JONES DAY

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HEALTH CARE COMPLIANCE AND ENFORCEMENT UPDATE

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The *Jones Day Health Care Compliance and Enforcement Update* is intended to keep our clients abreast of key legal developments affecting the health care industry. For more information about these and other matters of interest to you and your company, please contact your principal Jones Day representative or one of the lawyers listed below.

Recent trends in legislation, investigations, and litigation point toward heightened scrutiny of participants in the health care industry. Three of these trends—greater emphasis on individual accountability, increased resources for enforcement, and expanded scope of sanctionable conduct—and other developments are discussed in this *Update*.

RECENT CASES UNDERSCORE HEIGHTENED ENFORCEMENT ACTIVITY DIRECTED AT INDIVIDUALS

Former In-House Counsel with Pharmaceutical Company Reindicted. On April 13, 2011, a federal grand jury in Maryland returned an indictment charging Lauren Stevens, formerly a vice president and associate general counsel for GlaxoSmithKline (GSK), with obstruction of justice and making false statements to the Food and Drug Administration (FDA) in connection with an investigation into allegations that the drug Wellbutrin had been marketed for unapproved uses. Stevens had previously been indicted in November 2010, but that indictment was dismissed after federal District

Judge Roger Titus found that "erroneous and prejudicial legal advice [was] given to the grand jury" regarding the advice of counsel defense.

The government alleges that Stevens improperly withheld documents that should have been produced during the investigation and made false statements about activities related to the marketing of Wellbutrin. Trial is scheduled to begin April 26.

Current CEO Faces Possible Exclusion from Federal Health Care Programs. Last year, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published its "Guidance for Implementing Permissive Exclusion Authority." This guidance makes clear that officers and managing employees of health care companies may be excluded from participation in federal health care programs "based solely on their position within the entity," and it identifies relevant factors for the OIG to consider in determining whether to exclude such an officer or managing employee "in the absence of evidence that the person knew or should have known of the misconduct."

In what appears to be the first case of a possible exclusion action against a corporate officer under this guidance, Howard Solomon, Chairman, CEO, and President of Forest Laboratories, Inc., received a "notice of intent to exclude" letter from the OIG on April 12, 2011, based on matters that were settled by Forest in 2010. That settlement related to allegations that a subsidiary improperly distributed and promoted, and committed False Claims Act violations with respect to, certain drugs. As part of the settlement, the subsidiary agreed to pay more than $313 million, entered into a Corporate Integrity Agreement, and pleaded guilty to two strict liability misdemeanor violations of the federal Food, Drug, and Cosmetic Act and one criminal felony count of obstructing justice.

According to a Forest press release, there was "no finding of knowledge or wrongdoing by Mr. Solomon" in connection with the 2010 settlement, nor was he identified as a target during the government investigation. Instead, the press release states that the basis for the OIG's exclusion is that Solomon "associated with" the company. Solomon has 30 days to respond to the notice, and the company announced that he intends to challenge the exclusion.

Former CEO Sentenced to Home Detention and Probation in Off-Label Case; Motions for New Trial are Denied. On April 13, 2011, the former CEO of InterMune, W. Scott Harkonen, was sentenced to three years of probation, six months of home detention (stayed pending appeal), and 200 hours of community service, and ordered to pay a $20,000 fine, based on his 2009 federal wire fraud conviction for creating and distributing a false and misleading press release related to an unapproved use of the drug Actimmune. (Federal prosecutors had urged the court to sentence Harkonen to a 10-year term of imprisonment, citing the harm to patients and the magnitude of the actual and intended loss.) On April 18, 2011, federal District Judge Marilyn Hall Patel denied Harkonen's motions for a new trial. InterMune had previously entered into a deferred prosecution agreement and agreed to pay approximately $37 million to resolve criminal charges and civil liability related to the off-label promotion at issue. The company was also required to enter into a Corporate Integrity Agreement with the OIG.

Former CEO Sentenced to One Month Imprisonment and Ordered to Pay $1.9 Million. On March 10, 2011, the former CEO of K-V Pharmaceutical, Marc Hermelin, was sentenced to 30 days in prison after pleading guilty to two federal charges of misbranding drugs. Hermelin was also ordered to pay a fine of $1 million and restitution of $900,000.

In 2008, K-V Pharmaceutical had received complaints from pharmacists who reported finding oversized tablets. After an internal investigation, the company issued a recall of specific lots of morphine and submitted a field alert to the FDA referencing the oversized morphine tablets. But, according to the government, the company failed to disclose that it had also identified instances of oversized tablets of other drugs. In March 2009, K-V and its subsidiaries (including Ethex Corporation) entered into a consent decree barring them from the manufacture or distribution of drugs until an independent expert and FDA officials certified that they were in compliance with the Food, Drug, and Cosmetic Act. In February 2010, the company agreed to pay $27.6 million to settle criminal charges arising from the 2008 violations. In

November 2010, in order to avoid exclusion of the company, Hermelin voluntarily resigned from the board of directors and was individually excluded from participation in federal health programs.

