Ms. Winkler noted that the

investigator's priority is to follow the evidence, and, that when people are making high-level decisions, lawyers are often involved. In investigations where officers of a corporation are asserting an "advice of counsel" defense, a full investigation into the attorney's involvement will be necessary to settle the matter.

## The Government's Role in Enforcing Health Care Quality

The second panel focused on the government's recent initiatives to increase the quality of care delivered by imposing and enforcing civil and criminal liability for substandard care. This panel was moderated by Robin A. Johnson, Esq., of Johnson & Aceto, LLP. The panelists were Jeremy M. Sternberg, Esq., Assistant U.S. Attorney in the Criminal Health Care Fraud Unit in Boston, and Paul W. Shaw, Esq., of Brown Rudnick Berlack Israels LLP.

As health care quality emerges as an enforcement priority for government agencies, Mr. Sternberg noted that he is seeing at least three different types of cases being prosecuted. First, there are the traditional upcoding cases, where services are actually provided to a patient, but are overstated on the bill to Medicare. The question in prosecuting this type of fraud is whether to give credit for the care actually given, or to invalidate the entire claim. The second type of offense Steinberg cited was billing for services that are not provided at all. Situations like this also can lead to quality-of-care problems when, for example, a physician omits a visit with a patient because it appears from the patient's chart



that an examination was recently completed. The third common type of fraud is the billing of Medicare by unlicensed providers, Steinberg said. The Federal Sentencing Guidelines dictate that no payment whatsoever should be had for unlicensed services.

Mr. Shaw pointed out that one of the greatest enforcement tools for quality-of-care issues on the state level is Mass. Gen. Laws ch. 265 § 13K, which makes it a crime for any caretaker of an elderly person to “wantonly or recklessly” abuse, neglect, mistreat or cause serious bodily injury to an elderly person or a person with a disability. There is currently a case pending in Middlesex County, charging Life Care Centers of America, Inc. with manslaughter based on the death of an inpatient due to alleged wanton and reckless conduct. A Medicaid false claims charge is also pending in that case.<sup>4</sup>

### Settlement Issues and Ramifications

The third panel described the process of negotiating a settlement agreement with enforcement authorities. Post-settlement issues and other government enforcement tools were also discussed. This panel was moderated by Clarence H. Brown, Esq., of Kirkpatrick & Lockhart Preston Gates Ellis LLP. The panelists were: John W. O’Brien, Esq., Senior Counsel in the Office of Counsel to the Inspector General (“OIG”) at the United States Department of Health and Human Services; Mary Elizabeth Carmody, Esq., Assistant U.S. Attorney in the Criminal Division of the U.S. Attorney’s Office for the District of Massachusetts; and Melissa B. Tearney, Esq., of Nixon Peabody LLP. Both Ms. Carmody and Ms. Tearney were involved on opposite sides of the 2005 Sero Laboratories settlement<sup>5</sup>, which resulted in a

\$704 million recovery for the United States Government.

Ms. Carmody began by explaining the process of complex fraud resolution with the Criminal Division of the U.S. Attorney’s Office. First, a company will receive a draft “global settlement agreement,” laying out the specific allegations of misconduct. The purpose of the agreement is to resolve all civil, administrative, and, if applicable, any criminal charges. Negotiations then ensue between the company and the U.S. Attorney’s Office. The government begins to draft the “charging document,” containing the allegations that the company is going to agree to admit in some fashion. The company will often settle first and then the investigators will look into the actions of any individual parties involved in the matter.

The OIG’s mission, according to Mr. O’Brien, is to “protect the financial integrity of the Medicare and Medicaid programs and to protect the beneficiaries of those programs.” One of the OIG’s enforcement tools is the exclusion of providers from participation in federal health care programs. In cases of Medicare and Medicaid fraud, the Centers for Medicare and Medicaid Services (“CMS”) is the OIG’s client. Thus CMS weighs in on settlement amounts and exclusions.

From a defense perspective, Ms. Tearney pointed out that one of the largest considerations in what a company should admit is the effect on its public perception. Other key defense considerations are whether or not there are assurances that its individuals will be protected and that there are no additional civil or criminal investigations being conducted.

