Advances in medical technology have revolutionized how health care is delivered in the United States. Innovative medical device manufacturers have contributed significantly to improved patient outcomes, their quality of life, and how physicians practice medicine. Consider how scopes moved many invasive, high-risk inpatient procedures to non-invasive, lower-risk outpatient procedures. But these innovations come at a price. Makers of traditional medical devices and combination products (sophisticated technologies combining medical devices with drugs or biologics) spend millions upon millions of dollars annually to research, develop and ultimately market these new treatment options (pharmaceutical and biotech companies are, of course, also part of this equation). Physicians and consumers alike are faced with an array of studies and promises of improved patient outcomes resulting from their use of such technologies.

The U.S. Food and Drug Administration (FDA) does not require comparative studies to determine that a medical device is safe and effective for its intended use. And the Centers for Medicare & Medicaid Services (CMS) does not require comparative studies to determine that a medical device is reasonable and medically necessary to treat Medicare patients. It should come as no surprise, therefore, that there is limited empirical evidence comparing new technologies with those on the market, or comparisons of alternative treatments, which, as will be discussed below, are not always easy to identify.

Both the government and industry have debated the concept and merits of comparative effectiveness research for more than 20 years, but have made only relatively small-scale forays into this arena. Now, with the continued rise in health care costs in the U.S., due in no small part to costly new treatment options, policy-makers are more closely examining the idea of comparative effectiveness research.
and it seems almost inevitable that a much more robust government-sponsored comparative effectiveness research and implementation regime will become a reality. Exactly what that reality may look like and when it will take shape remains an open question.

**Comparative Effectiveness – What Is It?**

The term “comparative effectiveness” itself is open to various interpretations, although most people agree that it captures a certain core concept. Comparative effectiveness represents a comparison of “the effectiveness of two or more health care services or treatments,” as it “compares outcomes resulting from different treatments or services, and provides information about the relative effectiveness of treatments.” It has also been defined as a “rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients,” or an evaluation and comparison of “the clinical effect of alternative medical treatments.”

**Why Comparative Effectiveness?**

Regardless of the exact definition of comparative effectiveness, there is relative consensus among stakeholders that providing more and better quality medical evidence concerning treatment, prevention, and management of health conditions allows patients, providers, and health insurers to make more informed decisions about medical treatments. As AdvaMed, a trade association for the medical device industry, has stated, comparative effectiveness is one “tool to improve clinical outcomes and promote access to quality care.”

Underlying and intermingled with much of the discussion of clinical comparative effectiveness is cost. Health care costs have risen dramatically and now account for approximately 16 percent of the U.S. Gross Domestic Product. The upward trend shows no signs of slowing, and policy-makers continue to grapple with how to address the issue.

Sen. Max Baucus (D-MT), a leading proponent of comparative effectiveness, has stated, “more evidence on what works and doesn’t work can lead to better health care decisions and thus to improved quality of care, improved efficiency, and ultimately to the potential for cost savings throughout the health system.” The Congressional Research Service has also concluded that using comparative effectiveness information would help to use limited resources effectively and efficiently, which will become “even more necessary as resources become more limited, variation in medical practice patterns persist, and the rate of health care spending continues to rise.” Finally, the Congressional Budget Office has speculated that “over the long term, the combination of additional information and revised incentives would tend to reduce spending for health care below currently projected levels, potentially to a substantial degree.”

The inclusion of cost-effectiveness as a component of comparative effectiveness research would likely have a larger effect on medical treatment and practice than analysis of only the comparative clinical effectiveness of various treatments, “primarily because the results would sometimes highlight that benefits were small relative to the incremental costs.”

Yet there is substantial debate about whether cost should be
included at all in any comparative effectiveness assessment, or whether the realization of cost savings from better clinical information alone is as far as any cost consideration should go.

When one considers the real budget constraints our health care system faces, it seems very reasonable to recognize and acknowledge that cost is a factor and needs to be considered. To be consistent, however, with other federal policy and law designed to eliminate cost considerations from medical decision making (e.g., Federal Anti-kickback statute and Stark Self Referral laws), then there is no place for cost effectiveness in the comparative effectiveness equation. To put it simply, if we do not want physicians’ medical judgment to be clouded or driven by financial considerations in the Anti-kickback or Stark sense, then the federal government, whether by legislation or regulation, should not be permitted to impose or influence physicians’ treatment decisions through comparative cost effectiveness considerations. Consistency, however, is not a strong suit of our federal government, and particularly CMS. Over the years, CMS has, in several instances, utilized its regulatory discretion to limit payments for new technologies to those made for existing “comparable” technologies. To challenge these decisions, one has to succeed in convincing CMS that two or more technologies are not truly “comparable.”

There remains, therefore, an uneasy tension between the dual goals of purely improving clinical outcomes and realizing cost savings from comparative effectiveness research. The goals of better clinical outcomes and cost savings may be compatible on a large scale. Applying a comparative effectiveness model that integrates cost effectiveness on a patient-by-patient basis may prove challenging. Many members of Congress place a premium on the physician-patient relationship and believe, appropriately so, that medical decisions and treatment options are very personal ones that should be made between a physician and the patient. Seemingly aware of this dynamic, the Congressional Budget Office has stated, “better information about the costs, risks, and benefits of different treatment options, combined with new incentives reflecting the information, could eventually alter the way in which medicine is practiced and yield lower health care spending without having adverse effects on health.”

However, at times the goals may be mutually exclusive. Comparative effectiveness research very well may lead to instances of cost/benefit analyses of treatments that many people are uncomfortable with, and raises numerous troubling questions. For instance, at what point does a proven incremental health benefit justify a vastly increased cost?

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In an era of fixed resources and increasingly tight domestic budgets, does that benefit justify spending those resources in such a fashion? And who makes those decisions – patients, physicians, private health insurers or the federal government?

There also exists the question of why the profile of the comparative effectiveness debate has risen to a level never seen before. The concept has been in existence for more than two decades, but only recently has there been so much focus on it. Is it a pure desire for improved clinical outcomes that is engaging policymakers, or is money the real driving force?

History of Comparative Effectiveness Debate
The history of the comparative effectiveness debate demonstrates that both Congress and industry are unwilling to accept cost-based definitions of comparative effectiveness. CMS and its predecessor agency were rebuffed in previous efforts to inject cost-effectiveness determinations into the Medicare process. Recently, the pressure to implement more comparative effectiveness research has come from Congress, which seems determined to keep cost factors out of the research itself, at the same time that it promotes comparative effectiveness research as a driver for cost savings in the national health care system.