Purdue Executives Appeal Order Upholding Exclusion. On January 31, 2011, three former Purdue executives filed an appeal to challenge Judge Ellen Segal Huvelle's (D.D.C.) order upholding the HHS Secretary's decision to exclude them from participation in federal health care programs. The executives' exclusion followed a 2007 settlement agreement with the U.S. Attorney's Office for the Western District of Virginia in which the three executives pleaded guilty to a strict liability misdemeanor misbranding charge resulting from their positions as responsible corporate officers.

FDA Issues Guidelines for Responsible Corporate Officer Prosecutions. On January 26, 2011, the FDA issued guidelines setting forth factors that it will consider in recommending prosecutions under the Responsible Corporate Officer doctrine (commonly known as the "Park" doctrine).

The FDA guidelines note that a responsible corporate officer can be held liable under the Food, Drug, and Cosmetic Act even without proof that the officer acted with unlawful intent or was negligent, and even if the officer had no actual knowledge of, and did not participate in, the underlying conduct. Misdemeanor convictions may serve as the basis for exclusion (as demonstrated in the *Purdue* case discussed above), and any subsequent violation of this provision by the same person is treated as a felony.

In addition to considering the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation, the guidelines identify seven factors for the FDA to consider in deciding whether to recommend charging a misdemeanor violation, including, among others, whether the conduct involved actual or potential harm to the public and whether it reflects a pattern of illegal behavior and/or failure to heed prior warnings.

In an interview published in *The Philadelphia Inquirer*, FDA litigation chief Eric Blumberg projected the impact of the agency's emphasis on individual accountability: "In my view, one thing that will get executives' attention is a few cases in which we have convicted two-legged defendants."

FEDERAL AGENCIES EXPAND OUTREACH AND RAMP UP RESOURCES FOR HEALTH CARE ENFORCEMENT

HHS and the Department of Justice (DOJ) have initiated several programs to enhance awareness of health care compliance requirements and enforcement efforts and to significantly increase the resources devoted to detecting fraud and abuse in the health care industry:

- On February 17, 2011, the Medicare Fraud Strike Force carried out a nationwide operation, charging 111 individuals in nine cities with participation in alleged Medicare-fraud schemes involving more than $225 million. On the same day, the OIG announced that the Strike Force was being expanded to include Dallas and Chicago, in addition to the seven cities/regions previously covered (Baton Rouge, Brooklyn, Detroit, Houston, Los Angeles, Miami-Dade County, and Tampa Bay).

- On February 15, 2011, HHS and DOJ announced that 20 individuals had been charged with various health care fraud, kickback, and money-laundering schemes involving approximately $200 million in south Florida.

- On February 14, 2011, President Obama released the FY 2012 Budget Proposal, which includes $581 million for Health Care Fraud and Abuse Control. This amount represents an increase of $270 million from the amount allocated in FY 2010.

- On February 3, 2011, the OIG launched its "Most Wanted Fugitives" list, which provides photographs and profiles of individuals sought by law enforcement authorities on charges of health care fraud and abuse. There are currently more than 170 fugitives on the list.

- On January 31, 2011, the OIG announced that it would offer free Provider Compliance Training as part of its Health Care Fraud Prevention and Enforcement Action Team (HEAT) program. HEAT is a multiagency federal initiative that was launched in May 2009 and combines resources from HHS and DOJ to combat fraud in Medicaid and Medicare programs. Addressing similar issues, the OIG released "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse" in October 2010 and supplemented this with additional materials released in February 2011.

RECENTLY INTRODUCED LEGISLATION MAY HAVE SIGNIFICANT IMPACT ON HEALTH CARE INDUSTRY

Bill to Address Integrity and Accountability Is Introduced. On March 2, 2011, Senator Chuck Grassley (R-Iowa) introduced a bill (S. 454) containing several measures designed to address health care fraud (Strengthening Program Integrity and Accountability in Health Care Act of 2011). The bill's provisions include: expanding the scope of individuals who can be excluded from participation in federal health care programs; allowing Medicare to delay payment of claims when fraud is suspected; requiring states to verify with the FDA that a drug is approved for a particular use and properly marketed; establishing a national database of information to prevent and detect medical identity theft; and making Medicare provider payment information publicly available.

