CORRECTED COPY

ORAL ARGUMENT NOT YET SCHEDULED

No. 11-5028

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA

MICHAEL FRIEDMAN, PAUL GOLDENHEIM, AND HOWARD UDELL,

Plaintiffs-Appellants,

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND
DANIEL R. LEVINSON, IN HIS OFFICIAL CAPACITY AS
INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendants-Appellees.

On Appeal From The United States District Court
For The District Of Columbia (Huvelle, J.)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF APPELLANTS URGING REVERSAL

Daniel J. Popeo
Richard A. Samp
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, NW
Washington, DC 20036
(202) 588-0302

Michael A. Carvin
Daniel R. Volkmuth
JONES DAY
51 Louisiana Avenue, NW
Washington, DC 20001
(202) 879-3939

June 29, 2011

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, the Washington Legal Foundation ("WLF") certifies that it is a corporation organized under § 501(c)(3) of the Internal Revenue Code. WLF does not have a parent corporation, nor does it have any stock owned by a publicly held company.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

ADMINISTRATIVE OPINIONS

OTHER AUTHORITIES

TABLE OF ABBREVIATIONS

ABBREVIATION	MEANING
ALJ	Administrative Law Judge
DAB	Departmental Appeals Board
FDA Manual	FDA Regulatory Procedures Manual
FDCA	Food, Drug, and Cosmetic Act
Purdue	The Purdue Frederick Company
RCO	Responsible Corporate Officer
WLF	Washington Legal Foundation

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation ("WLF") is a public interest law and policy center with members and supporters in each and every state.[1] WLF devotes a substantial portion of its resources to defending individuals and businesses from undue government. WLF does not condone the dissemination of inaccurate information about medications, and it supports efforts to prevent such dissemination. It does, however, seek to ensure that the Government respects individual rights and that it does not impose criminal penalties on economic activity without evidence of blameworthiness.

WLF has members and supporters who are directly threatened by the Government's use of the "responsible corporate officer" ("RCO") doctrine to impose strict criminal liability on corporate officers and then impose harsh penalties such as exclusion from participation in federal programs. This case has assumed an even greater significance to WLF because the Government has announced plans to increase prosecutions of corporate executives pursuant to the RCO doctrine, and to pursue more exclusions of corporate officers upon that basis.

WLF has long opposed use of the criminal laws to punish executives for

[1] No party's counsel authored this amicus brief in whole or in part. No party, nor party's counsel contributed money that was intended to fund preparing or submitting this amicus brief. No person—other than the amicus curiae, its members, or its counsel—contributed money that was intended to fund preparing or submitting this amicus brief.

employee misconduct that the corporate officers neither condoned nor were aware of, and has appeared in multiple proceedings to express this 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). WLF has the same substantial interest here.

INTRODUCTION

Congress has empowered the Secretary of Health and Human Services to exclude individuals from participation in federal health care programs if they are convicted of certain statutorily-defined crimes. The purpose of this authority is to protect health care programs and their beneficiaries from fraud, abuse, and incompetent care by the excluded individuals. The exclusion authority is normally exercised in cases involving individuals who have committed crimes requiring proof of a culpable state of mind. In this case, however, the Secretary has broken with this practice and has excluded three executives on the basis of a misdemeanor conviction under the so-called "responsible corporate officer" doctrine.

The RCO doctrine allows corporate officers to be held criminally liable for violations of the Food, Drug, and Cosmetic Act ("FDCA") without evidence of individual culpability. The Government need not prove that the officers knew or should have known about employee violations. Instead, the Government satisfies its burden of proof if it establishes that the corporate officers, by reason of their position within the corporation, had responsibility and authority to prevent the violations.

In acquiescing to strict liability RCO offenses, the Supreme Court recognized that hardship would result where criminal sanctions are imposed "though consciousness of wrongdoing be totally wanting." *United States v. Dotterweich*, 320 U.S. 277, 284 (1943). Nevertheless, the Court satisfied itself that in such matters "the good sense of prosecutors . . . must be trusted" and that the "system of criminal justice necessarily depends on 'conscience and circumspection in prosecuting officers.'" *Id.* at 285. Indeed, in persuading the Court to reaffirm the RCO doctrine, the Government assured the Court that it would usually apply the doctrine only where the officer had some knowledge of possible violations:

> Even if investigation discloses the elements of liability, and indicates that an official bears a responsible relation to them, the agency will not ordinarily recommend prosecution unless that official, *after becoming aware of possible violations*, often (as with Park) as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations.

Pls' S. J. Reply Br. at 13, Dkt. 29, No. 1:09-cv-02028-ESH (quoting Brief of United States at 31-32, *United States v. Park*, No. 74-215 (U.S. Jan. 10, 1975) (emphasis added)).

Despite its past assurances, the Government has now abandoned this good sense application of the RCO doctrine, and as this case demonstrates, it is more than willing to prosecute and convict corporate officers who have no awareness of employee violations and are not even acting negligently. Indeed, the FDA has recently advised its regulators that a corporate official can be held liable for a misdemeanor "without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense." FDA Regulatory Procedures Manual § 6-5-3 (March 2010) ("FDA Manual").[2]

Furthermore, notwithstanding the fundamental unfairness of this new application of the RCO doctrine, the FDA Commissioner has also publicly called for the increased prosecution of "responsible corporate officers." *See* Letter from Margaret A. Hamburg, FDA Commissioner, to the Honorable Charles E. Grassley, ranking member of the Senate Finance Committee (Mar. 4, 2010).[3]

Coupled with increased enforcement is the Government's recent willingness to impose exclusions based upon RCO convictions. No longer satisfied with the small penalties the Supreme Court approved when it created the RCO doctrine, the Government is now taking aim at the livelihoods of corporate officers for the

---

[2] *See* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm.