A potential defendant may try to

secure a deferred prosecution agreement in lieu of formal charges. In such an agreement, the government sets forth its charges but allows a company a certain amount of time to come into compliance. If compliance is achieved, the crimes are not prosecuted. This process is often supervised by a federally appointed monitor, the cost of which is borne by the company. There have not yet been any corporate monitors appointed in Massachusetts, but Ms. Tearney noted that where such arrangements have been entered into, a defense practitioner should be wary of privilege concerns as the sharing of information between the monitor and the DOJ, OIG, and possibly other agencies, is required. The DOJ has recently issued guidance on the selection of monitors and the scope of the monitor’s responsibilities.<sup>6</sup>

### Conclusion

The program, which was well-attended, provided an interesting overview of current trends in health care fraud enforcement. Furthermore, the program’s three panels provided attendees with a wide-range of perspectives on health care fraud and enforcement issues.

### Endnotes

<sup>4</sup>Each government representative at the program provided their own views and comments, which are not to be construed as those of their respective employers.

<sup>2</sup>Case No. 07-61329 in the Southern District of Florida, filed September 18, 2007.

<sup>3</sup>DOJ has alleged that annual certifications submitted by Sulzbach in 1997 and 1998 pursuant to Tenet’s Corporate Integrity Agreement (“CIA”), stating that Tenet was in compliance with federal law, were knowingly false and allowed Tenet to bill Medicare for millions of dollars that it would otherwise not have been entitled to under the Stark law. DOJ has estimated

that the alleged false certifications led to 70,000 false claims, totaling \$18 million.

<sup>4</sup>See docket for *Commonwealth v. Life Care Centers of America, Inc.*, Commonwealth of Massachusetts, Middlesex Superior Court docket MICR 2007-00770, filed June 15, 2007.

<sup>5</sup>See, Department of Justice Press Release, “Serono To Pay \$704 Million for the Illegal Marketing of AIDS Drug.” October 17, 2005. Available at: [http://www.justice.gov/opa/pr/2005/October/05\\_civ\\_545.html](http://www.justice.gov/opa/pr/2005/October/05_civ_545.html).

<sup>6</sup>See [http://www.usdoj.gov/usao/eousa/foia\\_reading\\_room/usam/title9/crm00163.htm](http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/crm00163.htm).

## Local Health Law Briefs

### **Committee for Health Care for Massachusetts & Others v. Secretary of the Commonwealth, 450 Mass. 775, 881 N.E.2d 1137 (March 10, 2008)**

In this case, the Massachusetts Supreme Judicial Court (the “SJC”) addressed the question of whether or not the judicial branch could require the Legislature to vote on a proposed constitutional amendment. In 2003, the Committee for Health Care for Massachusetts, a small group of Massachusetts taxpayers, proposed an amendment to the Constitution of the Commonwealth of Massachusetts that would require the enactment of laws making health insurance coverage available to all Massachusetts residents (the “Health Care Amendment”). If passed, the Health Care Amendment would require the Legislature and state executive officials “to enact and implement such laws, subject to approval by the voters at a statewide election, as will ensure that no Massachusetts resident lacks comprehensive, affordable and equitably financed health insurance coverage for all medically necessary preventive, acute and chronic health

care and mental health care services, prescription drugs and devices.”

The Health Care Amendment, as with all initiative amendments under Article 48 of the Massachusetts Constitution, must undergo several rounds of popular and legislative approval before it can be submitted to the citizens of Massachusetts for an up-or-down vote. First, the Attorney General must certify that initiative amendment has (i) obtained signatures in favor of the initiative from at least 3% of the entire vote cast for Governor in the prior election, and (ii) obtained at least 50 votes at two consecutive biennial joint sessions of the Legislature in favor of placing the proposed amendment to a popular vote.

The Committee for Health Care for Massachusetts received certification from the Attorney General that it had obtained the requisite signatures, and the Health Care Amendment received the affirmative votes necessary from the Legislature at the 2003-2004 joint legislative session. The joint legislative session reconvened on July 12, 2006 where it was voted 118 to 76 to refer the Health Care Amendment to the Joint Committee on Health Care Financing, and the Committee for Health Care for Massachusetts reported that no further action was taken on the Amendment while it was in committee. The Amendment needed to be discharged from committee in order for it to be voted upon in the joint legislative session. On January 2, 2007, the last day of the 2005-2006 joint legislative session, a motion to release the Health Care Amendment from the Joint Committee on Health Care Financing was defeated 101-92. The Legislature then adjourned the 2005-2006 joint legislative session without taking the yea-or-nay vote required by Article 48 of the Massachusetts Constitution. The Committee for Health Care for Massachusetts

then sued the Secretary of the Commonwealth, seeking a judicial remedy for the failure of the joint session of the Legislature to vote on the amendment prior to adjourning on January 2, 2007.