Bill to Expand Exclusion Authority of HHS Is Reintroduced. On February 11, 2011, Representatives Wally Herger (R-Calif.) and Pete Stark (D-Calif.) reintroduced in the House a bipartisan bill (H.R. 675) that would expand the categories of persons subject to exclusion from participation in federal health care programs. In particular, the proposed bill (Strengthening Medicare Anti-Fraud Measures Act of 2011) would amend 42 U.S.C. § 1320a-7(b)(15) to authorize permissive exclusion of "Individuals or Entities Affiliated with a Sanctioned Entity." This provision would cover current and former officers and managing employees, as well as any current or former "person with an ownership or control interest … [who] knows or should know … of such conduct." Currently, the OIG may exclude only officers and employees who are with the sanctioned entity at the time the sanction is imposed. This bill would enable the OIG to exclude individuals even if they had left the sanctioned entity prior to the sanction. The bill was originally introduced last September (as H.R. 6130) and passed in the House by a voice vote. It was then sent to the Senate but did not make it out of committee before the end of the session.

In addition, the bill authorizes exclusion of "any affiliated entity of a sanctioned entity." Under this provision, a parent company could be excluded on the basis of the conviction or exclusion of a subsidiary, and the exclusion could extend to officers, managing employees, and persons with an ownership or control interest in the affiliated entity. The effect of this provision would be to not allow a company to avoid exclusion simply by having an affiliated entity plead guilty to the triggering offense.

Significantly, section 6502 of the Patient Protection and Affordable Care Act of 2010, which mandated the exclusion of affiliated entities from Medicaid participation, was repealed on December 15, 2010 due to concerns that it would deprive Medicare and Medicaid beneficiaries of access to many necessary drugs. By contrast, the permissive exclusion proposed by the reintroduced bill would allow the government to consider the full effect of exclusion before deciding whether to impose this sanction.

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

Recent notable False Claims Act (FCA) cases involving participants in the health care industry include the following:

Manufacturers

- On March 29, 2011, the Supreme Court unanimously reversed the Ninth Circuit's ruling in *County of Santa Clara, et al. v. Astra U.S.A. Inc., et al*. The Court held that when a statutory scheme is implemented by means of a contract, a person that benefits from the contract cannot sue to enforce it as a third-party beneficiary unless Congress

affirmatively conferred a private right of action. Therefore, certain public-health entities (Section 340B hospitals and clinics) lacked standing to bring an action to enforce ceiling-price contracts between drug manufacturers and the Secretary of HHS.

- In settlements announced on March 10, 2011, AstraZeneca Pharmaceuticals agreed to pay $68.5 million to 37 states and the District of Columbia to resolve allegations that it marketed Seroquel for uses not approved by the FDA (including use in pediatric and geriatric populations), that it failed to adequately disclose potential side effects, and that it withheld some negative studies concerning safety and efficacy. Several other states have ongoing actions related to the same allegations.

- On February 1, 2011, a Texas jury returned a $170 million verdict against Actavis Mid-Atlantic LLC, finding that the company had reported inflated prices to Texas Medicaid. The relator in the case was Ven-A-Care of the Florida Keys. This was the first drug-pricing case to go to trial in Texas.

Providers

- On February 18, 2011, the Seventh Circuit reversed a lower court's dismissal of an FCA suit alleging that Advanced Healthcare Associates submitted claims for services not rendered. The lower court had dismissed on the basis that there had been public disclosure of industry-wide fraud in the chiropractic arena and that the relator, Kelly Baltazar, was not an original source of that disclosure. In reversing the dismissal, the Seventh Circuit noted that "[o]ther courts of appeals have concluded that reports documenting a significant rate of false claims by an industry as a whole … do not prevent a *qui tam* suit against any particular member of the industry."

- In a settlement announced on January 4, 2011, seven additional hospitals agreed to pay more than $6.3 million to settle allegations that they performed kyphoplasty as an inpatient rather than an outpatient procedure in order to increase their Medicare billings. The relators in these cases were Craig Patrick, a former reimbursement manager for Kyphon, and Charles Bates, formerly a Kyphon regional sales manager. The relators will receive a total of approximately $1.1 million as their share of the settlement proceeds. These cases have been the subject of discussions and correspondence between the American Hospital Association (AHA) and DOJ, since the "fraud" is based on the location of the procedure rather than the need to perform it. The AHA's position is that physicians should have discretion in determining the appropriate procedure location. Even if some of the procedures could have been performed on an outpatient basis, performing them on an inpatient basis should be characterized as a mistake and/or overpayment and not as a deliberate fraud.

UPCOMING EVENTS

This month, the SEC is scheduled to implement the whistleblower reward program mandated by the Dodd-Frank Wall Street Reform and Consumer Protection Act. Watch for further information from Jones Day regarding this program after implementation.

On May 18, 2011, the OIG will present its Provider Compliance Training (referenced above) as a webcast. For more information, go to http://compliance.oig.hhs.gov/enrollment.html.

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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