IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MICHAEL FRIEDMAN, PAUL D. GOLDENHEIM, HOWARD R. UDELL, Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Civil Nos.1:09-cv-02028(ESH); 1:10-cv-78(ESH); 1:10-cv-130(ESH) ELECTRONIC CASE FILING

BRIEF OF *AMICUS CURIAE* WASHINGTON LEGAL FOUNDATION

SKADDEN, ARPS, SLATE, MEAGHER
& FLOM LLP
Amy R. Sabrin (D.C. Bar No. 409721)
1440 New York Avenue, N.W.
Washington, D.C. 20005
(202) 371-7000

WASHINGTON LEGAL FOUNDATION
Daniel J. Popeo (D.C. Bar No. 934711)
Richard A. Samp (D.C. Bar No. 367194)
2009 Massachusetts Avenue, N.W.
Washington, D.C. 20036
(202) 588-0302

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BRIEF OF THE WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS

INTERESTS OF *AMICUS CURIAE*

The interests of the Washington Legal Foundation ("WLF") are set forth more fully in the attached motion for leave to file this brief.

In short, WLF is a public interest law and policy center with members and supporters in all 50 states. WLF devotes a substantial portion of its resources to defending the right of individuals and businesses to go about their affairs without undue interference from government regulators. WLF does not condone the dissemination of inaccurate information about FDA-approved medications, and it applauds federal government efforts to prevent such dissemination. It does, however, seek to ensure that the government respects individual rights and that it does not impose restrictions on individual and economic activity in the absence of evidence of individual blameworthiness, or in a manner not authorized by law.

In particular, WLF's members and supporters include corporate executives who are directly threatened by the government's use of the responsible corporate officer ("RCO") doctrine to impose strict criminal liability on corporate officials and to impose harsh consequences therefore, such as lengthy exclusion from participation in government programs that occurred here. This case has taken on even greater significance to WLF's members and supporters because the Food and Drug Administration ("FDA") recently announced plans to increase the number of prosecutions of corporate executives pursuant to the RCO doctrine.[1]

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[1] *See* Letter from Margaret A. Hamburg, FDA Commissioner, to The Honorable Charles E. Grassley, ranking member of the Senate Finance Committee (Mar. 4, 2010), *available at* http://finance.senate.gov/press/Gpress/2010/prg030410b.pdf.

Accordingly, WLF has long opposed use of the criminal laws to punish executives for corporate misconduct that they neither condoned nor were even aware of, and has regularly appeared in court proceedings to express that view. *See, e.g.*, *United States v. Hanousek*, 176 F.3d 1116 (9th Cir. 1999); *United States v. Hansen*, 262 F.3d 1217 (11th Cir. 2001). It has the same substantial interest in being heard here as well.

INTRODUCTION

The Secretary of Health and Human Services ("HHS"), through the HHS Office of Inspector General ("OIG"), plays an important role in ensuring the integrity of federal health care programs. To maintain that integrity, the Secretary is authorized to exclude individuals from participation in federal health care programs when their personal conduct demonstrates that they cannot be trusted to comply with laws governing those programs. Of particular relevance here, Congress empowered the Secretary to exclude individuals and entities who have been convicted of certain offenses that implicate the integrity of federal health care programs. *See* 42 U.S.C. §§ 1320a-7(a)(1-2) (mandating exclusion for convictions of program-related crimes or crimes related to patient abuse); (a)(3-4) (mandating exclusion for felonies related to health care fraud or controlled substances); (b)(1-3) (permitting exclusion for misdemeanor convictions related to fraud, obstruction, or controlled substance offenses) (collectively, "the exclusion statute"). We respectfully submit, however, that the exclusion statute does not empower the Secretary to exclude an individual who has been convicted of a misdemeanor that is not premised on facts that he personally committed one of the offenses enumerated in the statute. Yet that is exactly what occurred here.

The Secretary excluded three pharmaceutical executives ("Plaintiffs") based on their guilty pleas to a misdemeanor violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") that was based on the fact that these individuals were responsible officers of a

pharmaceutical company at a time when certain other company employees engaged in the improper promotion of one of the company's drugs. The Agreed Statement of Facts accompanying their pleas did not include any facts that would support a finding that they participated in or knew of the misconduct, or that they were negligent for not knowing.

The Secretary asserts nonetheless that she may exclude Plaintiffs because their misdemeanor pleas "relate to" *other people's* commission of the kind of offenses that would justify exclusion. This interpretation effectively uncouples exclusion from individual responsibility and pushes the RCO doctrine well beyond what the Supreme Court intended when the doctrine was announced more than 60 years ago. Nor does it comport with a plain reading of the exclusion statute or its legislative history. Also, exclusion in these circumstances would not serve the purpose that the statute was intended to serve. The Secretary thus acted in clear derogation of her statutory responsibilities by basing exclusion on offenses that do not meet the statutory exclusion criteria.

Our legal system rarely permits the imputation of liability from one individual to another—even in civil cases. The RCO doctrine, first announced by the Supreme Court in *United States v. Dotterweich,* 320 U.S. 277 (1943), is a rare exception. The Court found it was permissible only in the narrow circumstance where it is deemed necessary to protect the public health and welfare and where the penalties visited on the individual are minor. Here, HHS has bootstrapped that narrow exception to impose draconian consequences—effectively depriving individuals of their livelihoods for more than a decade—thereby taking *Dotterweich* far beyond where the Supreme Court intended it to go.

BACKGROUND

Michael Friedman, Paul D. Goldenheim, and Howard R. Udell served for many years as senior executives of the Purdue Frederick Co., Inc. ("Purdue Frederick"). Purdue

Frederick developed and originally marketed OxyContin®, an opioid analgesic that has brought effective pain relief to countless Americans.