Agency Initiatives
Debate about comparative effectiveness, or versions of it, is not new, and its history is very much intertwined with debate about the cost of health care. The Health Care Financing Administration (HCFA), the predecessor agency to CMS, was the first federal entity to highlight the issue of cost-effectiveness in health care coverage determinations. In 1989 it issued a proposed rule that outlined cost-effectiveness as a key component of the coverage process. The rule would have included cost-effectiveness as a factor in determining whether a treatment was reasonable and necessary. However, the rule was never finalized, as HCFA received so much opposition from industry in particular, that it withdrew the rule and never re-issued it.
Despite HCFA’s withdrawal of the 1989 proposed rule, in the late 1990s, a congressionally-mandated report was issued showing that HCFA used comparability to alternative services as one of three coverage criteria, demonstrating that cost was in fact a central element in its coverage and payment analyses. The report stated in part:

Comparability is an additional criterion which allows for refining coverage/payment decision in cases where services are found to be more costly, but no more effective than the closely related alternatives. When such a finding is made, the service may be covered and paid at the rate of the lower cost alternative, or limited to specific patients or conditions for which it has been found more effective than the alternative services. The objective of this criterion is to assure value for the Medicare program and its beneficiaries.

It is worth noting that this report flowed from the National Emphysema Treatment Trial or NETT, which was designed to compare lung volume reduction surgery (LVRS) to pulmonary rehabilitation. The NETT was the byproduct of HCFA’s national non-coverage decision of LVRS. The agency enlisted the National Institutes of Health (NIH) to conduct the multi-centered trial to compare LVRS to pulmonary rehabilitation. There were several questions and challenges raised about the study design. In fact, one medical center’s Institutional Review Board did not approve of the study, questioning the ethics of randomizing late-stage emphysema patients to LVRS or pulmonary rehabilitation without the opportunity for cross-over for the surgery, when a qualified LVRS candidate needed to first “max out” on pulmonary rehabilitation. This experience illustrates that defining comparable treatment options is no easy task. Even NIH decisions on this front have not gone unchallenged.

Then, in 2000, HCFA published a notice of intent to publish a proposed rule on the topic. The notice stated that such a rule would be intended to clarify the definition of “reasonable and necessary” to require that new treatments provide “added value.” Yet again, HCFA never published such a proposed rule.

Despite past indications that CMS would like to include cost considerations into coverage and payment analyses, currently, as a practical matter, Medicare will cover any treatment or procedure that has not medical benefits, i.e., “benefits that outweigh the risks of the procedure – regardless of its cost or its effectiveness relative to alternative therapies.” In fact, Medicare is “effectively precluded from taking costs into account when making decisions about coverage and would probably need new legal authority to adjust payments to providers or cost-sharing requirements for enrollees to encourage the use of more cost-effective care.”

While CMS has used comparative clinical effectiveness research on a limited basis in making certain Medicare coverage determinations, e.g., not to cover lumbar artificial disc replacement, CMS’ coverage guidance specifically states that “cost effectiveness is not a factor CMS considers in making national coverage determinations,” and that “cost is not a factor in our review or determination to cover a particular technology.” While it may be true that CMS does not factor cost considerations into coverage determinations, i.e., answering the question will it pay, it is not precluded from taking into account cost for payment determinations, i.e., answering the question how much it will pay. Establishing a relatively low payment level will produce a de facto non-coverage determination.

A medical device industry group has cautioned that any comparative effectiveness regime must take into consideration the unique role that medical technologies would have in such research and highlight the differences that exist between drugs and medical devices.

According to The Medicare Payment Advisory Commission (MedPAC), an independent Congressional agency established to advise the U.S. Congress on issues affecting the Medicare program, “there is not enough credible, empirically-based comparative effectiveness information available to patients, providers, and payers to make informed treatment decisions.” Yet this state of affairs is due in no small part to the fact that there has been very limited demand for such research from the Medicare program, which remains the single largest and most influential payor of health care services.

Congressional Initiatives

Since 2000, CMS has not made large-scale public efforts to include comparative effectiveness analyses in their coverage or payment determinations. Yet Congress has picked up the mantle, and has increasingly become a driving force for change and implementation of comparative effectiveness research. In contrast to HCFA’s efforts, however, Congress has shied away from introducing cost into any comparative effective analysis, and has dictated that CMS do the same.

As part of the 2003 Medicare Modernization Act (MMA), Congress authorized the Agency for Health Care Research and Quality (AHRQ) to spend up to $50 million in 2004, and additional amounts in future years to conduct and
support research on “outcomes, comparative clinical effectiveness, and appropriateness of health care items and services” for Medicare and Medicaid. Actual funding appropriated under that authority has averaged approximately $15 million per year. At the same time, Congress prohibited CMS from using comparative effectiveness data to withhold coverage for a prescription drug.

The Comparative Effectiveness Research Act of 2008 (S. 3408) with modifications on July 31, 2008, has served as the basis for much of the current debate over comparative effectiveness.

Congressional interest in comparative effectiveness has increased dramatically over the past several years, as Congress sees such research as a means to both identify the most effective treatments, and to reduce health care costs. For instance, in the spring of 2007, Sen. Baucus introduced a Medicare Part D price negotiation bill that would have required the Department of Health and Human Services (HHS) to develop a prioritized list of comparative effectiveness studies. In May of last year, Reps. Tom Allen (D-ME) and Jo Ann Emerson (R-MO) introduced the bipartisan Enhanced Health Care Value for All Act of 2007 (H.R. 2184), which authorizes $3 billion for comparative effectiveness research and established a public-private funding mechanism for comparative effectiveness research, to be overseen by an independent advisory board. The House-passed Children's Health and Medicare Protection (CHAMP) Act would have established a public-private funding mechanism for comparative effectiveness research funded by a trust fund and overseen by an independent commission. This provision was not included in the House and Senate-passed Children's Health Insurance Program Reauthorization Act of 2007, which the President vetoed. Also, in June of 2007, the House Ways and Means Subcommittee on Health held a hearing on comparative effectiveness. Despite all of this congressional activity, there was no definitive movement on comparative effectiveness research in 2007.

Baucus has continued to push hard to establish a comparative effectiveness regime. He introduced legislation early in the spring of 2008 that would do so, although he very quickly withdrew the bill because of jurisdictional problems. Following a July 17, 2008 Senate Finance Committee hearing, Baucus re-introduced The Comparative Effectiveness Research Act of 2008 (S. 3408) with modifications on July 31, 2008. This legislation has served as a basis for much of the current debate over comparative effectiveness.

According to the Senator, the legislation “would create a new entity responsible for generating better information on the effectiveness of health care treatments.” The Health Care Comparative Effectiveness Research Institute would be a nonprofit corporation dedicated to researching the clinical comparative effectiveness of health care treatments including pharmaceuticals, medical devices, and surgical procedures without considering cost or health plan design factors. However, it would also include an expert methodology committee that would be responsible for studying whether comparative effectiveness research should incorporate cost or health plan design. The Institute would receive its funding through a combination of general revenues, the Medicare Trust Fund, and fees assessed to health insurance plans.

A medical device industry group has cautioned that any comparative effectiveness regime must take into consideration the unique role that medical technologies would have in such research and highlight the differences that exist between drugs and medical devices.

