2010 INSIGHTS:

In the remaining weeks of this year, the Daily Journal will be featuring columns written by select contributors touching upon this year's legal developments, lessons learned and what's to come.

Pharmaceutical Marketing: A Year of Interesting Times

By Bryan A. Liang and Tim K. Mackey

2010 was a busy year in pharmaceutical marketing. With pipelines dwindling, drug makers continue to concentrate on marketing to drive product sales. However, increasing regulatory scrutiny over the past year is reshaping the landscape of pharmaceutical promotion.

Headlining pharmaceutical marketing reform was the passage of physician payment disclosure provisions under the Affordable Care Act. Starting Jan. 1, 2012, drug and medical device manufacturers will be required to publicly report gifts and payments made to providers annually.

The legislation requires disclosure of compensation, food, travel, entertainment and gifts, consulting fees, equity, as well as research and medical education funding. Companies must disclose providers' names and contact information, payment value, and the product being promoted. Payments less than $10 and that do not meet an annual $100 aggregate spending per company per recipient, and certain other gifts and payments such as patient educational materials, are excluded.

Perhaps of broader interest, public disclosure of industry payments reflects a larger recognition and attempt to identify both individual and institutional conflicts of interests between providers and the industry. Conflicts of interests are widespread and can have significant negative consequences on patient safety, overutilization of expensive or unproven treatments, and degradation of scientific research integrity.

Individual conflicts of interests have garnered the most attention; yet institutional conflicts of interests are becoming more of a focus. Some academic medical centers have taken notice and have instituted policies prohibiting gifts and entertainment from industry. This includes Harvard Medical School, which recently revised its conflicts of interests policies after years of close financial ties between its physicians and industry and allegations of violations of federal and university policies. Other academic medical centers will no doubt follow suit as scrutiny of conflicts of interests is intensified.

The industry has been dramatically affected by these legal changes over the past year. Individual companies have either voluntarily anticipated the new regulations by implementing their own disclosure programs, or have responded to mandated disclosure under corporate integrity agreements, which compel compliance reforms after a health care fraud and abuse convinction . Johnson & Johnson, Pfizer, Eli Lilly, Merck and GlaxoSmithKline all have varying payment information publicly available on their websites, some required under corporate integrity agreements. This provides increased transparency for the public.

This disclosure mandate also appears to be reducing the number of physicians participating in drug company relationships. Indeed, according to one study, programmatic efforts weaning providers from a reliance upon industry appears to have decreased the number of physicians reporting a relationship with the industry. However, the prevalence of physician-industry relationships is still high at 84 percent, reflecting a need for a national disclosure system to assess the impact of conflicts of interests. Increased state and federal regulations, as well as strict conflicts of interests policies enacted by academic medical centers, are a beginning, but will not be the end of these efforts.

Current regulations, however, do not prohibit some questionable practices, and the system is still effectively reliant upon industry and provider self-policing to ensure compliance. Hence, the approaches to, and effects of, payment disclosure in addressing conflicts of interests are still in development.

In addition to a hardened focus on regulation, state and federal enforcement efforts involving health care fraud and abuse have reached record-breaking settlements, particularly in off-label marketing of drugs by manufacturers. For example, the Department of Justice intervened in a whistleblower false claims action lawsuit against Pfizer alleging illegal promotion of a kidney transplant drug. The allegations include targeting off-label marketing towards high-risk patients such as African Americans and patients seeking a second transplant.

The justice department's motion to intervene is notable given that in September 2009, Pfizer was assessed a $2.3 billion fine, the largest health care fraud settlement and criminal fine in history, for illegal off-label promotion of multiple products. As part of a corporate integrity agreement, Pfizer also disclosed in March 2010 that it had paid some $35 million in just six months to health care practitioners, academic medical centers, and research groups. As a repeat offender, Pfizer compliance status under its current corporate integrity agreement is under investigation — a trend that may be repeated as enforcement plays a greater role in attempting to stem these activities.