Relying on prior Massachusetts precedent, the SJC found that even though the Legislature has a constitutional duty to vote on initiative amendments, only the Governor – and not the Judicial Branch – could require the Legislature to take a vote. Justice Robert Cordy, writing for the unanimous Court stated: “We have stated previously that ‘[t]he members of the joint session have a constitutional duty to vote, by the yeas and nays, on the merits of all pending initiative amendments’ before recessing. We also have repeatedly stated that ‘there is no presently articulated judicial remedy for the Legislature’s indifference to, or defiance of, its constitutional duties’ under art. 48.” 450 Mass. at 777 (internal citations omitted).

The SJC held that “the only remedy provided in the Constitution for the failure of a joint session to act on an initiative amendment lies in the hands of the Governor,” *id.* at 778, and that if the SJC ordered the Legislature to take such a vote, it would violate the separation of powers required by the Massachusetts Constitution. Justice Cordy stated: “The relief sought by the plaintiffs, however, would address the violation of a constitutional duty (the duty to vote) by one branch of government, by means of an order of the court that both supplants the remedy specifically provided for in the Constitution and directs that another constitutional requirement be disregarded. This cannot be done consistently with the doctrine of separation of powers embodied in Art. 30 of the Massachusetts Declaration of Rights.” *Id.* at 779.

The substantive merits of the Health Care Amendment are subject to

debate, particularly in light of the passage and implementation of the Massachusetts comprehensive Health Care Reform Bill, Ch. 58 of the Acts of 2006. With that said, this case illustrates one of the many challenges proposed constitutional amendments must face, and raises the question of what role the Legislature should play in blocking citizen initiatives. In his Boston Globe column, Scott Lehigh quotes Donald Stern, an attorney supporting the Health Care Amendment campaign, who explains this importance of the case from his point of view: “The constitution provides that mechanism for voters to decide whether to amend the constitution or not. If the Legislature can simply not vote, and by that inaction deny the voters the right to have a matter placed on the ballot, they will have taken away an important right.”

**By Julia R. Hesse, Esq.**

**Chase v. Curran, 71 Mass. App. Ct. 258 (Feb. 25, 2008)**

The Massachusetts Appeals Court held that the medical malpractice statutes of repose, G. L. c. 231, § 60D, and G. L. c. 260, § 4, do not bar a mother’s and child’s claims against a treating physician and nurse for intentional falsification of their medical records. The Appeals Court, affirming the decision of a Superior Court judge, held that the plaintiffs’ causes of action for “fraudulent concealment” and “intentional misrepresentation – fraud” properly alleged that the defendants defrauded them of timely causes of action for medical malpractice. As such, these fraud claims survived the dismissal of the plaintiffs’ underlying negligence claims, which were filed after the expiration of the seven-year repose period.

In September 1995, plaintiff Sharon

Judkins gave birth to Andrew Chase by emergency Caesarian section. A complication required that Chase be resuscitated due to lack of oxygen upon delivery. On March 29, 2001, Judkins and Chase filed a medical malpractice action against the treating physician, alleging that negligence during the delivery caused Chase to suffer permanent and severe physical and mental disabilities.

During pretrial discovery in March 2004, Judkins and Chase first discovered the alleged falsification of their medical records. In June 2004, almost nine years after Chase’s birth, Judkins and Chase amended their complaint to allege that both defendants purposely failed to note in the medical record that there was a failed initial attempt to intubate Chase and that he was deprived of oxygen for several minutes. The Appeals Court characterized these fraud claims as “alleg[ing] the existence of a fiduciary relationship that gave rise to a duty on the defendants’ part to disclose adequately to the plaintiffs facts that would give rise to knowledge of a cause of action for substandard care in resuscitating [Chase].” *Id.* at 264.