Baucus stated that “doctors and patients need reliable, unbiased information about the effectiveness of treatments to determine the best care possible ... this bill will advance the process of reviewing and producing valuable information and making it available to health care providers, and to all Americans.” Sen. Kent Conrad (D-ND), the co-sponsor of the legislation further stated that doing more comparative effectiveness research will allow “patients and their doctors [to] make better decisions on treatment – meaning we could lower costs and improve health care outcomes.” Implicit in such statements is that while Congress is unwilling to insert cost considerations into comparative effectiveness research now, research supporters point to cost savings, and not pure clinical outcomes, as a driving force for initiating large scale research now, as health care costs are skyrocketing.

Medical Industry Reaction
While industry has been largely supportive of comparative effectiveness research in principle, it remains concerned about its implementation and implications in practice. It is natural to support initiatives that will give physicians better information with which to make medical decisions. It is more difficult to support initiatives that pit one technology against another with cost potentially being a key factor. It remains unclear who among the stakeholders will bear the economic cost of conducting this additional research. What is clear is that the medical device industry will bear the burden of carrying its investment costs until such additional data support appropriate coverage and reimbursement. And of course its R&D investments may never be recouped if the
new technology is shown to be less effective than existing treatments and/or to not meet a real or perceived cost/benefit standard either now or in the future.

The Pharmaceutical Research and Manufacturers of America (PhRMA) has stated that it “supports the development and use of high-quality evidence, including comparative clinical effectiveness evidence, for healthcare decision-making.”36 PhRMA has also created a set of principles to “establish a framework to help ensure government-supported health outcomes research, including research on comparative effectiveness, meets patients’ needs and supports improvements in medical care.”37

The Biotechnology Industry Association (BIO) also “strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making .... When appropriately applied, comparative effectiveness information is a valuable tool that, together with a variety of other types of medical evidence, can contribute to improving health care delivery.”14 Yet, “BIO is concerned that comparative effectiveness information may be used strictly as a means to contain costs, rather than deliver health care value by improving patient health outcomes.”57 To that end, BIO also has developed its own set of principles on comparative effectiveness research.15 BIO has also cautioned that “care must be used to make sure that there is a common understanding of what is meant by the term comparative effectiveness,” and that “any comparative effectiveness study can be useful to inform the clinical judgment and individual needs in medical decision-making as long as the limitations of each study are known.”16

AdvaMed has stated that it is “strongly committed to the principles of evidence-based medicine and we support comparative effectiveness research as a means to improve clinical outcomes and promote access to quality of care. Sound comparative effectiveness research can be used to assist patients and physicians in medical decision-making by identifying the relative advantages and disadvantages of alternative means to prevent, diagnose and treat disease, including non-treatment as a potential option.”14

AdvaMed’s principles regarding comparative effectiveness include that only clinical effectiveness, and not cost-effectiveness be considered in any study, that Congress should explicitly prohibit using comparative effectiveness to deny individuals Medicare coverage, and that device manufacturers, along with other stakeholders, be included in discussions regarding comparative effectiveness policies.42

AdvaMed has commented on Baucus’s legislation, stating that it was pleased that the bill would not authorize cost-effectiveness studies, adding, “As Congress considers comparative effectiveness legislation, we believe safeguards should be included to ensure that the final determination of what treatment option works best for each patient should be made by individuals and their physicians.”43 Similarly, the Medical Device Manufacturers Association (MDMA) has stated that it will “advocate the point that comparative effectiveness research should be truly about effectiveness and not about cost.”44

The device industry’s support of comparative effectiveness research has been more qualified than that of the pharmaceutical or biotechnology industry, as the nature of devices makes comparative effectiveness studies somewhat challenging to apply to such products.45 In contrast to individual drugs which remain on the market, unchanged, for long periods of time, devices are often developed in a short-turnaround, iterative fashion.46 To that end, AdvaMed’s President and CEO Steve Ubl has cautioned that it is “essential that research recognize the unique iterative nature of device innovation when establishing research priorities and conducting studies.”47 MDMA has also cautioned that any comparative effectiveness regime “take into consideration the unique role that medical technologies would have in comparative effectiveness research and [] highlight the significant differences that exist between drugs and devices.”48

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**PhRMA has created a set of principles to “establish a framework to help ensure government-supported health outcomes research, including research on comparative effectiveness, meets patients’ needs and supports improvements in medical care.”**

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**Insurance Industry Reaction**

In contrast, the private insurance industry has been extremely supportive of comparative effectiveness research, and has not shied away from expressing its support for the idea, based largely on cost considerations. For instance, the Blue Cross and Blue Shield Association has stated, “To improve tomorrow’s healthcare coverage we need to change the incentives in today’s healthcare system.” Comparative effectiveness research “will empower patients and providers by providing information on quality and value, and improve safety and affordability of healthcare for everyone.”49 The Pharmaceutical Care Management Association believes that “comparing the clinical effectiveness of competing drug therapies is an important tool in promoting value-based purchasing.”50 Finally, America’s Health Insurance Plans
has indicated “support for including cost considerations in comparative effectiveness research.”

The Future of Comparative Effectiveness
Access to affordable health care remains a premier concern for Americans, regardless of their political persuasion. With the new Obama Administration, we can and should expect comparative effectiveness legislation to be a key component of any health care policy debate during the 111th Congress. With Democrats gaining seats in both the House and Senate, Finance Committee Chairman Baucus likely will feel emboldened to press ahead with his comparative effectiveness legislation.

With the insurance industry in full support of head-to-head clinical trials envisioned by comparative effectiveness purists, the pharmaceutical, medical device, and biotech industries will need to be savvy in their advocacy to continue to support the overarching goal of comparative effectiveness research, i.e., to produce more insightful medical data, leading to higher quality affordable care for more Americans, while guarding against the infiltration of cost-effectiveness into the comparative effectiveness equation.

Our health care policy-makers need to be sensitive to the proper balance when pursuing the comparative effectiveness program. Controlling health care costs is a laudable and necessary goal – but it should not be done at the expense of dampening the innovative and entrepreneurial spirit represented by the medical device industry and its brethren in the pharmaceutical and biotech worlds.

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2 “Research on the Comparative Effectiveness of Medical Treatments,” Congressional Budget Office (December 2007), 3.


5 Floor Statement of Sen. Max Baucus.


7 CBO, “Research on the Comparative Effectiveness of Medical Treatments,” 1.


11 Id. at 26.

12 Id. at 1-2.

13 Id. at 31.


15 Id.


19 CBO, “Research on the Comparative Effectiveness of Medical Treatments,” 32.

20 Id. at 29.


22 CRS, “Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview.”


26 Medicare Modernization Act, § 1013.

27 AdvaMed, “Comparative Effectiveness Legislation.”


Firms Need an Investigation Plan, Much Like a Disaster Response Plan

Dan Small

Corporations have largely viewed government investigations as a reactive issue: responding to inquiries, events and allegations. But this is a dangerous misconception. Companies develop policies and procedures for all kinds of far-fetched situations but often do not consider being visited by the government.