In May 2007, Purdue Frederick entered a guilty plea to felony charges that some of its employees—not Plaintiffs—had misbranded OxyContin® by engaging in improper promotion of the drug. At the same time, each of the Plaintiffs pled guilty to a misdemeanor charge of introducing a misbranded drug into interstate commerce, in violation of the FDCA, 21 U.S.C. §§ 331(a), 333(a)(1). The factual basis for the individual pleas consisted entirely of the following:

> Between in or about January 1996 and on or about June 30, 2001, defendants MICHAEL FRIEDMAN, HOWARD R. UDELL, and PAUL D. GOLDENHEIM, were responsible corporate officers of PURDUE under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a).

Agreed Statement of Facts ("Agreed Statement") at ¶ 45. They also agreed that the court could accept facts pertaining to Purdue Frederick's guilty plea as part of the factual basis supporting their pleas. *Id.* The Agreed Statement did not assert that Plaintiffs had knowledge or notice of the misconduct, *see id.* at ¶ 46, and it did not indicate that they were reckless or negligent in any way in failing to acquire that knowledge.

In March 2008, the OIG informed Plaintiffs that they would be excluded from program participation for 20 years. The OIG based the exclusion decision on 42 U.S.C. § 1320a-7(b)(1), which permits exclusion of an individual who has been convicted of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct, and on 42 U.S.C. § 1320a-7(b)(3), which permits exclusion of an individual who has been convicted of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. After this initial determination, the OIG reduced Plaintiffs' exclusion to 15 years.

In decisions issued January 9, 2009, an administrative law judge ("ALJ") upheld the 15-year exclusions. The ALJ held that the (b)(1) exclusions were warranted because even though Plaintiffs themselves had not engaged in fraudulent conduct, their convictions were "related to" fraud because they were "in a position to prevent or correct the company's fraud, but failed to do so." ALJ Dec. at 7.[2] The ALJ further held that their (b)(3) exclusions were warranted because "the crime of misbranding is directly related to the drug's distribution" and thus their misbranding convictions "related to" the distribution of a controlled substance. ALJ Dec. at 8. The ALJ then identified three aggravating factors that, in her view, justified increasing the exclusion period to 15 years from the presumptively adequate three years. Those factors were: (1) Plaintiffs' "acts" caused, or reasonably could be expected to cause, financial losses of $5,000 or more to a government program; (2) the "acts" that resulted in Plaintiffs' convictions took place over a period of more than one year; and (3) the "acts" that resulted in Plaintiffs' convictions had a significant adverse physical or mental impact on one or more program beneficiaries. ALJ Dec. at 9-13. She found that Plaintiffs had demonstrated one mitigating factor (cooperation with law enforcement officials) and that the cooperation justified reducing the exclusion period from 20 to 15 years. *Id.* at 14.

Plaintiffs' appeals were consolidated before the HHS Departmental Appeals Board ("DAB"). On appeal, the DAB substantially upheld the ALJ's decision on the same grounds. The only point of significant deviation was the DAB's rejection of the third aggravating factor. The DAB found that there was inadequate evidence to show that the acts that

[2] The ALJ's decisions for the three plaintiffs are substantially similar to one another. Page citations in this brief are to the ALJ's decision regarding Udell.

resulted in Plaintiffs' convictions had a significant adverse physical or mental impact on one or more program beneficiaries. On that basis, the DAB reduced the exclusion period to 12 years.

ARGUMENT

I. ALLOWING THE SECRETARY TO EXCLUDE PLAINTIFFS FOR RESPONSIBLE CORPORATE OFFICER CONVICTIONS IS CONTRARY TO THE RATIONALE OF *DOTTERWEICH* AND ITS PROGENY

A. An FDCA Misdemeanor Under the Responsible Corporate Officer Doctrine Is a *Prima Facie* Strict Liability Offense

A general rule of criminal law is that society does not impose criminal sanctions on an individual without first determining that the individual acted with some blameworthy *mens rea*. *See Staples v. United States*, 511 U.S. 600, 605 (1994) ("the requirement of some *mens rea* for a crime is firmly embedded" in "the background rules of the common law"); *United States v. United States Gypsum Co.*, 438 U.S. 422, 436 (1978) ("The existence of a *mens rea* is the rule of, rather than the exception to, the principles of Anglo-American jurisprudence.") (quoting *Dennis v. United States*, 341 U.S. 494, 500) (1951)).

The Supreme Court has recognized a few very narrow exceptions to this principle, one involving the statute to which Plaintiffs pled guilty. The Court held in *Dotterweich* and again in *United States v. Park*, 421 U.S. 658 (1975), that corporate executives could be convicted of FDCA misdemeanors based solely on their responsibility and authority over those who violated the FDCA, even "though consciousness of wrongdoing be totally wanting." *Dotterweich*, 320 U.S. at 284.

Two related statutes formed the basis for conviction here and in *Dotterweich*: 21 U.S.C. § 331(a) prohibits the introduction or delivery for introduction into interstate commerce of any drug that is adulterated or misbranded, and 21 U.S.C. § 333(a)(1) provides that any person who violates § 331(a) is guilty of a misdemeanor. In *Dotterweich*, there was no evidence that the

company's president was personally guilty of the charged misconduct, that he participated in the misconduct, or that he even knew of the misconduct. *Dotterweich*, 320 U.S. at 285-86 (Murphy, J., dissenting). Dotterweich merely "share[d] responsibility in the business process" resulting in the misbranding, according to the Court, and this "responsible relation" provided the Court with enough justification to uphold his conviction. *Dotterweich*, 320 U.S. at 284-85.

Park affirmed and explained *Dotterweich*'s holding. Park was the president of a national food chain whose warehouses became infested with rodents. Park did not personally oversee the warehouses; rather, he delegated these responsibilities. In upholding Park's conviction, the Supreme Court explained that the Government may make out a *prima facie* case against a corporate officer by showing that the officer had "responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so." *Park*, 421 U.S. at 673-74. *Park* reaffirmed *Dotterweich*'s observation that an RCO defendant need not have knowledge of wrongdoing. *Id.* at 672.