The Appeals Court distinguished the plaintiffs’ fraud and negligence claims from each other by explaining that the former concerned the defendants’ alleged concealment of “the precise nature of the treatment they provided so that the plaintiffs would not have the knowledge they needed to sue them for it.” *Id.* at 265. As alleged, the fraud claims did not concern the quality of care rendered. There was no allegation, for example, that the misrepresentations caused Chase additional injury, prevented him from taking advantage of further medical treatment, or formed the basis of new treatment-related decisions. Therefore, in comparison to the medical malpractice claims, the fraud claims were held to be “separate,

otherwise valid, causes of action directly addressing [the] alleged fraudulent behavior” that permitted the defendants to invoke the protection of the statutes of repose in the first instance. *Id.* at 268. The question of whether the two causes of action for fraud were duplicative was left to the trial judge.

The court emphasized that the difference between the surviving fraud claims and the untimely medical malpractice claims, “although subtle, is real and is not simply an exercise in re-labeling.” *Id.* at 265. In order to succeed on the fraud claims, Judkins and Chase would have to establish “that the defendants made false representations of material facts . . . with knowledge of their falsity, for the purpose of inducing the plaintiffs to act thereon, and that the plaintiffs relied upon the representations as true and acted upon them to their detriment.” *Id.* at 263. Upon such a showing, Judkins and Chase could recover for the pecuniary loss associated with the missed opportunity to file a timely malpractice action. “Strictly speaking, those damages are not compensation for a personal injury incurred because of substandard medical care.” *Id.* at 264. The court suggested that the quality of care rendered would be irrelevant unless and until there is proof of fraud. At that point, however, “evidence on the merits of the malpractice claim becomes, in effect, evidence on the issue of damages for fraud.” *Id.* at 265.

The court also distinguished the fraud claims from medical malpractice actions premised upon inaccurate record-keeping or retrieval. Judkins and Chase had alleged that the falsification of their medical records wrongfully concealed a cause of action, not that it contributed to the delivery of poor-quality health care. Thus, whether the defendants breached the applicable standard of care was not central to their liability

on any such fraud-based claim. No assessment of policies or procedures regarding appropriate record-keeping was required to determine whether the defendants' actions were fraudulent.

Finally, the Appeals Court used this opinion as a vehicle to announce that subsequent unpublished Appeals Court decisions, issued pursuant to Appeals Court Rule 1:28, may be cited for their persuasive value, although not as binding precedent. The court's former policy of prohibiting citation to unpublished decisions still applies as to those decisions that were issued prior to this opinion.

**By Justin L. DiBiasio, Esq.**

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**Shaw v. Secretary of the Executive Office of Health & Human Servs., 71 Mass. App. Ct. 218 (Feb. 19, 2008)**

The Massachusetts Appeals Court held that a MassHealth hearing officer could not terminate a plaintiff's claim for authorization of a medically necessary surgical procedure as a retroactive request when the surgery was performed pending the appeal of MassHealth's initial refusal to authorize the surgery. In May 2004, the physicians of plaintiff-minor child Ashley Shaw requested from MassHealth authorization to perform the surgery at issue, which MassHealth had determined to be medically necessary. MassHealth denied that request by letter, stating that the procedure was not covered. Shaw appealed that decision but proceeded with the surgery despite the absence of MassHealth's prior approval. Without making a determination as to medical necessity, the hearing officer who heard the appeal denied Shaw's claim on the ground that she had already undergone the procedure. Shaw sought review in Superior Court pursuant to G. L. c. 30A, § 14, where

a judge affirmed the hearing officer's denial.

In vacating the Superior Court judge's decision, the Appeals Court held that the hearing officer erred by terminating Shaw's claim "because the procedure occurred without prior authorization and hence in his view the claim was properly denied." *Id.* at 221. The surgery, which MassHealth identified as liposuction, was for removal of an abnormal fat deposit that developed as a side effect of Shaw's HIV/AIDS medications. Shaw's physicians had determined that the treatment was medically necessary to address her disfigurement, pain, headaches, and insomnia. The court held that there was "no timely and reasonable alternative available" to Shaw after MassHealth's initial denial of authorization other than proceeding with the surgery. *Id.* The court explained that Shaw was not required to wait to receive authorization until after the completion of the appeals process, which had taken over three and one half years, in order to avoid termination of her claim.

The Appeals Court highlighted the importance of medical necessity in its analysis. This consideration was derived from 130 Code Mass. Regs. § 433.408(A)(1) & (2) (2006), which provides that MassHealth's prior approval is a prerequisite for the payment of certain medical services, and that prior authorization determines the medical necessity of such services. Interpreting the plain language of this section as a whole, the court held that the medical necessity of a request is the "controlling prerequisite" for MassHealth's prior authorization for payment of such services. *Id.* at 222.