Inside and outside corporate counsel need to convince the client that careful review, updating and training is imperative. Remember bird flu? Companies far from any danger scrambled to adopt policies. Companies in hurricane zones have earthquake policies. Yet the risk of a government investigation is far more real, and the likelihood is growing.

In April, the FBI reported it had 529 fraud investigations in 2007, nearly double the number from five years earlier. That’s just one of many agencies investigating the corporate world. Relying on “it can’t happen here” is an invitation to disaster.

While no readable policy can realistically cover every detail and contingency, the key is to focus on the most important and most explosive areas.

Corporate policies and procedures for possible future crises can defuse the anxiety and confusion that come with any crisis. They also can help people under stress avoid mistakes that can make a bad situation worse. Law enforcement agents at the office with a subpoena, at the plant or warehouse with a search warrant or at employees’ homes at night with “just a few questions” can easily cause panic, and panicked people without guidance can do all kinds of harmful things such as lying to agents, destroying documents and spreading wild rumors.

Companies need to make sure they develop, update and implement policies and procedures that can help guide their people before, during and after being visited by the government in a white-collar investigation.
policy can realistically cover every detail and contingency, the key is to focus on the most important and most explosive areas.

**White-Collar IEDs**

The three most explosive areas for white-collar IEDs are interviews, email and documents. We’ve all become grimly familiar with improvised explosive devices in the wartime context. In an investigation, the explosions are not physically deadly, but they are unexpected and must be anticipated. There must be clear and well-understood policies and procedures for each.

No employer should tell its employees not to cooperate with a government investigation. However, a criminal investigation is a complex and confusing jungle fraught with hazards for all involved, and a guide is recommended. Companies must help their employees understand that – whether at home or at the office – they do not have to speak with investigators without an attorney, and they would be ill-advised to do so.

They can politely but firmly take the questioners’ cards and say they will have a lawyer get in touch. The company needs to have a point person and a process for employees to report any government contact. In addition, the company needs to decide in advance when and how it will provide counsel to represent and prepare employee witnesses. Hopefully, it also has given some consideration to choosing counsel.

Unprepared witnesses with mistakes, gossip and guesses – or worse – can badly damage a company and at the very least send an investigation in unnecessary directions that cost dearly in time, money, anxiety and possibly even the company’s reputation.

Email has become the new office water cooler: we treat it as if it were casual conversation. We type things that we would never type if we thought we were creating a formal letter or document. In this day of servers and backups, pressing “delete” can be a meaningless gesture. Companies need policies on creation, retention and production of emails.

Employees need to be trained to understand the misconceptions and dangers of creating emails. Examples abound to support lawyers’ warnings not to write, type or text anything you wouldn’t be comfortable seeing again in court. Think of all the famous witnesses who were surprised and embarrassed by their own emails.

Retention means there must be policies in place for how long email in all forms and files are to be retained and procedures in place for purging those e-mails. If it comes down to production, there must be procedures in place so that, once there is a government inquiry, a hold can be put on all destruction of potentially relevant material, and someone or a team is in charge of coordinating, assembling, review and production.

The same three challenges are in play with documents. Do employees understand what makes a document privileged, or what destroys the privilege? Do they understand the kind of content that should be in a document and the kind of information that should not? The issue is often not what was intended to be stated in a document, but how it will be interpreted by others. All this and more needs to be defined.

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**In this day of servers and backups, pressing “delete” can be a meaningless gesture. Companies need policies on creation, retention and production of emails.**

The retention issues are similar to email. What is your retention policy, do your people know it, who is in charge of implementing it, and who is overseeing and reviewing the process? Is there a hold policy once an inquiry is made, and who is responsible for document retention and coordination? Over all of this is the fundamental “Ghostbusters” question: “Who ya gonna call?”

When government agents are swarming your facility, that is not the time to flip through the Yellow Pages or to call your corporate counsel and pray they know someone who does this type of work. Responding to investigations and white-collar defense is a niche practice. It requires extensive knowledge and experience. It’s worth investing the time to find and meet legal counsel you are comfortable with, just in case the unthinkable happens.

Many companies have bits and pieces of these policies and procedures in place. But few have more than that, and many of them should be more diligent to update and train on a regular basis. An investment now in developing effective policies, procedures and training can help lessen the disruption and damage, and increase the chances that further damage will not be self-inflicted once an investigation begins.

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Court Expands Duty to Corporate Officers and General Counsel to Implement Compliance and Ethics Programs

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Since 1996, it has been generally understood that corporate boards of directors, particularly those in heavily regulated industries, have had a fiduciary duty to ensure that their companies have in place an appropriately designed and implemented compliance program with internal controls sufficient to identify potential corporate wrongdoing and bring it to the attention of management and the board. That principle was adopted in the landmark case of In re Caremark International, Inc. Derivative Litigation by the Delaware Chancery Court and confirmed by the Delaware Supreme Court in the 2007 decision in Stone v. Ritter. Until recently, however, the Caremark obligations had not been formally extended to senior management of companies or their general counsel.

If executive management was of the notion that compliance and related internal controls were not its responsibility — that has now changed. In the case of Miller v. McDonald, et al. (In re World Health Alternatives, Inc.), the United States Bankruptcy Court for the District of Delaware held that corporate officers, and, in particular, the general counsel, can be held personally liable for corporate fraud and related wrongdoing, even if they do not have personal knowledge of, involvement in, or benefit from the underlying wrongful activities. The path to avoiding such liability is clear: senior management must take steps to ensure that appropriate compliance program structures and activities are in place and operating.

It has long been established that directors have responsibility to supervise and monitor the operations of a corporation. The legal presumption is that “in making a business decision, the directors of a corporation acted on an informed basis, in good faith, and in the honest belief that the action taken was in the best interests of the company.” This is called the “business judgment rule.” Directors’ actions are protected by the business judgment rule unless there is evidence that the directors have breached their fiduciary duty of care (i.e., have acted with gross negligence) or duty of loyalty (i.e., have acted with deliberate indifference and have failed to act in the face of a duty to act) or have acted in bad faith (i.e., have acted with a conscious and intentional disregard of their director responsibilities). The Caremark decision held that generally, where a claim of directorial liability for corporate loss is predicated upon ignorance of liability-creating activities within the corporation, … only a sustained or systematic failure of the board to exercise oversight — such as an utter failure to attempt to assure a reasonable information and reporting system exists — will establish the lack of good faith that is a necessary condition to liability.

The court continued to note that this test of liability for lack of good faith as evidenced by “a sustained or systematic failure … to exercise reasonable oversight” is quite high. In other words, unless the directors “sleep on the job” or choose not to receive timely and accurate corporate information that may give rise to suspicion of wrongdoing, they are generally protected from claims of personal liability under the business judgment rule. That protection is lost, however, if directors fail to ensure that an “information and reporting system,” now commonly understood to mean a corporate compliance program, has been implemented at the company.