The Court used language familiar from negligence standards in finding that Congress had imposed on RCOs a "positive duty to seek out and remedy violations, but also, and primarily, a duty to implement measures that will insure that violations will not occur." *Id.* at 659. But the reality of *Park* is that RCOs may be convicted on a strict liability basis. The presence of a "violation[]" necessarily means that the RCO "failed to [prevent or correct the violation]," making the RCO's "responsibility and authority" the *de facto* sole basis for liability. "It is, in effect, a *prima facie* strict liability standard because the defendant officer's negligence in presumed." *United States v. Cordoba-Hincapie*, 825 F. Supp. 485, 508 (E.D.N.Y. 1993).[3]

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[3] The three *Park* dissenters wanted to require a finding of negligence, to make it a true negligence offense. They would have adopted a rule that "before a person can be convicted of a criminal violation of [the FDCA], a jury must find—and must be clearly instructed that it

(cont'd)

Other courts and commentators have explicitly noted that the RCO doctrine provides for strict liability prosecutions under the FDCA. *See, e.g.*, *United States v. Poulin*, 926 F. Supp. 246, 253 (D. Mass. 1996) ("[A] corporate officer can be held personally liable for violations of law, where there is strict liability, because he is the person who had 'authority with respect to the conditions that formed the basis of the alleged violations'… [citing *Park*]."); *United States v. O'Mara*, 963 F.2d 1288, 1295 (9th Cir. 1992) ("[T]he two cases where the Court interpreted silence to allow strict and vicarious liability involved misdemeanors… [citing *Park* and *Dotterweich*]."); *Stepniewski v. Gagnon*, 732 F.2d 567, 573 (7th Cir. 1984) ("In *United States v. Dotterweich*…, for example, the Court recognized the reasonableness of imposing strict liability under the [FDCA]…"); *Allied Prods. Co. v. Fed. Mine Safety & Health Review Comm'n*, 666 F.2d 890, 893 (5th Cir. 1982) ("[I]t is a common regulatory practice to impose a kind of strict liability on the employer as an incentive…[citing *Park*]."); *Ft. Worth & Denver Ry. Co. v. Goldschmidt*, 518 F. Supp. 121, 130 (N.D. Tex. 1981), *rev'd on other grounds*, *Ft. Worth & Denver Ry. Co. v. Lewis*, 693 F.2d 432 (5th Cir. 1982) ("Plaintiffs claim that whenever the courts have upheld a standard of strict liability, they always have done so on the basis of a clearly expressed legislative intent to impose such liability… [citing *Park*]."). Many commentators have acknowledged the same. *See, e.g.*, Nicholas Frietag, *Federal Food and Drug Act Violations*, 41 Am. Crim. L. Rev. 647, 653 (2004) ("In *United States v. Dotterweich*, the Supreme Court established a standard of strict liability for violations of the FDCA…."); Amiad Kushner, *Applying the Responsible Corporate Officer Doctrine Outside the Public Welfare Context*, 93 J.

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must find—evidence beyond a reasonable doubt that he engaged in wrongful conduct amounting at least to common-law negligence. There were no such instructions, and clearly, therefore, no such findings in this case." *Park*, 421 U.S. at 683 (Stewart, J., dissenting).

Crim. L. & Criminology 681, 692-93 (2003) (Dotterweich's conviction… [was] premised on a strict liability theory… [and] *Park* not only reaffirmed the imposition of strict liability in principle, but applied it to a large corporation."); Joel M. Androphy et al., *General Corporate Criminal Liability*, 60 Tex. B. J. 121, 126 (1997) ("In both [*Park*] and [*Dotterweich*], the Court held that a corporate officer could be liable for the criminal acts of the corporation, despite the officer never having been aware of the criminal conduct at issue (*i.e.*, despite the officer having no guilty mind, or in other words, no mens rea)."); Timothy Wu and Yong-Sung (Jonathan) Kang, *Criminal Liability for the Actions of Subordinates—The Doctrine of Command Responsibility and Its Analogues in United States Law*, 38 Harv. Int'l L.J. 272, 280 (1997) (discussing the "strict liability RCO doctrine"); Cynthia H. Finn, *Comment: The Responsible Corporate Officer, Criminal Liability, And Mens Rea: Limitations on the RCO Doctrine*, Am. U. L. Rev. 543, 544 (1996) ("the RCO doctrine [as formulated by *Park* and *Dotterweich*] results in the imposition of a species of strict criminal liability"). The court in this case has likewise acknowledged the strict liability nature of the doctrine. *Friedman v. Sebelius*, No. 08-0586, 2009 WL 4572739, *1 (D.D.C. Dec. 7, 2009) (the RCO provision of 21 U.S.C. § 333 "establishes that executive officers may be convicted of strict liability misdemeanors if their company misbrands a drug in violation of 21 U.S.C. § 331(a)").

The connection between blameworthy conduct and RCO criminal liability is most noticeably lacking for senior executives, since scarcely anything at the company is outside their "authority and responsibility." According to appellate cases cited in *Park*, an officer is adequately "responsible" for purposes of the RCO doctrine when he or she is vested with the responsibility and power to devise whatever measures are necessary to ensure FDCA compliance. *Park* at 671-72, 672 n.14 (citing *Lelles v. United States*, 241 F.2d 21 (9th Cir. 1957); *United*

States v. Kaadt, 171 F.2d 600 (7th Cir. 1948)). Thus, to the extent responsibility and authority are a function of position on an organizational chart, so is RCO liability. Said one court, "the line… between a conviction based on corporate position alone and one based on a 'responsible relationship' to the violation is a fine one, and arguably no wider than a corporate bylaw." *United States v. New Eng. Grocers Supply Co.*, 488 F. Supp. 230, 234 (D. Mass. 1980).

