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KIRKLAND **ALERT**

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Individuals at Risk:

Recent Threatened Exclusion of Pharmaceutical Company CEO Reveals the Dangers of Increasingly Aggressive Enforcement Under Section 1128(b)(15) of the Social Security Act

Howard Solomon's Threatened Exclusion

On April 12, 2011, the Department of Health and Human Services' Office of Inspector General (HHS OIG) notified Howard Solomon, the long-time CEO and Chairman of Forest Laboratories, a leading manufacturer of antidepressant pharmaceuticals, that it was contemplating initiating proceedings to exclude him from all federal health care programs. The notification came in the wake of Forest Laboratories' civil and criminal settlement with the federal government. In its notification letter, HHS OIG gave no reason for its decision beyond the fact that Mr. Solomon was the company's CEO.

HHS OIG's actions were based on the global criminal and civil settlement that Forest Laboratories entered into with the federal government last year. That settlement resolved allegations of off-label marketing and other sales-related misconduct concerning the company's leading antidepressant drugs, Celexa and Lexapro, and the improper distribution of Levothroid, a drug used to treat hypothyroidism. The company paid over $300 million and admitted to misdemeanor counts of off-label marketing and misbranding and a felony count of obstruction of justice to settle the charges.

Critically, however, there was never any admission — or even evidence — of knowledge by Mr. Solomon of any of the conduct that triggered the charges against the company. Under such circumstances, HHS OIG's contemplated exclusion of Mr. Solomon based solely on his position as CEO was without precedent.

News of HHS OIG's actions to potentially exclude the 83-year-old CEO triggered substantial criticism, including a front page article in the *Wall Street Journal* on April 26, 2011. Editorials in leading national newspapers were published in opposition to HHS OIG's aggressive move. At the same time, Forest Laboratories issued a press release, stating that it was preparing to "commence immediate litigation" to defend Mr. Solomon.

Perhaps in response to this, on May 10, 2011, HHS OIG issued a press release, ostensibly to clarify the scope of its exclusion authority and "correct some inaccuracies" that it claimed had emerged in the media in recent weeks. The press release ended with the statement that "OIG has not excluded Howard Solomon[.]" Whether or not that release signals a retrenchment from its move against the CEO, HHS OIG's actions in the last month represented an unprecedented interference with a company's ability to select and retain management of its own choosing, where such management was not even charged with, let alone convicted of, wrongdoing.

Such actions must be seen as part of a larger and increasingly aggressive enforcement effort advanced by HHS OIG against the nation's health care companies. As discussed below, section 1128(b)(15) of the Social Security Act has fast become a favored weapon in the agency's enforcement campaign.

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HHS OIG's Exclusion Powers

HHS OIG has had the power to "exclude" for health care related misconduct since 1977. In the beginning, this power was relatively circumscribed: HHS OIG's exclusion authority was limited to "physician[s] or other practitioner[s]" and could only be exercised in the event that someone was convicted for a criminal offense related to his or her involvement in the Medicare or Medicaid programs.

Over time, however, the agency's power grew both in terms of *who* could be excluded and *what* could trigger an exclusion. "[P]hysician[s] or other practitioner[s]" became "physician[s and] other individual[s]" which in turn became "individuals and entities." In 1998, by an administrative rule, HHS OIG expanded its authority even further, claiming that it could exclude not just individuals and entities that directly billed federal health care programs for reimbursement, but also individuals and entities that simply supplied medical items and services to *other* individuals and entities that, in turn, billed federal health care programs for reimbursement.

Similarly, the types of misconduct that can trigger an exclusion have grown over time. Under the primary exclusion statute of the Social Security Act, there are now four separate categories of conduct that *mandate* HHS OIG exclusion of individuals and entities and fifteen separate categories of conduct that, though not mandating, *permit* exclusion of individuals and entities.

Exclusion Under Section 1128(b)(15)

Section 1128(b)(15) of the Social Security Act provides one of the fifteen permissive bases under which HHS OIG may exercise its exclusion authority. Under section 1128(b)(15), HHS OIG "may exclude . . . from participation in any Federal health care program . . . [a]ny individual . . . who is an officer or managing employee . . . of [a sanctioned] entity."

The Social Security Act defines a "sanctioned entity" to include companies that have been:

- Convicted of any criminal offense that triggers a mandatory exclusion under the Social Security Act, including criminal convictions for patient abuse, fraud against a health care program, substance abuse, and other serious health-care program-related crimes; or
- Convicted of any criminal offense related to the obstruction of an audit or investigation of: (1) a serious health care crime or (2) the use of funds received from federal health care programs; or
- Convicted of a criminal misdemeanor related to fraud against a health care program, the delivery of health care items or services, or substance abuse; or
- Otherwise excluded from participation under a Medicare or state health care program.

The Social Security Act defines "managing employee" to include *any* individual who "exercises operational or managerial control over the [company], or who directly or indirectly conducts the day-to-day operations of the [company]." The Social Security Act specifically mentions administrators, directors, managers, and general managers as possible "managing employees," though such employees must still exercise "operational or managerial control" or "directly or indirectly conduct the day-to-day operations of the [company]" before being deemed "managing employee[s.]"

