JONES DAY

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HEALTH CARE COMPLIANCE AND ENFORCEMENT UPDATE

CONTENTS

Key legal developments affecting the health care industry in the past few months include several Supreme Court and appellate court decisions, newly proposed legislation, and international developments of interest to multinational health care companies.

JUDICIAL DECISIONS SET NEW LEGAL RULES FOR HEALTH CARE INDUSTRY

Parameters of "Community of Interest" Privilege Narrowed. A federal judge in the Eastern District of Pennsylvania defined the parameters of what is protected by the "Community of Interest" privilege (sometimes referred to as the "Joint Defense" privilege). On July 5, 2011, in *King Drug v. Cephalon*, Judge Mitchell S. Goldberg found that parties must be engaged in an "ongoing, joint, coordinated defense strategy" in order to avail themselves of the privilege. Although a joint defense agreement had been entered into, the judge found that there were no "actual concrete, tangible steps" taken to implement that joint defense and that the sharing of legal expenses indicated a business or commercial interest rather than a common legal interest. While this analysis was tied closely to the facts presented, the court's relatively narrow conception of the privilege provides guidance for parties seeking to establish the privilege under particular circumstances. Specifically, the *King Drug* decision demonstrates the importance of not just invoking the privilege at the outset of coordinated multiparty activity, but thereafter effectuating this intent by creating an ongoing "context" indicative of a genuine, coordinated legal defense.

Laws that Prohibit the Sale of Certain Medical Information Held to Be an Unconstitutional Restraint Against Free Speech. In *Sorrell v. IMS Health Inc.*, the U.S. Supreme Court held that Vermont's "Prescription Confidentiality Law" imposes content-based and speaker-based burdens on expression and, as such, is subject to heightened judicial scrutiny. Under this analysis, the Court struck down the law as unconstitutional, concluding that Vermont's justifications for the law did not outweigh the benefits of protecting the right of free speech, while also acknowledging that its ruling leaves unresolved the serious personal privacy issues stemming from computer-based data mining. In the wake of this decision, the Second Circuit has requested supplemental briefing on the implications of *Sorrell* for its pending case, *United States v. Caronia*, a criminal case in which a pharmaceutical sales representative was convicted of misbranding a drug by promoting it for several off-label uses.

"No-Contact" Rule Does Not Apply During Investigation Stage of FCA Matter. As part of its investigation into allegations raised in *qui tam* suits under the False Claims Act ("FCA"), the government tried to interview several Amgen employees without an Amgen attorney present. Amgen argued that this was a violation of the "no-contact" attorney-conduct rule, which generally prohibits an attorney representing a client from communicating about the subject of the representation with a party that the attorney knows to be represented by another attorney in the matter, unless the attorney has the consent of the other attorney or the communication is authorized by law or court order. On June 10, 2011, Judge Sandra L. Townes in the Eastern District of New York adopted the Report and Recommendation of Magistrate Judge James Orenstein in its entirety and agreed that the court did not have "supervisory authority over the conduct of an investigation … that may never result in the government filing an action []." The Report and Recommendation further stated that the "no-contact" rule "governs the behavior of individuals who practice law" and does not constrain the rights of the government or establish rights for an adversary. Consistent with many jurisdictions, the court held that the no-contact rule applies "only to matters that fall literally within its scope" and relied heavily on narrow definitions of the key terms "party" and "matter."

First Circuit Expands Definition of "False or Fraudulent" Claim Under the FCA. In *US ex rel. Hutcheson v. Blackstone Medical Inc.*, decided on June 1, 2011, the First Circuit declined to "adopt any categorical rules as to what counts as a materially false or fraudulent claim under the FCA." The approach of other circuits requires that a claim be either "factually false" or "legally false." In addition, the First Circuit rejected the argument that "a claim can only be false or fraudulent if it fails to comply with a precondition of payment expressly stated in a statute or regulation." The court also rejected the argument that the compliance certification by the submitting entity "cannot incorporate an implied representation about the conduct of non-submitting entities." This ruling represents a significant departure from the standards applied by several other circuit courts and thereby further deepens a circuit split and increases the possibility of Supreme Court review.