The Court in *Park* created a defense that officers are not expected to prevent or remedy wrongdoing by doing the "objectively impossible." *Park*, 421 U.S. at 673. This defense is surely more useful to mid-level executives than senior executives. Even if the most thorough and assiduous supervision produced no evidence of a problem, it would always be "objectively []possible" for a CEO, who has authority over the entire company, to have prevented wrongdoing.[4] The requirement that RCOs exercise the utmost foresight can even lead to situations where it is objectively impossible for the RCO to stop the misconduct, and yet the RCO remains criminally liable because, at some prior time, it *was* objectively possible for the officer to have foreseen the misconduct. Wu and Kang, 38 Harv. Int'l L.J. at 296. Far from suggesting that the RCO doctrine requires a showing of negligence for conviction, the objective impossibility defense underscores the strictness of the doctrine and highlights the immateriality of blameworthiness to an RCO conviction.

The ALJ and DAB misunderstood the strict liability nature of the RCO doctrine. They mistook the "duty" language in *Park* as requiring the government to prove criminal negligence in order to obtain a conviction of an RCO. But, as has been shown, there is no

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[4] In *United States v. Starr*, a food company had rodents in its warehouse and the secretary-treasurer explicitly told a janitor to fix the problem. 535 F.2d 512, 516 (9th Cir. 1976). The janitor refused to fix the problem. The court upheld the officer's conviction in part because the secretary-treasurer failed to anticipate and counteract the janitor's insubordination.

negligence required for an RCO conviction, and there were no facts in the Agreed Statement to support the conclusions that these individuals were negligent. Thus, the ALJ and DAB misunderstood the nature of the crime.

B. Allowing the Secretary to Exclude Plaintiffs for These Convictions Is Contrary to the Supreme Court's Justification for Allowing Strict Liability Crimes

The Supreme Court has justified the existence of strict liability crimes in certain narrowly defined cases where penalties are small and there is no grave damage to the person's reputation. If Plaintiffs' exclusions for this strict liability crime were allowed to stand, the underlying conviction would no longer be justifiable under this reasoning.

As discussed *supra*, a bedrock rule of criminal jurisprudence is that society does not impose criminal sanctions on an individual who lacks a *mens rea*. The Supreme Court has carved out a few narrow exceptions, including the RCO doctrine, under which an individual may be criminally convicted of a strict liability crime. Much academic literature criticizes such strict liability crimes as being ineffective and unjust.[5] The Court rationalizes the existence of these crimes on the ground that penalties "are relatively small, and conviction does no grave damage to an offender's reputation." *Morissette v. United States*, 342 U.S. 246, 296 (1952). The basis for allowing a strict liability crime has broadened over the years, but two stalwart principles have remained: the size of the penalty and the gravity of the impact on the individual's reputation. *See United States v. Freed*, 189 Fed. App'x 888, 891-92 (11th Cir. 2006); *see also O'Mara*, 963 F.2d 1288.

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[5] *See, e.g.*, Assaf Hamdani, *Mens Rea and the Cost of Ignorance*, 93 Va. L. Rev. 415, 416-17 (2007) ("For decades, criminal law scholars have argued that this doctrine punishes innocent actors and is thus unjust, unconstitutional, and ineffective. But despite nearly unanimous vilification, strict liability continues to occupy an important place in modern criminal law.").

Respecting the dangers of permitting criminal convictions for strict liability crimes and the narrow confines of the exception, the Supreme Court has only applied the RCO doctrine in FDCA cases where the penalties were extremely small. In *Dotterweich*, the defendant received a $500 fine and 60 days probation. *United States v. Buffalo Pharmacal Co., Inc.*, 131 F.2d 500, 501 (2d Cir. 1942), *rev'd*, *Dotterweich*, 320 U.S. 277. In *Park*, the defendant received a $250 fine. *Park*, 421 U.S. at 666. Exclusion was never threatened, imagined, or possible in either of these cases, since HHS only began its exclusion program in 1977.

If RCO convictions can trigger lengthy exclusions, as happened here, the penalties for RCO convictions will be pushed far out of the small-bore realm of *Dotterweich* and *Park* and thereby frustrate the Supreme Court's intention to limit strict liability crimes to cases where penalties are small and conviction does no grave danger to reputation.[6] Quite the opposite: the additional penalty of a 12-year exclusion effectively ends the Plaintiffs' careers and will ruin their reputations. Courts have long recognized the serious harm of denying individuals the right to employment; thus, a 12-year exclusion that prevents their employment can hardly be deemed "relatively small." Last year, a District of Columbia district court agreed with a plaintiff that debarment from federal health care programs caused him "irreparable harm in the form of

[6] The size of the criminal fine here, had it been imposed by a court for an RCO offense, would also run afoul of the Supreme Court's *Dotterweich* rationale: a criminal fine of $34.5 million may well not meet *Morisette*'s requirement of a "relatively small" penalty. Five hundred dollars in 1943 (the year *Dotterweich* imposed a $500 fine) would be roughly $6,300 today; $250 in 1975 (the year *Park* imposed a $250 fine) would be roughly $1,000 today. United States Bureau of Labor Statistics, Inflation Calculator, *available at* http://data.bls.gov/cgi-bin/cpicalc.pl. But the district court hearing the criminal case against Plaintiffs never had to address an excessive fine issue because Plaintiffs voluntarily agreed to the $34.5 million fine. In any event, the large fine does not change the no-fault nature of Plaintiffs' misdemeanor conviction. Nor does the large fine relate in any way to the DAB's stated rationale for upholding a *de facto* lifetime exculsion from the pharmaceutical industry; the DAB's rationale would support a lengthy exclusion regardless of the size of the criminal fine.

damage to his future business prospects and professional reputation." *Alf v. Donley*, 666 F. Supp. 2d 60, 64 (D.D.C. 2009). The court was unmoved by the government's argument that, even though the plaintiff was barred from doing any business with the government, "a wide universe of alternative employment and investment opportunities remain[ed] open to him." *Id.* If the Secretary is permitted to impose lengthy exclusions on executives convicted solely on the basis of the RCO doctrine, without evidence of individual culpable conduct, the Supreme Court's rationale for permitting conviction without proof of *mens rea* will be eviscerated.