Although the court acknowledged the deference due to an agency's interpretation of its own regulations, it expressly rejected the hearing officer's view that Shaw's claim could be

terminated, without a determination of whether the procedure was medically necessary, because it was performed without authorization while her appeal was pending. The court held that this would be inharmonious with the regulation's "principal purpose" and as a result improperly "treat prior authorization as overriding all other considerations." *Id.* at 221-222. Therefore, a subsequent finding that Shaw's surgery was medically necessary would have allowed her to meet the regulation's "overarching" medical necessity requirement, even though such an authorization technically would not have been made prior to the rendition of care. *Id.* at 222. Accordingly, the court remanded the matter to MassHealth to conduct a review of whether the procedure was medically necessary.

**By Justin L. DiBiasio, Esq.**

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# Editors

## Catherine L. Annas, Esq.

Catherine L. Annas is the Director of the Eastern Massachusetts Healthcare 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.

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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. She teaches a stem cell research law and policy course at Boalt Hall, has been an advisor to the Interstate Alliance on Stem Cell Research since its inception in 2007, and recently was an invited speaker presenting on U.S. stem cell law and policy at the European Commission's launch of its new stem cell registry (hESCreg) in Berlin. Ms. Stayn previously worked for many years in the Office of the General Counsel of Partners HealthCare System, Inc. She serves on the BBA Health Law Steering Committee, co-chairs its Communications Committee, and was selected as a BBA Public Interest Leader in 2004-05. Prior to joining Partners, she 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. Ms. Stayn is a graduate of Harvard College and Columbia Law School, where she was editor-in-chief of the Columbia Law Review.



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Jarrett Tomás Barrios serves as the President of the Blue Cross Blue Shield of Massachusetts Foundation.

A graduate of Harvard College ('90-'91) and Georgetown University Law Center ('95), Mr. Barrios worked for the Boston City Council, the Lawyers' Committee for Civil Rights Under Law, the Federal Trade Commission's Bureau of Consumer Protection and the law firms of Hill & Barlow and DLA Piper. In 1998 he was elected to the Massachusetts House of Representatives and then to the State Senate in 2002 where he was the Senate Chair of the Joint Committee on Public Safety and Homeland Security.

"An open hand holds little water," says Mr. Barrios. "Philanthropy is the joining of many open hands, together capable of holding an ocean." His past work on health and wellness, as well as for other forms of individual empowerment—against violence, for education, for consumer protection to name a few—inform his current work. He speaks English and Spanish, and is proficient in Portuguese.

## Barbara E. Bierer, M.D.

Barbara E. Bierer, M.D. is Senior Vice President for Research at the Brigham and Women's Hospital and Professor of Medicine at Harvard Medical School. Dr. Bierer, a graduate of Harvard Medical School, completed her internal medicine residency at the Massachusetts General Hospital and her hematology and medical oncology training at the Brigham and Women's Hospital and the Dana-Farber Cancer Institute. Dr. Bierer maintained a research laboratory in the Department of Pediatric Oncology

at Dana-Farber Cancer Institute and was appointed Director of Pediatric Stem Cell Transplantation at Dana-Farber Cancer Institute and Children's Hospital in 1993. In 1997, she was named Chief of the Laboratory of Lymphocyte Biology at the National Heart, Lung and Blood Institute at the National Institutes of Health in Bethesda, MD. She served on the Scholars Committee of the Howard Hughes Medical Institute and on the Admissions Committee of the Biomedical Research Training Program for Underrepresented Minorities at NHLBI, where she received the Director's Award in 1999. She returned to the Dana-Farber Cancer Institute in July 2002, as Vice President of Patient Safety and Director of the Center for Patient Safety. In 2003, Dr. Bierer moved to the Brigham and Women's Hospital to assume her current position. In addition, in 2006, Dr. Bierer established the Center for Faculty Development and Diversity at the Brigham and Women's Hospital and now serves as its first director.