Indeed, Pfizer was not alone in record-setting government actions in 2010. Other fines included a $520 million settlement against AstraZeneca, a $600 million settlement against Botox manufacturer Allergen, and a $422 million settlement against Novartis. The settlements involved false claims and kickbacks for off-label promotion of products, and were also initiated by whistleblowers.

Beyond such public attempts, private health care insurers have joined the fray of suing pharmaceutical manufacturers for fraudulent marketing of their products. In November 2010, Kaiser Permanente was successful in a lawsuit against Pfizer to recover expenditures lost from drugs purchased that were illegally promoted off-label. The litigation was in conjunction with an earlier state and federal settlement of $430 million against Pfizer in 2004, and opens the door to future civil litigation initiated by private health care stakeholders.

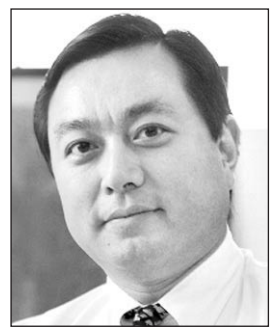
Yet despite these public and private efforts, illegal pharmaceutical marketing does not appear to be effectively deterred. The current system lacks active surveillance by regulators and relies heavily on incentives to whistleblowers under fraud and abuse laws. This has led to regulatory pronouncement that agencies will pursue cases directly against industry executives. Indeed, the Food and Drug Administration (FDA) believes use of the "Park doctrine" (*U.S. v. Park*, 421 U.S. 658 (1975)) will better deter illegal off-label marketing by allowing misdemeanor criminal convictions against company officials for violating the federal Food, Drug, and Cosmetic Act if the official had authority to prevent or correct the violation and did not do so — even if the corporate official was unaware of the violation's existence.

In addition to the extension of domestic enforcement over the past year, pharmaceutical companies have been under special attention internationally. The Securities Exchange Commission and Department of Justice have increased their scrunity of overseas payments that may constitute violation of anti-corruption and bribery statutes, particularly the Foreign Corrupt Practices Act (FCPA.) Potential violations of FCPA include corruption or bribery of foreign state health officials, particularly for marketing and performance of foreign clinical trials. In August 2010 it was reported that at least a dozen major drug and device manufacturers were under investigation for FCPA violations, including Merck, Johnson & Johnson, Eli Lilly, and Medtronic.

In parallel or in response to additional regulation and enforcement activities, pharmaceutical companies continue to investigate other marketing efforts such as direct-to-consumer advertising. The FDA and others are only beginning to recognize the issues that accompany such marketing, which bypasses physicians and influences consumer demand for drug products directly. Resource constraints at the FDA and lack of guidance to the industry on how to present such information has lead to increased costs for the health care system through unnecessary spending on expensive prescription drugs and has perhaps unduly influenced consumers about efficacy and safety of drugs, potentially endangering public health. Regulators continue to struggle with guidelines to ensure a fair balance of presentation of benefits and risks of pharmaceuticals in direct-to-consumer advertising.

But even as regulators struggle with this balance and scrutinize drug company marketing, innovative forms of direct-to-consumer advertising continue to emerge. Pharmaceutical companies have begun using social media to actively engage with consumers. The FDA has taken notice of this development and recently issued a warning letter to Novartis regarding misrepresentations of drug efficacy on Facebook. No doubt regulation in this area will develop as companies increasingly adopt and adapt these marketing and communication means.

If 2010 is any guide, 2011 regulation of pharmaceutical marketing will continue to be a rapidly evolving field in both the legal and health care arena, and in both public and private realms. More complexity will be added as issues such as implementation of health care reform occurs and other modern pharmaceutical concerns such as follow-on biologic approval and promotion become more apparent. There is no question that, like 2010, 2011 will be a year of interesting times in pharmaceutical marketing.