II. THE SECRETARY IS NOT AUTHORIZED TO EXCLUDE INDIVIDUALS CONVICTED OF STATUS OFFENSES WHO HAVE NOT ENGAGED IN ANY WRONGFUL CONDUCT THEMSELVES

To protect federal health care programs and beneficiaries, Congress has authorized the Secretary to exclude an individual or entity that has been found to have engaged in conduct violative of certain laws. This mission provides the Secretary with the responsibility to exclude on the basis of many forms of misconduct. The statute does not, however, authorize the Secretary to exclude an individual based solely on the misconduct of others. No language in the statute expressly provides for this, and nothing in its legislative history or purpose suggests Congress intended that result. There is no evidence, moreover, that the Secretary ever contemplated such an exclusion, until now. The Secretary may not exclude Plaintiffs on the basis of a strict liability RCO conviction, where that conviction does not evidence any wrongful conduct on the part of Plaintiffs.

A. Allowing the Secretary to Exclude Plaintiffs for These Convictions Does Not Serve the Purpose of Exclusion

Exclusion is aimed at keeping untrustworthy health care providers out of the system:

> Section 1128 seeks to protect the funds of Federal health care programs and the programs' beneficiaries and recipients from untrustworthy providers…. In

> *Manocchio*, the [11th Circuit] looked at the legislative history of this provision and concluded that its primary goal was to protect present and future beneficiaries of Federal health care programs from abusers of these programs.

Joann Fletcher Cash, DAB 1725 (2000) (citing *Manocchio v. Sullivan*, 961 F.2d 1539, 1541-1543 (11th Cir. 1992)); *see also Greene v. Sullivan*, 731 F. Supp. 838, 839-40 (E.D. Tenn. 1990); *Dana R. Duke, Inmate SPN/ID* 9809/183021, DAB CR1761 (2008); *Neil R. Hirsch, M.D.*, DAB 1550 (1995); *Carolyn Westin*, DAB 1381 (1993); *Douglas Schram, R.Ph.*, DAB CR215 (1992); *Janet Wallace, L.P.N.*, DAB 1326 (1992). The legislative history is clear: "The basic purpose of the Committee bill is to improve the ability of [HHS] to protect [government health care] programs from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care." Medicare and Medicaid Patient and Program Protection Act of 1987, S. Rep. No. 100-109, at 1-2 (1987). By their convictions, Plaintiffs were deemed to be in a supervisory position over others who engaged in wrongdoing. This does not suggest that they are themselves threats to the integrity of federal health programs.

The DAB cited a case where an executive claimed a lack of knowledge of a mislabeling scheme, for the principle that "it is the fact of [the executive's] conviction relating to the scheme that is material, and not [his] particular role in that scheme." DAB Dec. at 13 (quoting *Lyle Kai, R.Ph.*, DAB 1979 (2005)). But in *Kai*, the crime required a *mens rea* of recklessness and was thus a plausible basis for exclusion. In that case, the Secretary could make a viable argument that an executive was untrustworthy to participate in a federal health care program because he was reckless. Here, it is the lack of any *mens rea* that logically forecloses a determination of such untrustworthiness.

Indeed, HHS's action here is unprecedented. Heretofore, the RCO doctrine has been used only a handful of times as a basis for FDCA conviction, and there has never been an

exclusion based on a conviction such as those here which are premised exclusively on RCO status. The OIG could not identify a prior exclusion in remotely similar circumstances. In fact, there have only been two prior instances where HHS excluded individuals for strict liability convictions, and in both cases, the record showed serious personal misconduct by the defendant. Because there is no basis here for HHS to find the Plaintiffs untrustworthy, exclusion here is contrary to the purpose of the exclusion statute and is thus impermissible.

Moreover, the FDA's announced intention to employ the RCO doctrine more frequently in the future makes it all the more crucial for the Court to send a clear message that in cases where the conviction is based on the defendant's status alone, the Secretary cannot rely on the misconduct of others to impose an exclusion on a corporate executive.

B. The Status Offense at Issue Here Does Not Come Within the Scope of the Specific Exclusion Provisions Relied on by the Secretary

1. Plaintiffs' Convictions Do Not "Relat[e] to Fraud, Theft, Embezzlement, Breach of Fiduciary Responsibility or Other Financial Misconduct"

As discussed *supra*, the Secretary asserts that the misdemeanor of which Plaintiffs were convicted is one "relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct" because there is a "nexus or common sense connection" between their strict liability conviction and the fraud of *other employees* at Purdue. Because the Plaintiffs' misdemeanor does not relate to an act of financial misconduct as required by (b)(1), the Plaintiffs cannot be excluded under (b)(1).

a. The Proper Interpretation Of (b)(1) Is That An Individual Is Eligible For Exclusion If He Or She Commits A Crime That Is Related To Or Similar To One Of The Listed Crimes

We urge the Court to adopt a simple, logical interpretation of (b)(1). The section lists four specific categories of financial crimes that can justify exclusion from federal health

programs—fraud, theft, embezzlement, and breach of fiduciary responsibility—plus a catch-all fifth category of "other financial misconduct." The most logical interpretation of the "relating to" language, then, is that an individual is eligible for exclusion if he or she commits a crime that is related to or similar to one of the listed crimes. For example, one convicted of obtaining funds under false pretenses would be logically eligible for exclusion under (b)(1). But nothing in the language of (b)(1) suggests that someone can be excluded for the financial misconduct of others, merely because the convicted person's crime is linked, in any remote way, with that misconduct.