Response to FOIA Request Cannot Form the Basis of FCA Suit by Private Plaintiff. In *Schindler Elevator Corp. v. US ex rel. Kirk*, issued on May 16, 2011, the Supreme Court held that a federal agency's response to a FOIA request constitutes a "report" for purposes of barring the information from being used by a private plaintiff as a basis for an action under the FCA. In reversing the decision of the Second Circuit, the Court found that since the information was already in the government's possession, the alleged fraud had already been disclosed to the government. The Court's ruling resolved a circuit split over the question of whether a FOIA response is appropriately characterized as an administrative report or an administrative investigation.

INDUSTRY VICTORIES IN HEALTH CARE CASES

OIG Closes Exclusion Case Against Forest Laboratories CEO. On August 5, 2011, the Department of Health and Human Services Office of Inspector General ("HHS-OIG") notified Forest Laboratories Inc. CEO Howard Solomon that it would not seek his exclusion from federal health care programs. According to a Forest press release, the HHS-OIG, in its notice to Solomon, stated that it had "decided to close this case" without pursuing Solomon's exclusion "[b]ased on

a review of the information in our file and consideration of the information that your attorneys provided to us, both in writing and during an in-person meeting." The HHS-OIG had notified Solomon of his proposed exclusion in April 2011, and Forest had supported Solomon in his defense.

Two Amicus Briefs Filed on Behalf of Purdue Executives in Appeal Before the D.C. Circuit Court. In July 2011, two groups filed friend-of-the-court briefs in support of three former Purdue executives, including a former general counsel, who are appealing their exclusion from federal health care programs by the HHS-OIG. In its amicus brief in support of the executives, the Association of Corporate Counsel cited the inappropriateness of excluding general counsel on the basis of their corporate clients' wrongdoing. In a separate amicus brief, the Washington Legal Foundation, represented by Jones Day, argued that the exclusions raise serious constitutional due process concerns relating to the nature of a strict liability offense and the severity of the penalty. Final briefing in the case is scheduled to be completed on September 29, 2011.

Former GlaxoSmithKline In-House Counsel Acquitted. On May 10, 2011, Judge Roger Titus in the District of Maryland acquitted Lauren Stevens, a former associate general counsel for GlaxoSmithKline, of obstructing justice and lying to federal authorities. The government had presented documentary evidence and called GSK employees to testify, in an attempt to prove that Stevens deliberately withheld information from the government and lied when she represented that she had produced all of the information requested by the government in an investigation relating to potential off-label marketing. After the government rested its case at trial, the defense moved for acquittal, and Judge Titus granted the motion, declaring that "it would be a miscarriage of justice to permit this case to go to the jury." Judge Titus added that "a lawyer should never fear prosecution because of advice that he or she has given to a client" in good faith.

Trial Victory in Abbott Product Liability Case. Jones Day successfully defended Abbott Laboratories in a pharmaceutical product liability trial in federal court in Las Vegas involving the prescription drug Lupron. A doctor prescribed Lupron to a 17-year-old plaintiff. Alleging that the drug rendered her permanently disabled, plaintiff asserted various failure-to-warn claims and sought punitive damages against Abbott and its former joint venture, TAP Pharmaceutical Products Inc. At the close of plaintiff's case, the judge granted Abbott and TAP judgment as a matter of law on plaintiff's punitive damages claim. Later, the jury returned a unanimous verdict for Abbott and TAP on all remaining claims.

FEDERAL AGENCIES USE NEW TECHNOLOGIES TO SUPPORT HEALTH CARE ENFORCEMENT EFFORTS

Predictive Modeling Will Be Used to Identify Potential Fraud. In June 2011, the Centers for Medicare & Medicaid Services ("CMS") announced that it will use predictive modeling technology to identify potentially fraudulent Medicare claims and to stop payments before they are made. The technology will use algorithms based on past CMS claims data (beneficiary, provider, service origin, etc.) to track patterns, assign risk scores, and spot suspect claims.

HHS-OIG Joins Twitter. In May 2011, the HHS-OIG joined Twitter as part of its ongoing efforts to quickly and effectively distribute information. Many of the posts on the Twitter site have related to the "Most Wanted Fugitives" list that was launched earlier this year.