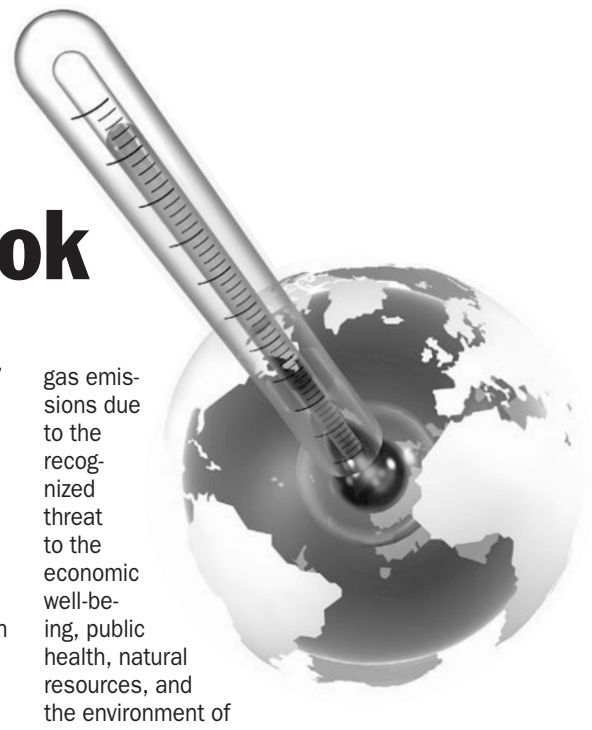


Bryan A. Liang is executive director of the Institute of Health Law Studies at California Western School of Law, and director of the San Diego Center for Patient Safety at the UCSD School of Medicine.

Tim K. Mackey is a senior research associate at the Institute of Health Law Studies and is a student in the joint doctoral program in Global Health at the University of California, San Diego and San Diego State University.

Using the Courts to Fight Climate Change:

Taking a Page From the Civil Rights Playbook



By Jennifer K. Berg

"My friends, I must say to you that we have not made a single gain in civil rights without determined legal and nonviolent pressure. Lamentably, it is an historical fact that privileged groups seldom give up their privileges voluntarily." *Martin Luther King, Letter from a Birmingham Jail, April 16, 1963.*

Our courts have been an effective avenue for redress of critical national issues such as discrimination, a woman's right of choice and more recently, the right to marry. *Brown v. Board of Education*, for example, made clear that the establishment of separate schools for black and white students was inherently unequal and a violation of the Equal Protection Clause. This legal victory paved the way for the civil rights movement. Similarly, legislation concerning harmful substances like tobacco and asbestos was preceded by litigation, which demonstrated their dangers. The battle over climate change, one of the most pressing issues of our time, must also be waged, at least in part, in the courts, since political gridlock and the priority of other issues may continue to limit progress in the legislative arena.

The midterm elections made clear that the issue of global warming and the appropriate response to it is largely split down party lines. According to a study by ThinkProgress, 50 percent of incoming congressional Republicans deny that changes to the climate are caused by human behavior, and 86 percent are opposed to any climate change legislation that increases government revenue. This skepticism, coupled with the economic problems facing this nation, make it almost certain that there will be no federal legislation aimed at combating climate change in the immediate future. Logically, the Environmental Protection Agency (EPA), charged with protecting the environment, should promulgate national standards; however, the agency is dependent on Congress for its funding and authority, and therefore walks a very thin line. Some legislators have already hinted that they will seek to suspend EPA regulations related to climate change or will otherwise limit the agency's authority in this area. The courts, under our tripartite system of government, may be the most effective arena to forge this battle. Several recent decisions illustrate the effectiveness of litigation in addressing issues relating to climate change.

Jennifer K. Berg is an attorney practicing in Oakland. She has an executive MBA in sustainable management.

In 2002, AB1493, known as the Pavley bill, was signed into law in California. It established a mandatory 30 percent reduction in motor vehicle emissions by 2016. The automakers filed suit, challenging the regulations based on federal preemption, despite Congress having provided California with the authority to adopt stricter vehicle standards than the federal regulations, as long as the EPA granted a waiver. In 2006, partially in response to this challenge, then Atty. Gen. Bill Lockyer filed a complaint for damages against the largest automakers alleging that their vehicle emissions contributed significantly to global warming, and harmed California's infrastructure, environment and the health of its citizens, causing millions of dollars in past and future damages. Under federal and state common law, the automakers allegedly created a public nuisance by producing "millions of vehicles that collectively emit massive quantities of carbon dioxide," a greenhouse gas that traps atmospheric heat and causes global warming.