This statute is ripe for the *noscitur a sociis* canon of statutory construction: a word should be given meaning by the words around it.[7] Section (b)(1) specifies a variety of financial crimes that warrant exclusion and states that exclusion is warranted when the individual's or entity's misdemeanor is one "relating to" one of the specified financial crimes or misconduct. Applying *noscitur a sociis*, the most likely intention of Congress is that a person could be excluded for the listed crimes or similar, related crimes.

Indeed, the Secretary has interpreted (b)(1) in the past in precisely this manner. *Chander Kachoria*, a case cited in the ALJ decision, involved a pharmacist who had pled guilty in Ohio to one count of theft and faced exclusion under (b)(1). DAB 1380 (1993). His appeal focused on a different component of (b)(1): he insisted that his crime was not connected with delivery of a health care item. But in the course of explaining the (b)(1) language that is at issue in this case, the DAB stated: "Section 1128(b)(1) requires only that *the conviction be for theft or*

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[7] As the Supreme Court has explained: "The maxim *noscitur a sociis*, that a word is known by the company it keeps, while not an inescapable rule, is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress." *Jarecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961); *accord Nat'l Muffler Dealers Ass'n v. United States*, 440 U.S. 472, 485 n.20 (1972); *Gustavson v. Alloyd Co.*, 513 U.S. 561, 575 (1995).

other financial misconduct and that the conduct be in connection with health care delivery." *Id.* at 3 (emphasis added and internal quotations omitted). The DAB could not have been clearer that (b)(1) requires conviction of one of the listed crimes or similar, related crimes. Here, the Plaintiffs were convicted only of the crime of being an RCO; they were not convicted of fraud or any other financial crime.

Other cases cited in the below DAB decision support our interpretation of the "relating to" language. The below DAB decision cites *Carolyn Westin*, DAB 1381 (1993), for the proposition that the OIG did not have to prove that the petitioner, who was convicted of disregard of a state health regulation for failing to file an incident report, committed patient abuse or neglect to exclude her under (a)(2).[8] Unlike Westin, however, Plaintiffs are not arguing that they must have been convicted of one of the specific crimes listed in (b)(1) and that the literal words of the exclusion statute must appear in the statute of conviction, as Westin argued with respect to (a)(2). *Id.* Rather, Plaintiffs are arguing for a broader standard, entirely in keeping with *Westin*, that their crime of conviction must be similar to or related to one of the specific crimes listed.

b. The Supreme Court and Past HHS Cases Do Not Support the Secretary's Overly Broad Standard

The Secretary is seeking to exclude the Plaintiffs on the basis of a purported "nexus or common sense connection" between the financial misconduct of others and Plaintiffs'

[8] This section provides for mandatory exclusion for a conviction relating to patient neglect or abuse.

status conviction. DAB Dec. at 12. Past decisions, however, counsel against this overly broad interpretation.[9]

The Supreme Court has explicitly warned against overly expansive interpretations of federal statutes containing the word "relate." In *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, the Court preferred a moderate interpretation of "relate to" in rejecting a challenge to a state surcharge that would have been preempted by federal law had it "relate[d]" to an ERISA plan. 514 U.S. 645 (1995). The Court explained:

> Section 514(a) marks for pre-emption "all state laws insofar as they… relate to any employee benefit plan" covered by ERISA, and one might be excused for wondering, at first blush, whether the words of limitation ("insofar as they… relate") do much limiting. If "relate to" were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for "really, universally, relations stop nowhere." But that, of course, would be to read Congress's words of limitation as mere sham.

Id. at 655 (internal citation omitted). Similarly, the Secretary is undoubtedly correct that in a metaphysical sense there is *some* relationship between Plaintiffs' misdemeanors and the fraud committed by others, but the language of (b)(1) indicates that this is not the type of relationship Congress had in mind when it authorized exclusion of an individual or entity that has been convicted of "a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct." *See also Abuelhawa v. United States*, 129 S. Ct. 2102, 2103 (2009) ("because statutes are not read as a collection of isolated phrases, a word in a statute may or may not extend to the outer limits of its definitional possibilities") (internal quotations omitted).

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[9] The interpretation is not entitled to any degree of deference, because it is not a longstanding interpretation adopted through rulemaking proceedings but rather is one adopted for purposes of this litigation. *See Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

Importantly, the Secretary has been unable to cite a single case in which the "relating to" language of (b)(1) has been interpreted in the manner she espouses. All of the cases cited by the OIG, ALJ, and DAB construe the meaning of the words "relating to" or "related to" in other exclusion provisions, but not (b)(1). Moreover, those cases are actually far more favorable to Plaintiffs than they are to the Secretary. In every instance, the offense deemed to be "related to" an offense set forth in the Act was the offense of the individual facing exclusion, and did not (as here) involve the offense of a third party. *See, e.g.*, *Kai*, DAB 1979 (pharmacist's felony conviction was deemed "related to" the "delivery of an item or service" under Medicare within the meaning of (a)(1) based on his personal participation in a scheme to recycle used drugs, not based on others' criminal activities).

The legislative history of the exclusion statute strongly supports our view. When (b)(1) was created, it was intended to "permit the Secretary to exclude persons and entities who have already been convicted of offenses relating to *their* financial integrity." S. Rep. 100-109 at 7 (1987) (emphasis added). Congress never intended to allow the Secretary to exclude people under (b)(1) who were convicted of offenses relating to other people's financial integrity.

