
CLIENT NEWSLETTER

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SJC Expands Physician Liability

On December 10, 2007, the Massachusetts Supreme Judicial Court (“SJC”) issued an opinion which expands the potential liability for physicians in Massachusetts to “everyone foreseeably put at risk” by a physician’s failure to warn of the side effects of his/her treatment of a patient. The decision, which was issued in the matter of *Lyn Ann Coombes v. Ronald J. Florio* (SJC-09869), does not expand the obligations of physicians, but it does increase their potential liability exposure as a result of the increased number of potential Plaintiffs.

The Plaintiff in *Coombes* is the mother of Kevin Coombes, a 10 year old boy who was struck and killed by an automobile driven by David Sacca. At the time of the accident in March of 2002, Mr. Sacca was under the care of the Defendant-physician, Ronald Florio. Mr. Sacca was seventy-five years old and had been diagnosed with a number of serious medical conditions, including asbestosis, chronic bronchitis, emphysema, high blood pressure and metastatic lung cancer that had spread to his lymph nodes. As Mr. Sacca’s primary care physician, Dr. Florio coordinated the multiple specialists who were involved in Mr. Sacca’s care and was also responsible for all of the prescriptions that Mr. Sacca used.

At the time of the accident, Mr. Sacca had prescriptions from Dr. Florio for Oxycodone, Zarahoxlyn, Prednisone, Flomax, Potassium, Paxil, Oxazepan and Furosemide. The potential

side-effects of these prescription medications include: drowsiness, dizziness, light-headedness, fainting, altered consciousness and sedation. The Plaintiff's expert testified that when used in combination these drugs have the potential to cause "additive side-effects" that could be more severe than side-effects resulting from the separate use of these medications. The Plaintiff's expert testified that the sedating effects of these drugs can be more severe in older patients and that the standard of care for a primary care physician includes warning elderly or chronically ill patients about the potential side effects of these drugs and their effect on a patient's ability to drive. The Plaintiff's expert also testified that the accident was probably caused by a combination of Mr. Sacca's medical conditions and the medications he was taking. Mr. Sacca was not warned by Dr. Florio of any potential side-effects of the medications prior to the accident.

The Plaintiff brought suit against Dr. Florio for negligently prescribing medication without warning Mr. Sacca of the dangers posed by its side-effects and without warning Mr. Sacca not to drive. A Superior Court judge granted Summary Judgment for Dr. Florio, ruling that there was no special relationship between Dr. Florio and Kevin Coombes, and that Dr. Florio owed Kevin Coombes no duty under the law. The Plaintiff appealed the Superior Court decision and the SJC took the matter on its own Motion.

In a split decision, the SJC ruled that a physician does indeed owe a duty of reasonable care to everyone foreseeably put at risk by the physician's failure to warn of the side-effects of his treatment of a patient. Specifically, the Court held that "when a doctor prescribes medication it is both a foreseeable and intended result that a patient will take the medication. The occurrence of known side-effects, and the impact of such side-effects on the patient's ability to drive, are foreseeable results of that prescription." The SJC held that sound public policy favors a duty in these circumstances. Furthermore, the SJC noted that the duty described does not impose a heavy burden on the physician because it requires nothing more than is already required by the physician's duty to his patient. In particular, the Court referenced the fact that in the context of medical professionals, a physician's duty of reasonable care, owed to a patient, includes the duty to provide appropriate warnings about side-effects when providing drugs. *Kottam v. CVS Pharmacy*, 436 Mass. 316 (2002).

Dr. Florio argued to the SJC that expanding the physician's duty of reasonable care to everyone foreseeably put at risk by a physician's failure to warn of the side-effects of treatment of a patient, will increase the number of potential Plaintiffs, which will in turn create a fear of litigation that would intrude into a physician's very decision of what medication to prescribe or what treatment to pursue. The SJC responded to this argument by stating that "allowing a larger number of potential Plaintiffs may result in some increase in litigation, and that may in turn result in an increase in medical malpractice rates. However, I would leave to the Legislature the task of determining whether to impose further limits on doctors' liability."

As previously stated, this decision by the SJC does not increase the obligations of a physician. The decision does, however, expand the potential Plaintiffs who could bring a medical malpractice case against a physician. It is our recommendation that: (1) a physician inform his/her patient of any potential side-effects from the medication which

he/she has prescribed the patient and which side-effects are relevant for the patient to know in making an informed decision, including operating an automobile or machinery; and (2) the physician should document in the patient's medical record that he/she prescribed to the patient the potential side-effects of the medication.

If you have any specific questions regarding a physician's duty to warn in Massachusetts, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Massachusetts Legislature Receives "Doctor Gratuity Reporting" Bill

A bill was recently filed with the Massachusetts Legislature which would mandate that physicians disclose to the Board of Registration in Medicine the gifts they receive from pharmaceutical companies and medical device manufacturers. The bill, which is entitled "An Act Requiring Doctor Gratuity Reporting" (the "Bill") amends Section 2 of Chapter 112 of the Massachusetts General Laws by adding the following paragraph:

The Board (of Registration in Medicine) shall require as a condition of granting or renewing a physician's certificate of registration, that the physician disclose in writing each gift, benefit, gratuity, blandishment or incentive of any kind received from any agent or manufacturer of drugs, pharmaceuticals or other medications, or from any agent or manufacturer of any medical device, treatment or service the physician has or could provide to patients under his care. For each gift, gratuity, blandishment or incentive, the disclosure shall include a description, the estimated cash value and the name and company of the donor.