Section 1128(b)(15) thus subjects a wide swath of individuals in the pharmaceutical industry to a risk of exclusion by HHS OIG. Not merely companies' chief executives are at risk; ordinary front-line employees with modest levels of managerial involvement in a convicted or excluded company also face a real danger of exclusion.

The Effects of Exclusion

The primary effects of exclusion by HHS OIG are twofold. First, individuals or entities that are excluded are prohibited from receiving reimbursement from Federal health care programs for any medical items or services they furnish. The term "Federal health care program" is defined so as to include payments from joint state-federal Medicaid programs. Second, if a non-excluded individual or entity contracts or otherwise arranges with an excluded individual or entity for the furnishing of medical items or services, it is subject to severe monetary penalties; if a non-excluded entity is controlled by an excluded individual or entity, it is also at risk of being excluded.

For example, if a hospital contracted with an excluded physician to work at the hospital, the hospital would be subject to substantial civil penalties for every health care reimbursement claim submitted by or on behalf

of the physician for services provided through his employment there. If the physician was in a position of control over the hospital (for example, through a substantial ownership interest), the hospital would also be at risk of being excluded by HHS OIG.

HHS OIG has openly admitted that the practical effect of an exclusion for many individuals "is to preclude [their] employment . . . in any capacity by a health care provider that receives reimbursement, indirectly or directly, from any Federal health care program." This reality was reflected in Forest Laboratories' April 13 press release, where it acknowledged that an exclusion of Mr. Solomon would necessitate him "step[ping] down from his present executive positions."

For mandatory exclusions based on a first conviction, the period of exclusion must last a minimum of five years. A second conviction results in a minimum ten-year exclusion. A third conviction results in an exclusion that is permanent. The length of permissive exclusions will vary depending on the specific basis for exclusion, but many permissive exclusions require a minimum exclusionary period of three years.

Section 1128(b)(15) Enforcement: A Brief History

The potential scope of enforcement under section 1128(b)(15) was not always apparent. Brought into force in 1997 as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the first decade of enforcement activity under section 1128(b)(15) was minimal to non-existent, at least for officers and managing employees at large health care companies.

In 2009, that state of affairs began to change. In July of that year, Emmanuel Bernabe, CEO of Pleasant Care Corporation, California's then-second-largest nursing home business, was permanently excluded by HHS OIG. The exclusion came at the conclusion of a multi-year investigation into the quality of care at the company's 29+ nursing home facilities across the state. Bernabe contested all allegations against his company while denying any liability; no judgment or finding of liability was ever made against him.

Despite this, the CEO ultimately agreed to be permanently excluded. HHS OIG's claimed technical basis for its action was section 1128(b)(6)(B) of the Social Security Act, a provision aimed at preventing the furnishing of health care services "of a quality which fails to meet professional recognized standards of health care[.]" Nevertheless, its unprecedented exclusion of a large health care corporation's CEO absent any admission of knowledge or wrongdoing presaged the novel era of aggressive enforcement against individuals under section 1128(b)(15).

That novel era fully emerged this past year. In late-February of 2010, Ethex Corporation, a subsidiary of K-V Pharmaceutical Company, pled guilty to criminal charges for misbranding and adulterating its pharmaceutical products and failing to file reports on those products with the Food and Drug Administration. Shortly thereafter, K-V Pharmaceutical's CEO, Marc Hermelin, pled guilty to two misdemeanor counts under the "responsible corporate officer" doctrine. That doctrine provides for expansive strict misdemeanor criminal liability for senior officers (and others) under the Federal Food, Drug, and Cosmetic Act if the government chooses to invoke it.

In November of 2010, Hermelin entered into an agreement with HHS OIG providing for his exclusion under section 1128(b)(15). Importantly, HHS OIG emphasized that Hermelin's exclusion was based on the guilty plea of Ethex; Hermelin's own plea agreement did not factor into the agency's exclusion determination.

In December of 2010, a federal district court upheld HHS OIG's permissive exclusions of three Purdue Pharma executives based on earlier plea agreements entered into by the executives and their company for wrongful promotional and medical claims regarding the painkiller OxyContin. It is important to note that each of the three executives pled to a criminal offense, though, in each instance, the offense was a strict liability misdemeanor. HHS OIG claimed it had authority to exclude the executives under sections 1128(b)(1) and 1128(b)(3) of the Social Security Act. Nevertheless, its move against the executives was recognized as part of a larger emerging effort by the agency to use its exclusion powers against individuals in the industry.

Against this backdrop, HHS OIG's April, 2011 announcement that it was contemplating excluding Howard Solomon under section 1128(b)(15) appears as a mere continuation of this trend of increasingly aggressive enforcement tactics against officers and employees of pharmaceutical companies. That this most recent proposed exclusion was directed against an individual who neither knew of any misconduct nor was charged with any criminal or civil offense only highlights the growing aggressiveness of HHS OIG's enforcement approach.