2. Plaintiffs' Convictions Are Under the FDCA, and Do Not Relate to the "Unlawful Manufacture, Distribution, Prescription, or Dispensing of a Controlled Substance"

Section (b)(3) permits the Secretary to exclude individuals or entities convicted of misdemeanors "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." The Plaintiffs pled guilty to misbranding under the FDCA. The Secretary's contention that an FDCA conviction is a proper basis for a (b)(3) exclusion is incorrect. Based on the statutory text, legislative history, and past practice, it is clear that (b)(3) is only intended to exclude individuals for violations of the Controlled Substances Act ("CSA") and similar state laws, not the FDCA.

a. The Statutory Structure Shows that Plaintiffs Should Not Have Been Excluded Under (b)(3)

It is extraordinary to suggest, as does the Secretary, that (b)(3) and the CSA are unrelated. The CSA is the federal law that creates crimes relating to controlled substances, while (b)(3) supplements the CSA by providing for exclusions based on such crimes. Even the language is nearly parallel. The CSA forbids any person to knowingly or intentionally "manufacture, distribute, or dispense… a controlled substance." 21 U.S.C. § 841(a). Section (b)(3) provides for exclusion for a conviction relating to "manufacture, distribution, prescription, or dispensing of a controlled substance." 42 U.S.C. § 1320a-7(b)(3).

Given the close relationship between the CSA and (b)(3), it is self-evident that Congress expected for certain terms, undefined in (b)(3), to be defined and contextualized by reference to the CSA. Section (b)(3) does not define any of the words characterizing the conviction that results in (b)(3) exclusion, except "controlled substance." These words are defined in the CSA, however, and this is the statute that should be used to interpret their meaning in (b)(3). When convenient to her argument, the Secretary herself turns to the CSA to define a term from (b)(3). She seeks to define "controlled substance" via the CSA, even though 42 C.F.R. § 1001.401(b) explicitly orders that the definition of "controlled substance" is the one that applies to the law forming the basis for conviction—*i.e.*, the FDCA. The FDCA does not define this term, of course, so the Secretary turns to the CSA. *See* II.C, *supra*. And yet, when it comes to defining other words in the same sentence, the Secretary acts as if the CSA is an exotic statute with no applicability. The inconsistency is fatal to her position.

If one looks to the CSA definition, there is only one plausible conclusion: Plaintiffs' misbranding misdemeanor convictions are not ones "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." *See, e.g.*, 21

U.S.C. §§ 802(8), 802(11) (defining "deliver" and "distribute" as used in the CSA). The CSA definition proscribes drug trafficking offenses involving illicit drugs or the diversion of prescription drugs for nonmedical use. Plaintiffs, whose crime consisted of misbranding by virtue of having been responsible corporate officers at a time when others employed by Purdue engaged in misbranding with intent to defraud, cannot reasonably be said to have engaged in the "delivery" and "unlawful distribution" of controlled substances, as those terms are used in the CSA. Therefore, they cannot be excluded under (b)(3).

b. Legislative History Does Not Show that Congress Intended (b)(3) To Apply To The FDCA

Contrary to the argument advanced by the OIG and ALJ, (b)(3)'s legislative history does not support the interpretation that Congress intended (b)(3) to apply broadly to exclude based on conviction under the FDCA's misbranding provision. As the OIG and ALJ noted, the legislative history indicates that Congress assumed "most" cases falling under (b)(3) "will result in exclusion," but Congress nonetheless wished to give the Secretary discretion to avoid exclusion in order to prevent situations in which an exclusion would "jeopardize another investigation." ALJ Dec. at 9 (citing S. Rep. 100-109 at 6 (1987)); OIG Opp. Br. at 18, 24. While that legislative history suggests that Congress expected the Secretary to exercise her exclusion discretion broadly in cases to which (b)(3) applied, *i.e.*, drug trafficking offenses involving illicit drugs or the diversion of prescription drugs for nonmedical use; it does not suggest that Congress intended for (b)(3) to be read broadly to apply to cases to which the statutory language might not normally be understood to apply.

c. HHS Regulations Indicate that (b)(3) Was Never Intended to Apply to the FDCA

The Secretary's own regulations show that HHS never intended (b)(3) to provide a basis for exclusion for an FDCA crime.

First, (b)(3) regulations define "controlled substance" by referring to "the law forming the basis for the underlying conviction." 42 C.F.R. § 1001.401(b). But the FDCA does not include a definition for "controlled substance." Nor is a "controlled substance" a part of the charged offense. The CSA, of course, defines "controlled substance," as do similar state laws.[10] There is only one plausible conclusion to be derived from the language of § 1001.401(b): When drafting the regulation, the Secretary did not believe that a conviction for violation of the FDCA could form the basis for a (b)(3) exclusion because (b)(3) is only intended to apply to CSA offenses.

Second, the Secretary's understanding that (b)(3) was never intended to apply to the FDCA is apparent from the regulations setting forth "aggravating" factors to be considered in determining the period of exclusion for a (b)(3) offense. The regulations list five identical aggravating factors for exclusion under (b)(1) and (b)(3), but the (b)(1) regulations list a sixth factor not included in the (b)(3) regulations: "The acts resulting in the conviction, or similar acts that caused, or reasonably could have been expected to cause, a financial loss of $5,000 or more to a Government program or to one or more other entities." *Compare* 42 C.F.R. § 1001.201(b)(2)(i) *with* 42 C.F.R. § 1001.401(c)(2). If, as the Secretary now suggests, she understood (b)(3) exclusions to apply to all misdemeanor misbranding convictions in which the misbranded drug happened to be a controlled substance within the meaning of the CSA, then one would reasonably expect that the Secretary would have included "financial loss of $5,000 or more to a Government program" as one of (b)(3)'s aggravating factors—because such loss would be a plausible result of the misbranding. On the other hand, when an individual is

[10] The desire to accommodate variable state definitions of "controlled substance" is probably the reason that HHS did not simply cite the federal CSA's definition.

convicted of a drug trafficking offense involving illicit drugs, the activity is unlikely to cause financial loss to such a government program. The Secretary's omission of "financial loss" from the list of aggravating factors in a (b)(3) case thus has one very plausible explanation: the Secretary contemplated that few if any (b)(3) cases would involve "financial loss" to a government program because she anticipated that all such cases would focus on individuals convicted of drug trafficking offenses involving illicit drugs or the diversion of prescription drugs for nonmedical uses.

d. Past Cases Show That (b)(3) Was Never Intended to Apply to the FDCA

The Secretary heretofore has consistently interpreted (b)(3) to apply only to drug trafficking offenses involving illicit drugs or the diversion of prescription drugs for nonmedical uses—the offenses described in the CSA and similar state laws. Moreover, the Secretary has apparently never excluded a company for misbranding under the mandatory felony controlled substances exclusion provision. This telling history precludes the Secretary from now arguing that misbranding is a basis for (b)(3) exclusion.