Once the information is disclosed to the Board of Registration in Medicine, it will become available to the public. The proponents of the Bill state that its purpose is to allow the public to see the potential conflicts of interest doctors have with pharmaceutical companies and medical device manufacturers and to hopefully lead to physicians not accepting gifts which could influence their prescribing practices. The proponents of the Bill also point out that similar disclosure laws in Minnesota and Vermont have proven to be effective in exposing the harmful side-effects caused by hidden financial ties between doctors and pharmaceutical companies and medical device manufacturers.

The Rogers Law Firm will continue to monitor the Bill and will provide updates accordingly.

CMS Proposes Additional E-Prescribing Standards

On November 16, 2007, the Centers for Medicare and Medicaid Services (“CMS”) issued a proposed rule to adopt final uniform standards for electronic prescribing (“e-prescribing”) (the “Rule”). According to the U.S. Department of Health and Human Services (“HHS”), the adoption of the Rule would permit prescribers to electronically transmit accurate prescriptions and medical histories to pharmacies and would enhance efficiency and reduce chances for potentially harmful drug interactions due to prescription errors. Furthermore, the Rule advances HHS’ broader goals of creating a safer, cheaper and more convenient prescription drug delivery system.

The Medicare Modernization Act of 2003 (“MMA”), which created Medicare Part B—the prescription drug benefit, requires protections for e-prescribing technology. In January of 2006, CMS adopted certain e-prescribing standards (known as the “foundation standards”). At the same time, CMS entered into a pilot test project to evaluate additional e-prescribing standards. These additional e-prescribing standards have now been completely tested as part of the pilot project and CMS is ready to adopt these standards as part of the Rule. The proposed additional standards include the following:

- Retirement of National Council for Prescription Drug Programs (“NCPDP”) SCRIPT 5.0 and adoption of NCPDP SCRIPT 8.1;
- Adoption of the NCPDP SCRIPT 8.1 for electronic medication history transactions among the plan sponsor, prescriber, and the dispenser when e-prescribing for covered Medicare Part D drugs for Medicare Part D eligible individuals;
- Adoption of the NCPDP Formulary and Benefit Standard 1.0 for the transaction of communicating formulary and benefit information between the prescriber and the plan sponsor when e-prescribing for covered Medicare Part D drugs for Medicare Part D eligible individuals; and
- Adoption of the National Provider Identifier (“NPI”) as a standard for use in e-prescribing transactions among the plan sponsor, prescriber and the dispenser.

CMS is accepting public comments on the Rule up until January 15, 2008. Pursuant to the MMA, HHS has until April 1, 2008, to issue the final uniform standards for e-prescribing. Once issued, the final uniform standards will become effective within one year.

A complete copy of the Rule can be found in Volume 72 (No. 221) of the *Federal Register*. The Rogers Law Firm will continue to monitor the Rule and will provide updates accordingly.

IRS Announces Whistleblower Procedure for Tax Law Violations

On December 19, 2007, the United States Internal Revenue Service (“IRS”) issued IRS Notice 2008-4 (the “Notice”) outlining how individuals, or “whistleblowers”, can report tax law violations to the IRS and potentially recover a significant award. The IRS released the Notice following a recent increase in the number of whistleblowers reporting information to the IRS over the past year.

Pursuant to Section 7623(b) of the Internal Revenue Code (“IRS”), individuals who are the original source of tips to the IRS that lead to recovery of taxes from taxable or tax-exempt organizations, can receive an award of up to fifteen to thirty percent of the total recovery by the IRS (including taxes, penalties and interest recovered). The Notice states that to make a claim, whistleblowers must file with the IRS a Form 211-Application for Award for Original Information. The Form 211 asks the individual for an estimate of the tax owed, a description of the relevant facts, and an explanation of how the whistleblower obtained the information. The whistleblower is required to submit the Form 211 under a Penalties of Perjury Declaration.

The amount of an award to a whistleblower under a Form 211 is determined by the IRS’ Whistleblower Office. In order to qualify for an award, the whistleblower’s information must be “specific and credible” and his/her efforts must have substantially contributed to the collection of the tax.

As a result of the increasing transparency for not-for-profit organizations, whistleblowers have a substantial base of information from which to gather facts for a claim to the IRS under the Form 211. Furthermore, under Section 7623(b) the report of a tax law violation to the IRS is not limited to income taxes. A whistleblower could report information to the IRS that leads to the recovery of excise taxes on an excess benefit transaction involving an exempt organization.

The Notice from the IRS serves as a reminder to exempt organizations to be vigilant in their proper reporting of tax information and to be compliant with applicable IRS regulations.