In the Miller v. McDonald case, the U.S. Bankruptcy Court for the District of Delaware specifically expanded the Caremark principles to senior officers of the company, including the general counsel. The Miller court took the position that under Delaware law, the “fiduciary duties of officers have been assumed to be identical to those of directors.” While both directors and officers enjoy the presumption of the

Corporate officers, and, in particular, the general counsel, can be held personally liable for corporate fraud and related wrongdoing, even if they do not have personal knowledge of, involvement in, or benefit from the underlying wrongful activities.
business judgment rule, the rule can be overcome by evidence of gross negligence, including the failure to implement and utilize a reasonably adequate corporate “information and reporting system” (i.e., compliance program).

World Health was a nationwide health care-staffing services provider to hospitals and other health care facilities. The company filed a Chapter 11 bankruptcy petition in February of 2006, which was later converted to a Chapter 7 case. The bankruptcy trustee, Miller, brought suit against several senior executives of the company, including Brian Licastro, who served as the company’s vice president of operations and “in-house general counsel.” Three of the other defendants were also members of the board of directors. According to the complaint, in 2003 and 2004, World Health began an aggressive strategy of growth, primarily through a series of private placement transactions. During this process, the company purportedly raised more than $45 million and made eight acquisitions of smaller staffing companies around the United States. By the end of 2004, however, the company had spent all of the money it had raised and began to borrow heavily. In February of 2006, the Internal Revenue Service filed liens on company property, alleging an unpaid tax liability of more than $4 million.

The trustee’s lawsuit against Licastro and the other executives alleged that they had allowed the “routine waste of World Health’s limited resources on expensive and unnecessary luxuries for their personal benefits.” The alleged waste included such luxury items for the executives as extensive time on private jets and luxury car leases for the executives. In addition, the lawsuit alleged fraudulent tax reporting to the IRS, misstatement of financial reports on related-party loans, misrepresentations on company financial statements and securities filings, false press releases, and false certifications under Sections 302 and 906 of the Sarbanes-Oxley Act. It was alleged that all of these activities led to the collapse and subsequent bankruptcy of World Health.

One of the claims against Licastro, the former general counsel, was that he had “breached his duty of care by failing to implement an adequate monitoring system and/or the failure to utilize such system to safeguard against corporate wrongdoing” based on the Caremark decision and the subsequent decision by the Delaware Supreme Court in Stone v. Ritter.⁶ Licastro moved to dismiss the breach of fiduciary duty claim, in part, on the ground that Caremark and subsequent cases “addressed the fiduciary duties of directors, not officers,” and that the trustee was attempting to improperly expand the concept to employees.

**Even without reasonable suspicions, liability may be imposed if the company does not have a reasonable, operating compliance program in place.**

The court held that even though Licastro may not have personally gained from the wrongdoing, or had knowledge of, or affirmatively participated in the wrongdoing, his failure to “implement an adequate monitoring system and/or the failure to utilize such system to safeguard against corporate wrongdoing” was sufficient to give rise to liability for his breach of duty of care owed to the corporation and its shareholders.

The court also noted that Section 307 of the Sarbanes-Oxley Act of 2002 directs the Securities and Exchange Commission (SEC) to issue rules that set forth minimum standards of professional conduct for attorneys who appear and practice before the SEC, and such standards must contain a rule requiring “an attorney to report evidence of a material violation of securities law or breach of fiduciary duty or similar violation” by the issuer up-the-ladder within the corporation.⁸ The court held that the in-house general counsel, as the only lawyer in top management, had the duty to know and should have known of the malfeasance and should have reported the management’s breach of fiduciary duties up the chain of command.

The court further inferred under Section 307 of the Sarbanes-Oxley Act that the in-house counsel had an affirmative duty to inspect the truthfulness of the corporation’s SEC filings. By failing to provide oversight and advice that would have prevented the corporation from making material misrepresentations in its SEC filings and press releases when he should have been aware of wrongdoing and discrepancies in the corporation’s revenues, the former general counsel exposed himself to potential claims for breach of fiduciary duty, negligent misrepresentations, and professional negligence.

The Caremark standards still apply and “only a sustained or systematic failure of the board to exercise oversight – such as an utter failure to attempt to assure a reasonable information and reporting system exists – will establish the lack of good faith that is a necessary condition to liability.” Among other egregious failures, the health care staffing company had tax liens filed against it for unpaid income taxes and reported debt which was under-stated by over $20 million.⁹
Assuming the allegations of the complaint were true, as it was required to do in the preliminary phases of the litigation, the court found that such an utter failure did exist and held management responsible.

The Miller decision should serve as a wakeup call to all in-house counsel and senior executives, many of whom are also officers of their corporations. The court has made clear that non-director corporate officers owe to the corporation the same Caremark and related fiduciary duties as those owed by directors. Although under the Attorney Conduct Rules promulgated by the SEC under Section 307 of the Sarbanes-Oxley Act, counsel has a duty to report only a material violation of the law that he or she becomes aware of, the Miller decision has gone beyond that and has determined that in-house counsel also has the duty to take affirmative steps to provide oversight and “safeguard against corporate wrongdoing.” Lack of personal benefit or knowledge of actual wrongdoing is not enough to absolve in-house counsel of these liabilities. Instead, he or she must be vigilant and make sure that the company implements a reasonable compliance system and utilizes the system to monitor fraud and other kinds of corporate wrongdoing. When there is a reason to suspect a material violation of the law, he or she must promptly take other affirmative actions, such as up-the-ladder reporting and corrective or remedial actions to reduce the adverse impact of the wrongdoing on the corporation and its shareholders. Even without reasonable suspicions, liability may be imposed if the company does not have a reasonable, operating compliance program in place.

This article, which appears here with permission from the Society of Corporate Compliance and Ethics, was first published in the October 2008 Compliance and Ethics Magazine.

U.S. Supreme Court Holds That “Reasonable Factor Other Than Age” Must Be Proven by Employers

William B. deMeza

The United States Supreme Court has just decided that an employer claiming it did not violate the federal Age Discrimination in Employment Act, 29 USC 621 et seq. (ADEA), because a decision having an adverse impact on older workers was based on a “reasonable factor other than age” must actually prove that contention at trial. In Meacham v. Knolls Atomic Power Laboratory, Inc.,1 the Court held that a

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1 698 A.2d 959 (Del. 1996).
2 911 A.2d 362, 370 (Del. 2006).
5 Id. at 971.
6 911 A.2d at 370.
8 Id.
9 According to filings with the SEC, World Health had total assets of $112 million, total liabilities of $54 million and shareholder equity of $50 million in March of 2005.
10 17 C.F.R. Part 205.

The ruling will complicate and make more expensive an employer’s defense of a disparate impact age discrimination claim and, in fact, Meacham may induce additional disparate impact claims by unhappy older workers.
claimed “reasonable factor other than age” (RFOA) is an affirmative defense to an alleged ADEA violation which must be proven by the employer because “the burden of proving an exception [to the statute] is on the party claiming it.” The ruling will complicate and make more expensive an employer’s defense of a disparate impact age discrimination claim and, in fact, Meacham may induce additional disparate impact claims by unhappy older workers.