Despite the creative lawyering by the attorney general, the defendants' motion to dismiss was granted in 2007 on the grounds that the issues raised were "political questions." Newly elected Atty. Gen. Jerry Brown vowed to continue the fight and filed an appeal with the 9th U.S. Circuit Court of Appeals.

In the meantime, the Supreme Court issued its ruling in *Massachusetts v. EPA* 127 S.Ct. 1438 (2007), a case brought by California and other states. Writing for the majority, Justice John Paul Stevens commented that "a well documented rise in global temperatures has coincided with a significant increase in the concentration of carbon dioxide in the atmosphere. Respected scientists believe the two trends are related." Carbon dioxide and other greenhouse gases were determined to be "pollutants" under the Clean Air Act and the EPA had to determine if the emissions from cars and light trucks should be regulated.

By the summer of 2009, with Lisa Jackson now at the helm, the EPA reversed the denial of California's waiver of the federal regulations issued during the Bush administration, and the automakers legal challenges to the Pavley Bill were dismissed. With this confluence of events, the interested parties and states reached an agreement that resulted in a new national standard for fuel efficiency. The competing court actions, coupled with a more environmentally friendly White House, resulted in a collective agreement that will benefit present and future generations alike.

State actions have also had beneficial results during the past year as exemplified by the following cases that were resolved this year. In July 2008, The Center for Biological Diversity filed a petition for writ of mandate against the town of Yucca Valley and others contending that they violated the California Environmental Quality Act (CEQA) when they approved a retail plan and certified the environmental impact report for a proposed Wal-Mart. The plaintiffs contended that measures that would limit green house gas emissions and reduce the carbon footprint of the new megastore were not considered. In April, a settlement was reached whereby Wal-Mart agreed to install rooftop solar facilities, include energy efficiency measures into the design, and make a $120,000 contribution to the Mojave Desert Land Trust for land-conservation purposes.

In *Communities For A Better Environment v. City of Richmond* (April 26, 2010), 184 Cal.App.4th 70, environmental groups petitioned for a writ of mandate challenging the Richmond City Council's approval of permits for upgrades at the Chevron Refinery. Specifically, the plaintiffs alleged that the environmental review of the project was flawed because it failed to define mitigation measures for greenhouse gas emissions. The 1st District found support for evaluation of climate-change impacts under CEQA, and pursuant to the Global Warming Solutions Act of 2006 (AB32), which "implements deep reductions in green house gas emissions due to the recognized threat to the economic well-being, public health, natural resources, and the environment of California." The court found the environmental impact report inadequate and ordered that a revised report take advantage of any new information when analyzing the potential greenhouse gas emissions, their cumulative impact on climate change, and to define mitigation measures to avoid those impacts. This ruling has been hailed as precedent setting in its insistence that greenhouse gas emissions be considered.

Our state legislature and public agencies have enacted laws and regulations that provide the courts with the authority to evaluate the effects of our actions on the environment. With this authority, the courts do not need to engage in the political tug of war that defines the other two branches of government. Further, the recent election made clear that Californians have accepted the need to fight climate change with the sound defeat of Proposition 23. Moreover, like her two predecessors, Kamala Harris will likely bring environmental actions, considering she ran on a platform that pledged to use her powers to vigorously enforce AB32 and to pioneer state efforts to both mitigate and adapt to the myriad of environmental threats posed by climate change.

I do not advocate flooding our already overburdened and underfunded courts with a tidal wave of lawsuits related to climate change. However, with creative lawyering by groups like the NRDC, The Center for Biological Diversity and attorneys general, the independence of the courts coupled with legal authority and sound science are the surest bet that action will be taken. Since climate change has emerged as the hot button political issue of the day, resulting in much rhetoric but little action on the legislative front, once again it is the courts that must lead in order to effectuate the change that is so urgently needed.