The October 2010 HHS OIG Guidelines

Tied to this trend of aggressive enforcement is the October, 2010 publication of a set of aggressive guidelines, outlining how HHS OIG will interpret and enforce section 1128(b)(15) going forward. Though non-binding, these guidelines have proven to be predictive of the agency's enforcement behaviors.

The October, 2010 guidelines (the "Guidelines") create a two-pronged regime for section 1128(b)(15) exclusions. *First*, there is a *presumption* that an individual officer or managing employee should be excluded when there is evidence that that officer or employee knew or should have known of the conduct giving rise to the corporation's conviction or exclusion. This presumption can only be overcome if there are significant factors weighing against exclusion.

Second, *even in the absence of any evidence* that the officer or employee knew or should have known of the conduct giving rise to the corporation's conviction or exclusion, an individual or officer is still *at risk* of exclusion. Specifically, in such circumstances, the Guidelines indicate that HHS OIG will consider four factors in determining whether to exclude:

- The circumstances and seriousness of the company's misconduct (for example, whether the misconduct was an isolated incident or part of a larger pattern);
- The individual's role at the sanctioned entity (for example, the relationship between the individual's position and the misconduct that occurred);
- The individual's response to the misconduct (for example, did the individual cooperate with investigators);
- Background information about the sanctioned entity (for example, had the sanctioned entity been previously convicted).

Take note that only the third factor is under the direct control of an individual at risk of being excluded.

HHS OIG Congressional Testimony

Coming on the heels of the Guidelines' release, HHS and HHS OIG leadership has used congressional testimony to express an intent to move more aggressively against executives at health care, medical devices, and pharmaceutical companies under section 1128(b)(15). For example, on March 9, 2011, in testimony before a subcommittee of the U.S. Senate's Committee on Homeland Security and Governmental Affairs, Daniel Levinson, Inspector General of HHS OIG, freely admitted that the agency was focused on the possibility of using section 1128(b)(15) against executives of "major health care entit[ies.]" The Inspector General emphasized that this could occur even in cases where HHS OIG determines that it is in the nation's best interest to *not* exclude the company itself.

Similarly, on April 5, 2011, in testimony before a subcommittee of the U.S. House of Representatives' Committee on Oversight and Government Reform, Gerald Roy, Deputy Inspector General for Investigations at HHS OIG, acknowledged that, until recently, section 1128(b)(15) exclusion actions had been focused on "smaller companies" like pharmacies and billing services. However, Roy went on to admit that HHS OIG "intend[s] to use [section 1128(b)(15)] in a broader range of circumstances" going forward. Roy made specific reference to the exclusion of Marc Hermelin and the three Purdue Pharma executives.

The upshot of this and other HHS OIG testimony is that the agency and its leadership are focused on section 1128(b)(15) and its enforcement power.

Intelligent Strategies

Permissive exclusions of individuals under section 1128(b)(15) and other related sections of the Social Security Act are difficult to anticipate, difficult to guard against, and, as shown by the outcome in the case of the three Purdue Pharma executives (each of whom lost their appeals within the agency and at the federal district court level), difficult to effectively respond to legally. Nevertheless, there are certain intelligent steps that every organization should take in this increased climate of individual exclusion risk.

Recall, only one of the four factors that HHS OIG will consider in determining whether to initiate exclusion proceedings is under the direct control of individuals at risk of exclusion. That factor, the individual's response to the corporate misconduct, is evaluated in terms of three specific sub-factors as enumerated in the Guidelines:

- Whether appropriate prior actions were taken by the individual (for example, reporting the disciplinary problems of an employee if the corporate misconduct related to that employee);
- Whether, following the misconduct, the individ-

ual cooperated with any investigation (for example, by timely producing documents);

- Whether the misconduct can be shown to have been unpreventable (for example, if it can be shown that the misconduct would have occurred in spite of the individual's exercise of "extraordinary care").

Based on these sub-factors, companies should create training and reporting programs and systems; such programs and systems will be aided by broader efforts to foster an institutional culture that encourages individual behavior which minimizes the risk of non-knowledge-based exclusion under the Guidelines' second prong.

Looking Forward

HHS OIG's increasingly aggressive enforcement under section 1128(b)(15) runs the risk of creating a climate of substantial uncertainty within the health care industry, discouraging individuals' participation and investment in a critical sector of the nation's economy. As discussed above, there are certain steps that all companies within the industry should take to guard against individual exclusion risks. In the longer run, it may be necessary to consider regulatory or even legislative modifications to ensure that the set of tools HHS OIG has available to it serve to protect the nation's health care laws while still guaranteeing that individuals in the health care industry are able to effectively participate in the critical task of providing medical care and products to the country. Whether the current regime of enforcement under section 1128(b)(15) is satisfying this requirement is an open question, sure to further develop in the coming months. We will continue to update our clients regarding these specific issues as they emerge and evolve.

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