Congressional Oversight Committee Examines Executive Pay and Compensation Consultants

On December 5, 2007, a Congressional Oversight Committee released a report entitled “Executive Pay: Conflicts Of Interest Among Compensation Consultants” (the “Report”) that concluded that consulting firms that advise companies on setting executive compensation have potential conflicts with those companies as a result of other services they provide to the companies. The analysis was released by the House Committee on Oversight and Government Reform.

The Report concludes that corporate consultants can have a financial conflict of interest if they provide both executive compensation advice and other services to the same company. According to experts on corporate governance, consultants hired by corporate executives to administer employee benefit plans or to provide other services to a company may not be able to provide objective advice about the compensation of the executives who hire them. These experts have recommended that corporate boards should retain a compensation consultant that performs no other services for the company.

The Report examines whether the compensation consultants hired by large publicly traded companies meet this standard of independence. The Report is based on nonpublic information provided to the Committee by the leading compensation consultants in the United States. For each consultant, the Committee requested and received data on the value of the executive compensation services and other services provided to the 250 largest publicly traded companies as determined by *Fortune* magazine.

The Report finds that compensation consultant conflicts of interest are widespread. Over 100 large publicly traded companies hired compensation consultants with substantial conflicts of interest in 2006. In many cases, the consultants who are advising on executive pay are simultaneously receiving millions of dollars from the corporate executives whose compensation they are supposed to assess.

Key findings in the Report are:

- **Compensation consultant conflicts of interest are pervasive.**

In 2006, at least 113 of the Fortune 250 companies received executive pay advice from consultants that were providing other services to the company.

- **The fees earned by compensation consultants for providing other services often far exceed those earned for advising on executive compensation.**

In 2006, the consultants providing both executive compensation advice and other services to Fortune 250 companies were paid almost 11 times more for providing other services than they were paid for providing

executive compensation advice. On average, the companies paid these consultants over \$2.3 million for other services and less than \$220,000 for executive compensation advice.

- **Some compensation consultants received over \$10 million in 2006 to provide other services.**

One Fortune 250 company paid a compensation consultant over \$11 million for other services in 2006, over 70 times more than the company paid the consultant for executive compensation services. Another Fortune 250 company also paid a compensation consultant over \$11 million for other services, over 50 times more than it paid the consultant for executive compensation advice.

The information provided to the Committee represents comprehensive information on the extent of conflicts of interest among executive compensation consultants. An analysis of this information shows that in 2006, over 100 Fortune 250 companies used compensation consultants that provided both executive compensation advice and other services to the company at the same. In many cases, the consultants hired to provide executive compensation advice were paid millions of dollars by the executives whose pay they were supposed to assess. The information provided to the Committee also shows that many of these conflicts of interest were not disclosed to the investing public in company SEC filings.

Although the Report focuses on publicly traded companies, the analysis is certainly applicable to not-for-profit corporations.

The full Report is available online at: <http://oversight.house.gov/documents/20071205100928.pdf>. If you have any specific questions regarding executive pay and compensation consultants, please do not hesitate to contact any of the attorneys at The Rogers Law Firm.

Lawmakers Introduce Bills to Encourage Physicians to Implement E-Prescribing

Legislators have introduced bills in the U.S. Senate and House of Representatives (S. 2408 and H.R. 4296) that would expedite the adoption of electronic prescribing (“e-prescribing”) technology by providing permanent Medicare funding for a one-time bonus to physicians for the initial cost of purchasing and implementing such technology. The bills are sponsored in the Senate by Senators Kerry (D-MA) and Ensign (R-NV), Stabenow (D-MI) and Martinez (R-FL), and in the House by Representatives Schwartz (D-PA) and Porter (R-NV).

As a result of prescription errors, American hospital patients have experienced 1.5 million injuries each year, according to the Institute of Medicine. According to that organization, medication errors will kill at least 7,000 Americans in 2007. Of the more than three billion prescriptions written each year, doctors report nearly one billion require a follow-up between providers and pharmacies for clarification. The health-care system costs have been calculated in the billions.

The bills would foster the adoption of e-prescribing by providing permanent Medicare funding for payment bonuses to physicians who acquire e-prescribing technology. In addition, for every Medicare prescription a doctor writes electronically, they will be paid an extra 1% bonus. Starting in 2011, Medicare physicians who are not electronically prescribing would face financial penalties. Furthermore, the bills would:

- Provide permanent Medicare funding for one-time grants to physicians to help offset the start-up costs to physicians of acquiring and implementing e-prescribing technology.
- Provide permanent Medicare funding for payment bonuses to physicians for use of e-prescribing. For every Medicare prescription that is written electronically, physicians will be paid an extra 1% bonus.
- Require physicians, starting on January 1, 2011, to write their Medicare outpatient prescriptions electronically. Physicians that continue to write prescriptions by hand will face a per-claim financial penalty.
- Give authority to the Secretary of HHS to grant one- or two-year hardship waivers for physicians who face particular difficulties in acquiring and implementing e-prescribing – especially those from rural areas or very small (or solo) practices.
- Direct the General Accounting Office and the Centers for Medicare and Medicaid Services to report within two years on the status of e-prescribing adoption within Medicare.

The Rogers Law Firm will continue to monitor the bills and will provide updates accordingly.

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