REGULATORY AND LEGISLATIVE DEVELOPMENTS MAY HAVE SIGNIFICANT IMPACT ON HEALTH CARE INDUSTRY

SEC Alleges Securities Fraud By Biopharmaceutical Company and Executives. On August 1, 2011, the SEC brought suit against Immunosyn Corporation, Argyll Biotechnologies LLC, and four executives, alleging that they had committed securities fraud related to misleading statements regarding the status of regulatory approvals during 2006–10. Three of the executives, as well as Argyll, Argyll Equities, and Padmore Holdings Ltd., were also alleged to have engaged in insider trading. According to the complaint, public filings stated that Argyll planned to begin the regulatory approval process or that the process was underway but failed to disclose that the U.S. Food and Drug Administration had already twice issued clinical holds that prohibited clinical trials from occurring.

SEC Adopts Final Rules for Dodd-Frank Whistleblower Provisions. On May 25, 2011, the SEC adopted final rules for the implementation of the whistleblowers provisions of the Dodd-Frank Act. Among other things, the final rules:

- Do not require whistleblowers to first report possible securities violations to an internal legal or compliance department or other internal personnel before making a disclosure to the SEC. But, in determining the amount of a whistleblower's award, the SEC will consider whether the whistleblower made an initial internal report.
- Provide that if a whistleblower makes an initial internal report and thereafter reports the same conduct to the SEC, the report to the SEC will relate back to the date of the whistleblower's internal report, as long as the SEC report was made within 120 days after the internal report (the preliminary rules provided for a 90-day "look back" period).
- Permit a person to be a whistleblower even if his employer received a request, inquiry, or demand from the SEC (or certain other government entities) for information in the whistleblower's possession, as long as the request, inquiry, or demand was not directed to the whistleblower personally (or to the whistleblower's representative).
- Permit officers/directors, trustees, auditors, internal compliance personnel, and investigators to become whistleblowers under various circumstances, including after the passage of at least 120 days from the date that information related to a securities law violation was provided to the company's audit committee or certain persons with compliance responsibilities.

The program went into effect on August 12, 2011. In connection with this program, the SEC launched a new webpage that includes information on eligibility requirements, as well as directions on how to submit a complaint and how to apply for an award.

For additional insight into the final rules, see this *Jones Day Commentary*.

Bill to Implement Government Reporting Requirements on FCA Cases Introduced. On May 5, 2011, Senator Patrick Leahy (D-VT) and three cosponsors introduced a bill entitled the "Fighting Fraud to Protect Taxpayers Act of 2011." On June 30, 2011, congressional hearings were held on the bill, which would create greater transparency with respect to FCA cases and likely speed up the handling and resolution of such cases. In particular, the bill would require the Attorney General to provide a report to Congress each year that would describe the settlement or compromise of any FCA cases and include, among other things, the date on which the complaint was originally filed, a description of the period the matter remained under seal, the date on which the government determined whether to intervene, and the date on which the settlement or compromise was finalized.

RECENT DEVELOPMENTS IN FCA CASES: FILINGS, MOTIONS, AND SETTLEMENTS

Recent notable FCA cases involving participants in the health care industry include the following:

Manufacturers

- In July 2011, Medco and AstraZeneca received joint DOJ subpoenas related to the drugs Prilosec and Nexium. An FCA lawsuit brought by a former Medco executive is ongoing.
- In June 2011, UCB, a Belgian pharmaceutical company, agreed to pay $34 million to settle an FCA suit alleging off-label promotion of the epilepsy drug Keppra for use for headaches and mood control.

Providers

- In July 2011, the U.S. elected to intervene in a lawsuit against Nurses' Registry and Home Health Corporation. The complaint alleges that the company exaggerated the medical conditions and needs of its patients in order to qualify for Medicare claims.
- In May 2011, Quest Diagnostics, the largest provider of medical lab services in California, agreed to pay $241 million to settle a whistleblower suit that alleged that it had overcharged the state Medi-Cal program and that it had paid illegal kickbacks to doctors, hospitals, and clinics in exchange for referrals. It is the largest settlement yet under the California False Claims Act.
- Also in May 2011, a federal judge in Tennessee granted the government's motion for summary judgment and

ordered Fresenius Medical Care AG, the largest provider of kidney dialysis, to pay $82.6 million in damages (trebled damages of $38.9 million and statutory penalties of $43.7 million). The company has announced it will appeal.