Meacham’s Disparate Impact Claim
Knolls Laboratory is a federal contractor that was ordered by the federal government to reduce its workforce. Although 73 percent of the employees subject to discharge were at least 40-years-old, 30 out of 31, or 97 percent, of those selected for layoff were over 40. Knolls picked the employees for discharge by scoring the at-risk population not only as to job performance (using prior performance evaluations) and years of service, but also as to subjective “flexibility” and “critical skills” assessments by the employees’ immediate supervisors. Meacham was discharged and together with 27 co-workers sued Knolls alleging various ADEA violations, including “disparate impact” discrimination.

Meacham prevailed before a jury verdict on the “disparate impact” claim (but, interestingly, lost on his claim that Knolls intentionally discriminated because of his age). Meacham’s “impact” evidence included the opinions of an expert statistician that, given the ages of the Knolls employee population, the odds were one in 1,260 that 30 of the 31 persons selected would be over 40-years-old and, further, that the supervisors’ subjective “flexibility” and “job criticality” scores were those most closely tied to the actual individual termination decisions. Meacham’s verdict eventually was overturned by the appellate court and he sought review in the U.S. Supreme Court.

ADEA “Disparate Impact” Claims and Defenses
The ADEA prohibits employers from discriminating against workers who have reached their 40th birthdays. But the statute also expressly recognizes that an otherwise prohibited act is not illegal “age discrimination” if “the differentiation is based on reasonable factors other than age.”

The Supreme Court first recognized disparate impact ADEA claims in a 2005 case challenging an employer’s pay plan which, though it did not mention employees’ ages, gave larger pay raises to less-senior and generally younger employees. Smith v. City of Jackson, 544 US 228 (2005). The Court there found that “disparate impact” age discrimination occurs when an employer’s decisions or policies disadvantage older employees even though the decision/policy does not mention ages, is age-neutral on its face and, in fact, was made without any actual intent to discriminate against older workers. (Disparate impact cases often are class actions in which one or more workers assert claims on behalf of a group of similarly situated people.)

Though age discrimination is prohibited, certain employer actions could have a disparate impact on older workers yet not violate the ADEA because they are based on other “reasonable” factors as a matter of law.

The Supreme Court’s City of Jackson opinion held that even if a plaintiff showed that a specific employer practice had a disparate impact on older workers, the employer could avoid liability by showing that the practice was justified by a reasonable factor other than age. But the Court then did not expressly address which of the parties – plaintiff or defendant – had the burden of proof on the RFOA issue. The RFOA burden of proof issue is more than an abstract theoretical question: it can determine the outcome of lengthy and expensive disparate impact litigation. If the employee must disprove a RFOA but fails, the employee loses, but if the employer must prove a RFOA and fails, it loses. Meacham finally resolved this important issue.

The U.S. Supreme Court’s Decision
The Supreme Court held in Meacham that a “reasonable factor other than age” is an affirmative defense and, thus, employer Knolls had the burden of proving the existence of a RFOA justifying its reduction-in-force selection procedures. Justice Souter’s opinion (joined by five other justices), relied on the ADEA’s language and the history of its enactment as well as the Court’s prior opinions interpreting that law and analogous portions of Title VII of the Civil Rights Act of 1964. The Court continued to recognize that, though age discrimination is prohibited, certain employer actions could have a disparate impact on older workers yet not violate the ADEA because they are based on other “reasonable” factors as a matter of law.

The Meacham majority opinion rejected Knolls’ argument that it should not be required to prove (rather than simply produce evidence of) the RFOA because requiring such proof would create greater burdens and expenses for employers. Although recognizing that its decision might create additional difficulties for employers, the Court noted that the language of the ADEA required its ruling (“[w]e have to read it the way Congress wrote it”) and, in any event, any
such burdens were somewhat offset by the plaintiffs’ initial requirement of proving disparate impact liability. Justice Souter reiterated the Court’s 2005 pronouncement that a disparate impact plaintiff must “isolate[e] and identify[ ] the specific employment practices” by which older workers were disadvantaged, an obligation that he described as “not a trivial burden.”

**Implications of Meacham**
The Supreme Court’s Meacham opinion likely will make it more difficult for employers to successfully defend the growing number of disparate impact age discrimination cases (a number likely to continue to rise with the increasing number of reductions-in-force economically-mandated by the nation’s faltering economy). Meacham will make it more difficult for employers to get such cases dismissed with a motion for summary judgment and likely will make them more difficult to win at a jury trial. Further, because employees’ lawyers will quickly recognize that Meacham has changed the ground rules for defending disparate impact cases, it may well lead additional plaintiffs with questionable claims to “take a shot” with litigation. But employers have been helped by the Meacham majority’s emphasis on plaintiffs’ obligations to allege and prove specifically how older workers have been disparately impacted; thus, in defending disparate impact litigation, employers must focus on and aggressively attack the specificity (or not) of plaintiffs’ allegations.

Meacham also instructs employers that any decisions adversely affecting older workers must be carefully considered, reviewed and documented. Although subjective factors (“flexibility”; “creativity”; “team play”; “enthusiasm”; “initiative”) still can be considered in making decisions, the use of such hard-to-quantify criteria must be studied to ensure that they are truly “reasonable” under the specific circumstances and the resulting decisions must be examined – at least by senior management and, with large reductions-in-force, by legal counsel and possibly by expert statisticians – to ensure that the use of such subjective criteria do not unconsciously disadvantage older workers.

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1 128 S.Ct. 2395.  
3 Smith v. City of Jackson, 544 US 228 (2005).  
4 Disparate impact cases often are class actions in which one or more workers assert claims on behalf of a group of similarly situated people.
MedPAC Advisory Committee
The Medicare Payment Advisory Committee (MedPAC) November 2008 meeting discussed establishing new financial reporting requirements between physicians, drug and medical device manufacturers, and other providers. This is just one of the many recommendations set forth in a MedPAC report issued in June 2008. The report is available at: http://www.medpac.gov/documents/ Jun08_EntireReport.pdf

FDA Calls for New Warnings for Children’s Cold Medicine
The Food and Drug Administration (FDA) recently urged manufacturers of over-the-counter cold medicines to change the labeling on their products to state that the products should not be ingested by children under the age of four. This recommendation comes on the heels of a Centers for Disease Control and Prevention (CDC) study that illustrated the high prevalence of cold medicine related emergency room visits due to improper ingestion by children under the age of four. This is the second labeling change for cold medicines in the past year. Manufacturers recently modified labels so as to no longer market products for use by children under the age of two.