Dr. Bierer's laboratory research interests include mechanisms of T cell activation and of immunosuppression, interests that complement her clinical commitment to hematology. In addition to her academic responsibilities, Dr. Bierer was elected to the Board of Directors of the Association for Accreditation of Human Research Protection Programs (AAHRPP), serving as its President from 2003-2007 and was on the Board of Directors of the Federation of American Societies for Experimental Biology (FASEB). She was a member of the Medical and Scientific Advisory Board and, later, the Board of Directors of ViaCell, Inc. She is on the editorial boards of a number of journals including Current Protocols of Immunology, Journal of Immunology, and Blood. She is currently a member of the

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Justin L. DiBiasio is completing a clerkship at the Massachusetts Appeals Court. He currently serves as law clerk to Justice Francis R. Fecteau, and previously was a law clerk to former Chief Justice Christopher J. Armstrong. Mr. DiBiasio has also served as a law clerk to the Justices of the Superior Court of Massachusetts, where he clerked for retired Justice Allan van Gestel in the Business Litigation Session. Mr. DiBiasio received his J.D., cum laude, from Boston College Law School in 2006. As a law student, Mr. DiBiasio wrote for a commercial law journal, performed externships at two Boston area hospitals, and performed internships at the Disability Law Center and the Office of the General Counsel of the U.S. Department of Education. In 2003, Mr. DiBiasio earned his B.A. in English and Psychology, summa cum laude, from the University of Rhode Island. This fall, Mr. DiBiasio will join Foley & Lardner LLP as an associate and member of the firm's Health Care Industry Team. He is licensed to practice law in Massachusetts and Rhode Island.

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Robert E. Driscoll, Jr. is an associate at The Rogers Law Firm. He is a member of the firm's corporate and health care practice groups. He advises health care providers with regard to corporate compliance, fraud and abuse issues, HIPAA compliance, patient care

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Julia R. Hesse is an associate in the Health Care practice group of Ropes & Gray, LLP. Ms. Hesse's practice focuses on representation of academic medical centers and institutional providers in a full range of health care-related regulatory issues and other business and transactional matters. Ms. Hesse also represents research institutions and industry sponsors on human subjects research issues. She is a graduate of Williams College and the University of Pennsylvania, where she received degrees in both law and bioethics.

### **Alpana Kumar, Esq.**

Alpana Kumar is an associate with Foley & Lardner and a member of the firm's Health Care Industry Team. Ms. Kumar's practice focuses on the representation of individual and institutional health care providers with regard to regulatory, compliance, and general business matters. Prior to joining Foley & Lardner, Ms. Kumar worked in the health care industry as a regulatory and legal specialist at a start-up managed care company specializing in the coordination of care for seniors who are both Medicare and Medicaid eligible. She also worked as a volunteer attorney for Health Law Advocates; providing low-income clients with pro-bono assistance in matters relating to health insurance coverage. Ms. Kumar earned her

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### **Melissa 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 body art 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.

### **Anya Rader Wallack, Ph.D.**

Anya Rader Wallack is the Executive Director of the Massachusetts Medicaid Policy Institute (MMPI). MMPI is an independent and nonpartisan source for information about the Massachusetts Medicaid program. MMPI seeks to facilitate and enhance

the development of effective Medicaid policy approaches and solutions. It conducts and commissions research and distributes information about the Massachusetts Medicaid program, highlighting the program's successes and helping to identify the challenges ahead. MMPI collaborates with a broad spectrum of policy makers, researchers, providers, advocacy groups, consumer organizations, businesses and other stakeholders to create a more effective state Medicaid program.

Prior to joining MMPI, Anya was a policy consultant to the Office of the Rhode Island Health Insurance Commissioner (OHIC), where she was responsible for development of conceptual models for expanding affordable health insurance coverage in Rhode Island and for related research and technical support, as well as advising on longer-term policies and political strategies. Anya also has consulted with a variety of private non-profit organizations and state government clients on health policy-related projects. Clients have included the Vermont Program for Quality in Health Care, the National Academy for State Health Policy and the Vermont Department of Aging and Disabilities.

From 1995-1998, Anya was the Executive Director of the Vermont Program for Quality in Health Care, Inc., a quasi-governmental agency that works with state government, health care practitioners, consumers and insurers to measure and improve the quality of Vermont's health care system. She worked from 1991-1994 as Deputy Chief of Staff and Special Assistant for Health Policy for Governor Howard Dean of Vermont, including representing Governor Dean on the task force that developed President Clinton's health care reform proposal.

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