INTERNATIONAL DEVELOPMENTS IN HEALTH CARE

German Physicians and Company Representatives May Face Personal Criminal Liability. Two panels of the German Federal Supreme Court have recently referred cases to the full court that may result in licensed doctors-in-residence (*Vertragsärzte*) being subject to personal criminal liability for accepting inducements or incentives from drug and device manufacturers. The potential liability would stem from anti-corruption statutes targeted at public officials or, in the alternative, from statutes criminalizing corrupt business activities. Such liability would then extend to any company representatives involved.

To date in Germany, only public hospitals have been exposed to criminal liability under these theories. By contrast, doctors-in-residence so far have been considered neither public officials nor business affiliates of the public health insurance organizations. If this assessment changes, however, both doctors-in-residence and companies will be exposed to enforcement by public prosecutors and police authorities. Currently, enforcement is conducted by professional organizations (for doctors) and by supervisory authorities (for companies). The decision of the full court is expected in 2012.

UK Bribery Act Affects Pharmaceutical Industry. In April 2011, the Association of the British Pharmaceutical Industry ("ABPI") and its Code of Practice administrative arm, the Prescription Medicines Code of Practice Authority ("PMCPA"), developed a Memorandum of Understanding with the Serious Fraud Office ("SFO") to clarify which agency is likely to be responsible for enforcement when a Code breach also involves a potential breach of the UK Bribery Act. The UK Bribery Act went into effect on July 1, 2011. The underlying premise of the memorandum is:

> Self regulation should be the first means of dealing with complaints. Both the PMCPA and the SFO deal with complaints whatever their source. The SFO focus is on dealing with complaints that are not covered by the ABPI Code or other self regulatory authorities and which meet its criteria of serious fraud.

The approach of the SFO is outlined in the memorandum:

- Companies need to have in place robustly defined and implemented antibribery procedures with clear ownership from the top of the organization;
- The SFO and others agree that sensible proportionate promotional expenditure is entirely legitimate and not outlawed by the Bribery Act;
- The SFO will not routinely intervene in matters covered by the Code but reserves the right to take action if the issue is deemed serious enough to merit SFO investigation and will submit complaints to the PMCPA when appropriate;
- The SFO will not seek to prosecute unless it considers that prosecuting is in the public interest. In reaching such a decision, the SFO will take into account relevant action taken by the PMCPA and the MHRA; and
- The SFO is aware of the requirements of other industry codes, including the International Federation of Pharmaceutical Manufacturers and Associations Code of Pharmaceutical Marketing Practices.

JONES DAY ATTORNEYS ASSUME LEADERSHIP ROLES IN AHLA

In July 2011, Jones Day partner **Gerry Griffith** (Chicago) assumed the role of the President of the American Health Lawyers Association ("AHLA") for 2011–12. AHLA is the nation's largest educational organization devoted to legal issues in the health industry and has more than 10,000 members who provide leadership, legal representation, and corporate and regulatory counsel to an industry estimated to exceed 13 percent of the gross domestic product—nearly $1 trillion.

Other Jones Day attorneys are also currently serving in leadership positions for AHLA:

- **Kevin Lyles** (Columbus)–Co-Leader, Electronic Health Records
- **Jeff Kapp** (Cleveland)–Vice Chair, Business Law & Governance
- **Heather O'Shea** (Chicago)–Vice Chair, Fraud & Abuse

- **James Dutro** (San Francisco)–Member, Program Planning Committee for Hospitals and Health Systems Law Institute
- **Toby Singer** (Washington)–Member, Program Planning Committee for Antitrust in Healthcare Program (Past Chair, Antitrust Practice Group)
- **Jim King** (Columbus)–Member, Program Planning Committee for Tax Issues for Healthcare Organizations (Past Chair, Tax & Finance Practice Group)
- **Travis Jackson** (Boston)–Vice Chair, Tax & Finance Practice Group; Member of the Diversity Council

LAWYER CONTACTS

For more information regarding matters related to any of the above issues, please contact your principal Jones Day representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com. Jones Day prepares summaries of significant health care litigation and policy events as a service to clients and interested readers in order to provide timely insight on these matters. Please use our Publications Sign-Up Form, available at www.jonesday.com/newsknowledge/PublicationSignup.aspx, to add your name to our distribution list.

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