GAO Report About Medicare Cuts for Imaging Services
On September 26, 2008, the Government Accountability Office (GAO) released a report, “Medicare: Trends in Fees, Utilization, and Expenditures for Imaging Services before and after Implementation of the Deficit Reduction Act of 2005.” The Deficit Reduction Act (DRA) called for caps on certain types of medical imaging services. GAO found that there were over $1.7 billion of reimbursement cuts in 2007. Utilization of the services increased, despite the lower reimbursement rates. The Centers for Medicare and Medicaid Services (CMS) views this as successful, while industry asserts that the cuts have been harmful to medical imaging services. This report is available at: http://www.gao.gov/new.items/d081102r.pdf.

Medicare Improvement for Patients and Provider Act
Over the summer, Congress passed the Medicare Improvement for Patients and Providers Act which halted a 10.6 percent cut in physician reimbursement for Medicare services. The Act raised the financial threshold for Medicare assistance, allowing more senior citizens to qualify. Further, the Act created the same co-payments for mental health services as it does any other doctor’s visit. The Act also will deduct back taxes from any Medicare reimbursement from physicians and other medical service providers who are delinquent in paying their federal income taxes. The Act halted the competitive bidding program for DME providers.

Increase in CMS Oversight
In response to the discontinuation of the competitive bidding program for DME providers under the Medicare Improvement for Patients and Providers Act, CMS is increasing its anti-fraud initiatives. CMS intends to increase the focus of the recovery audit contractors (RACs) in particular states, namely Florida, California, Texas, Illinois, Michigan, North Carolina and New York. The RACs will focus their efforts on home health agencies and DME suppliers.

SCHIP Reauthorization
Democrats decided not to pursue a vote to expand the State Children’s Health Insurance Program (SCHIP) several weeks before the November 4, 2008 election. Legislation seeking to expand SCHIP was vetoed two times by President George W. Bush. SCHIP, formed in 1997, covers approximately 10 million children and is set to expire in March 2009 without additional legislative intervention. It is expected that Congress will resume debate on SCHIP and reauthorize the legislation in the new year.

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Chicago’s Health Care Team Closes Major Hospital Acquisition

*Health Law Team Leads Conversion of St. Francis Hospital and Health Center to For-Profit Status. The historic hospital faced closure prior to acquisition.*

Anne Murphy

Chicago partners **Anne Murphy** and **Elias Matsakis** led a national team of Holland & Knight attorneys representing MSMC Investors LLC d/b/a MetroSouth Medical Center and related entities in the acquisition of St. Francis Hospital and Health Center from SSM Health Care. The historic 410-bed hospital, founded in 1905, was slated for closure after earlier efforts to find a buyer were unsuccessful. The hospital is the largest employer in Blue Island, and is known for its high quality service and excellence in cardiac care.

The asset purchase, also included a licensed hospice and home health agency. As a result of the transaction, the hospital converted from nonprofit tax-exempt status to for-profit status. This transaction presented several unique challenges. Because the hospital closure was announced before the acquisition opportunity surfaced, the time pressure to close the deal was intense. Due diligence and negotiation of the asset purchase agreement were completed in less than a month and the deal closed less than three months from inception.

Also, because the transaction involved conversion of a tax-exempt hospital to for-profit status, it required approval from the Illinois attorney general. In addition, the transaction involved transfer of hospital assets from a Catholic entity to a non-Catholic entity. So, the transaction also required Vatican approval.

In addition to addressing these unique issues, Holland & Knight also represented the client in the associated regulatory and contracting matters. These included securing licensure, certificate of need, accreditation, Medicare/Medicaid certification, and negotiating contracts and approvals with vendors and others.

The scope and challenges of the project required the assembly of a cross-office team of health care and transactional attorneys. **Maria Currier**, **Dana Gryniuk** and **Jose Fernandez** (all Miami) were a central part of the team. In addition to Anne Murphy, Elias Matsakis and Maria Currier, the team included: **Tom Skallas** (supervised the corporate M&A team), **Larry Zanger** (coordinated and structured the information technology agreements), **Tony Frink** (real estate aspects), **Ken Jenero** (labor and employment aspects), **Tom Kinasz** (tax matters), and **Mark Steger** (environmental matters). They were ably assisted by a team of associates and paralegals that included **Lisa Sterneck**, **Robyn Axberg**, **Liz Berlinsky**, **Robyn Sterling** and **Maureen Drews** (all Chicago) and **Linda Harrison Autrey** (Atlanta). A key to the success of the transaction was a close working relationship with Hartford, Connecticut-based law firm Tyler Cooper, which serves as outside general counsel to buyer.

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Health Law Team Works on Land and at Sea to Secure Partnership for Hospital

Boston and Miami attorneys work together to help Partners Healthcare System, Inc. increase its global reach.

Robert Pupo

Robert Pupo (Miami), Steve Wright (Boston) and a talented team of Holland & Knight lawyers recently helped Boston-based Partners Healthcare System, Inc. (Partners) take operational control of Harvard Medical International (HMI). Partners, a not-for-profit health care system, operates several major hospitals in the Boston area. As an internationally-renowned provider of consulting services, Harvard Medical International focuses on the provision of health care services in over 35 developing countries around the world, and is owned by Harvard Medical School.

Because HMI had been affiliated with Partners and had been operated as a Partners entity for many years, the decision to transfer the operation of HMI to Partners made good sense in many capacities. By taking on HMI, Partners hopes to increase its global reach. The combined entity will be known as Partners Harvard Medical International.

Mr. Pupo and Mr. Wright were assisted on the transaction by a multi-office team of partners and associates. Sherri DiMarco (Miami) provided corporate, health care and international experience. Partner Dan Hampton (Boston) and associate Gillian Rattray (Boston) provided IP guidance. Mauricio Rivero (Miami) advised on tax issues.

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Medicare Part D Update
Tracking Important Developments Affecting the Medicare Prescription Drug Benefit Program

Jonathan Anderman

Medicare Improvements for Patients and Providers Act (MIPPA)
The recently enacted MIPPA implements a variety of substantial changes in the health care industry. Some of the key provisions relevant to Medicare Part D include:

E-Prescribing: encouraging physicians to prescribe electronically by allowing an increase in payments for professional services starting at 2 percent in 2009 and phasing down to 0.5 percent in 2013; and, penalizing physicians who do not prescribe electronically by reducing payments to 99 percent in 2012 and phasing down to 98 percent in 2014 and subsequent years

Prompt Pay: requiring Part D plan sponsors to pay electronic claims within 14 days and paper claims within 30 days of receipt from pharmacies, or suffer a financial penalty

Marketing: increasing regulatory requirements and prohibitions on marketing by Medicare Advantage Organizations and Part D plan sponsors

2009 CMS Call Letter – Limiting Copayments to Negotiated Price
The 2009 CMS Call Letter for Medicare Advantage (MA), Medicare Advantage-Prescription Drug (MA-PD), Cost-Based Plan, and Stand Alone Prescription Drug Plan (PDP) discusses CMS’ plans to implement, revise, and expand regulations relevant to these organizations in the upcoming year. One noteworthy section discusses new limits on beneficiary copayments to a Part D plan. Previously, Part D sponsors could apply either a copayment or the actual negotiated price. The new policy will remove this option and require Part D plan sponsors to amend their payment systems to charge beneficiaries the lesser of a drug’s negotiated price or the applicable copayment amount. Thus, Part D plans no longer will be able to benefit financially from the difference between the copayment amount and the negotiated price.