Section (b)(3) has always been a basis for exclusion for CSA and similar state offenses. *See, e.g.*, *Ronald B. Phillips*, DAB CR485 (1997) (physician convicted of obtaining a controlled substance by fraud, misrepresentation and deception for his own personal use and for no legitimate medical purpose); *Eulalia Marie Jones*, DAB CR593 (1999) (nurse convicted of knowingly and intentionally distributing and possessing with intent to distribute, methadone in violation of 21 U.S.C. § 841(a)(1)); *Robert Mark Armentrout*, DAB CR786 (2001) (therapist convicted of unlawfully obtaining a prescription drug by making and uttering a forged prescription); *Dinkar N. Patel*, DAB 1818 (2002) (physician convicted of knowingly, intentionally and unlawfully distributing and dispensing a controlled substance without a

legitimate medical purpose in the usual course of his professional medical practice and beyond the bounds of medical practice, in violation of 21 U.S.C. § 841(b)(3)). By contrast, the Plaintiffs' case is apparently the only one where the Secretary has ever excluded individuals under (b)(3) for an FDCA violation. A search for "1128(b)(3)" and "FDCA" on the DAB website yields five results: Michael Friedman, Paul Goldenheim, Howard Udell, a duplicate Howard Udell, and their collective appeal. A search for "1128(b)(3)" and "misbranding" yields the same five results.

In fact, the Secretary is precluded from excluding Plaintiffs on (b)(3) grounds because of its past practice. Orphan Medical, Inc. ("Orphan") was convicted of felony misbranding of the Schedule I/III[11] "date rape" drug GHB but was not excluded under (a)(4), the felony equivalent of (b)(3).[12] For a felony relating to a controlled substance, the Secretary is *required* to exclude the entity under (a)(4). The Secretary has long maintained that its obligation to exclude pursuant to mandatory exclusion provisions is absolutely binding. *See, e.g.*,

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[11] GHB is generally Schedule I; when sold as Xyrem, it is Schedule III.

[12] The provisions are functionally identical:

> "Felony conviction relating to controlled substance.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance."

42 U.S.C. § 1320a-7(a)(4).

> "Misdemeanor conviction relating to controlled substance.—Any individual or entity that has been convicted, under Federal or State law, of a criminal offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance."

42 U.S.C. § 1320a-7(b)(3).

Catherine Gaddy, DAB CR1901 (2009). Therefore, the implication is clear: The Secretary understands that an FDCA misbranding conviction does not "relat[e] to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." Plaintiffs were convicted of FDCA misbranding, just like Orphan. And, just like with Orphan, their conviction cannot be the basis of a controlled substances exclusion.

C. Allowing The Secretary to Exclude Plaintiffs for These Convictions Is Contrary to the Language in HHS Regulations

Regulations pursuant to (b)(1) and (b)(3) consistently refer to "acts," which are not part of a RCO misdemeanor crime. This suggests that HHS did not contemplate exclusion for status crimes. Because HHS did not intend to exclude individuals for convictions of this type of crime, it was inappropriate for the Secretary to exclude these individuals in this case.

The Secretary promulgated regulations at 42 C.F.R. §§ 1001.201 and 1001.401 to implement subsections (b)(1) and (b)(3) of the exclusion statute, respectively. Both regulations consistently refer to "acts" as forming the basis for the conviction and do not leave open the possibility, based on a plain reading of the text, that HHS could exclude someone for a conviction that was not based on an "act." It is therefore clear that HHS never contemplated excluding someone for a non-act conviction, *i.e.*, a status offense.

For example, a regulation published pursuant to (b)(1) provides that the following, if proven, may be an aggravating factor: "The *acts* resulting in the conviction[] or similar *acts*… caused, or reasonably could have been expected to cause, a financial loss of $5,000 or more…." 42 C.F.R. § 1001.201(c)(2)(i) (emphasis added). Based on its own regulation, HHS never contemplated that something other than an "act" could be the basis for a conviction. Twice more in its (b)(1) regulations, HHS refers to "[t]he *acts* that resulted in the conviction." 42 C.F.R. §§ 1001.201(c)(2)(ii), 1001.201(c)(2)(iii) (emphasis added). The same holds true in the (b)(3)

regulations; HHS twice again refers to "[t]he *acts* that resulted in the conviction" and avoids even insinuating that status crimes could be the basis for a conviction that leads to exclusion under the statute. 42 C.F.R. §§ 1001.401(c)(2)(i), 1001.401(c)(2)(ii) (emphasis added).

CONCLUSION

For the foregoing reasons, the Court should declare that the Secretary's final order excluding Plaintiffs from participation in federal health programs was contrary to law, arbitrary, and capricious, an abuse of discretion, and not supported by substantial evidence, in violation of the Administrative Procedure Act, 5 U.S.C. § 706, and should issue an order vacating and enjoining the exclusions or, alternatively, remanding for further administrative review.

Respectfully submitted,

/s/ Amy R. Sabrin
Amy R. Sabrin (D.C. Bar No. 409721)
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005-2111
(202) 371-7000
amy.sabrin@skadden.com

Attorney for Amicus Curiae
Washington Legal Foundation

Date: March 22, 2010