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Announcement
Former Senior DOJ Official, Dan Fridman, Joins Miami Office as a Partner in the South Florida Litigation Group

Dan Fridman has joined Holland & Knight’s Miami office as a Partner in the South Florida litigation group. He has an extensive background in the health care industry and in white-collar criminal defense.

From 2006-2007, Dan served as senior counsel to the United States deputy attorney general and special counsel for health care fraud at the Department of Justice in Washington, D.C. In that capacity, he advised the attorney general and the deputy attorney general on health care policy, and coordinated anti-fraud enforcement efforts among the Civil Division, Criminal Division, U.S. Attorney’s Offices, Civil Rights Division and the FBI. He was also responsible for funding and promoting an initiative to target areas experiencing high amounts of health care fraud, including South Florida. From 2004-2006, and again in 2007, Dan was a prosecutor in the U.S. Attorney’s Office in the Southern District of Florida. Earlier in his career, he was a civil litigator in private practice in South Florida and clerked for The Honorable Alan S. Gold of the U.S. District Court for the Southern District of Florida.

Dan received his B.A. with highest honors from the University of Florida, where he was co-valedictorian of his graduating class. He received his J.D., cum laude, from Harvard Law School. He has testified before Congress on various health care issues, including the Medicare program. He has also appeared in and been quoted by the news media on criminal enforcement issues.
About the Editor

Michael R. Manthei

Michael Manthei is a Partner in the Boston office of Holland & Knight. He represents clients exclusively in the Health Care and Life Sciences industries. Mr. Manthei represents clients primarily in health care fraud, abuse and compliance matters, in privacy matters, and in other health care regulatory matters. He routinely represents clients before state and federal regulatory and law enforcement authorities including the Department of Justice, United States Attorneys offices, State Attorneys General offices, the Center For Medicare and Medicaid Services and the Office of Inspector General for the Department of Health and Human Services. He is a frequent speaker and is a co-author of the PLI Corporate Compliance Help Book that was published in the fall of 2008.

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Michael M. Gaba is a partner in the Washington, D.C. office of Holland & Knight where he is the Federal Policy leader of the firm's national Health Law and Life Sciences Team. His regulatory and legislative life sciences practice includes counseling and representing medical device and biotech companies before the Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the U.S. Congress. More specifically, Mr. Gaba works on a range of issues related to health care reform with an emphasis on HHS integration, the FDA Amendments Act, post-market surveillance and enforcement, with a particular focus on combination product approval and labeling, as well as coverage, coding, and reimbursement for these sophisticated products.

Renee R. Wentzel

Renee R. Wentzel is an Associate in the Public Policy and Regulation Practice Group in the Washington, D.C. office of Holland & Knight LLP. She advises corporations on matters pertaining to environmental, health, and telecommunications law in particular. Ms. Wentzel also has significant experience in the area of government contracts. Notably, she has assisted numerous clients as they pursue federal business, to include representing clients' policy and program-specific interests before Legislative and Executive Branch officials, and working to secure program funding in Appropriations bills.

Dan Small

Dan Small practices in the area of litigation, focusing on witness preparation, government and internal investigations, white-collar criminal law and complex civil litigation. He has extensive investigation, jury trial and other litigation experience.

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Christopher A. Myers is Chair of Holland & Knight’s Compliance Services Team and a member of the firm’s White Collar Defense Team. He is a former federal prosecutor and has experience in a broad range of complex matters affecting heavily regulated industries, including health care, government contracts, financial institutions, real estate, securities and other companies. He has represented clients with respect to matters involving civil and criminal fraud investigations, corporate governance, anti-money laundering, design and implementation of compliance programs, and administrative litigation. Mr. Myers is certified as an Anti-Money Laundering Specialist and as a Certified Compliance & Ethics Professional.

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Michael M. Mannix practices corporate and securities law especially in connection with mergers and acquisitions and corporate finance in the government contracting industry and related to telecommunications and other technology companies.
Jane K.P. Tam
Jane K. P. Tam devotes substantially all of her practice to representing corporate clients ranging from promising start-ups to established domestic and international corporations. Ms. Tam has represented businesses in such diverse areas as information technology, government contracting, biotechnology, Internet services, telecommunications, computer software, financial services, and transportation. She represents private and public issuers, private equity funds and investment banks in registered public offerings and private placements of securities, debt financings and exchange offers. During the last 18 years of her practice, Ms. Tam has helped companies raise an aggregate of over $2 billion. Ms. Tam was the lead securities counsel for two public companies’ merger valued at $7.2 billion.

Bill DeMeza
William B. deMeza Jr. represents employer clients in labor, employment discrimination, minimum wage/overtime, employment contract and OSHA matters throughout the United States. Clients have included restaurants, manufacturers, financial institutions, department stores, hospitals, physicians’ professional associations, employee leasing companies, government contractors, insurance companies, shipyards, and mining companies.

Anne Murphy
Anne Murphy has more than 20 years of senior government and private sector experience in health law and litigation. Her practice focuses on resolution of complex regulatory, compliance, legal risk management, corporate governance and transactional matters, on behalf of health care and life sciences industry clients.

Robert Pupo
Roberto R. Pupo has substantial experience in complex domestic and international mergers and acquisition matters and corporate financings. He has served as counsel to some of the world’s largest financial institutions and private and public companies. Much of the domestic corporate and mergers and acquisitions work handled by Mr. Pupo has involved health care businesses, including hospital systems, health maintenance organizations, provider networks and physician management companies. At the international level, Mr. Pupo has represented some of the largest U.S. and European financial institutions, including commercial lenders, investment banks and multi-laterals, in complex international financial transactions. He also has worked with numerous U.S., European and Latin American multinational corporations in cross-border acquisitions, joint ventures, and affiliations.

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Jonathan E. Anderman is an associate in Holland & Knight’s Boston office. He is a member of the firm’s national Health Law and Life Sciences Team and the Business section. He advises clients in various sectors on health care regulatory matters, on compliance matters, and on corporate transactional matters.

About Our Health Law & Life Sciences Practice
The rapid-fire changes occurring today in the legal and regulatory arenas that shape health care law, create an array of compliance, transactional and litigation issues that can make your day-to-day operations increasingly complicated. With nearly 100 years of combined experience representing health care and related businesses, Holland & Knight’s Health Law & Life Sciences Team members are positioned to guide you through the maze. As one of the largest health law and life sciences practices in the U.S., Holland & Knight’s dedicated health law attorneys and professionals apply in-depth knowledge of the industry and the resources of the firm to promote and protect your interests.

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