[3] *See* http://grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf.

misconduct of their employees that the officer neither knew of nor had reason to know of.

In this case, the Secretary excluded Appellants for twelve years. Because this penalty effectively ends their careers and significantly impedes their ability to earn a comparable living, it far exceeds the small fines the Supreme Court found acceptable in upholding past RCO convictions. And, because the purpose of exclusion is to protect against fraud, abuse, and incompetence, Appellants' exclusion will cause grievous harm to their reputations.

Given the harshness of the penalty, the Secretary's interpretation of the exclusion statute to include RCO convictions raises serious due process concerns. The Court should avoid this constitutional thicket altogether, by interpreting the exclusion statute in a manner that precludes the penalty imposed by the Secretary and vacate the lengthy exclusion.

STATEMENT OF FACTS

Appellants Michael Friedman, Paul D. Goldenheim, and Howard R. Udell were senior executives of Purdue Pharma L.P. The Purdue Frederick Company ("Purdue"), an affiliate of Purdue Pharma, developed OxyContin, a Schedule II opioid analgesic used to treat pain.

After several years of investigation, the federal government charged Purdue with one felony count of misbranding of OxyContin with intent to defraud under the FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2). In 2007, Purdue pleaded guilty to this charge. According to the Agreed Statement of Facts, which is the sole basis for the conviction, certain unidentified Purdue supervisors and employees (not including Appellants), with the intent to defraud or mislead, departed from the FDA-approved label and marketed OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. *See* Agreed Statement of Facts.

The U.S. Attorney also brought a misdemeanor misbranding count against Appellants as "responsible corporate officers." The RCO doctrine allows corporate officers to be held strictly liable for an employee's improper promotion if, by reason of their position, they had responsibility and authority to prevent the violation but failed to do so. *See United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277 (1943). Appellants pleaded guilty to the misdemeanor. The sole factual basis for their plea consisted of one sentence in the Agreed Statement of Facts:

> 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 ¶ 45. Appellants specifically disclaimed personal knowledge of the improper promotion (*id.* ¶ 46), and nothing in the Agreed Statement of Facts indicates they were reckless or negligent in failing to acquire that knowledge or in preventing the violations. Based upon their pleas, the court sentenced each Appellant with three years' probation, 400 hours of community service and a $5,000 fine. Appellants also agreed collectively to disgorgement of $34.5 million, which was indemnified by Purdue.

Eight months after entering their pleas, the Secretary of Health and Human Services, through the Office of Inspector General, notified Appellants that they would be excluded from participation in all federal health care programs for twenty years—later reduced to fifteen years—under 42 U.S.C. § 1320a-7(b)(1), (3) ("the exclusion statute"). Subsection (b)(1) permits exclusion of any individual convicted of "a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct." *Id.* § 1320a-7(b)(1)(A). Subsection (b)(3) permits exclusion for conviction of "a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." *Id.* § 1320a-7(b)(3). The Secretary based Appellants' exclusions upon their RCO convictions.

Appellants appealed their exclusion to an Administrative Law Judge ("ALJ") and then to the Departmental Appeals Board ("DAB"). The ALJ affirmed the 15-year exclusion, and the DAB subsequently affirmed, although it reduced the exclusion to 12 years. The DAB upheld the exclusion on the ground that Appellants' misdemeanors "related to" the wrongful conduct of Purdue's employees, notwithstanding that Appellants did not themselves engage in the misconduct. *In re Goldenheim*, DAB 2268 at 13-17, 20 (2009).[4] The DAB also held that Appellants' exclusion furthered the remedial purpose of the exclusion statute to protect federal health care programs from untrustworthy individuals, even though there was no evidence that Appellants committed, or even knew about, the violations. *Id.* at 17-19. The DAB ultimately agreed with the ALJ that "a culpable omission" by Appellants was "inherent" in their strict liability convictions. *Id.* at 14, 17.

After the Secretary's exclusion decision became final, Appellants filed this suit arguing that exclusion on the sole basis of a strict liability RCO conviction was contrary to the text and purpose of the exclusion statute because excludable offenses encompassed an individual's own misconduct only, not the misconduct of others. The district court rejected that argument, holding that the plain language of the statute authorized exclusion for Appellants' RCO convictions because they "relate to"—in the broad sense of the phrase—the underlying employee violations. *Friedman v. Sebelius*, 755 F. Supp. 2d 98, 107-08 (D.D.C. 2010). The court held that Congress did not intend to "limit the universe" of individuals eligible for exclusion only to those who had actually been convicted of the offenses

---

[4] *See* http://www.hhs.gov/dab/decisions/dabdecisions/dab2268-goldenheim_et_al.pdf. The DAB also upheld exclusion under Subsection (b)(3).

enumerated in Section 1320a-(7)(b)(1). *Id.* at 108. The district court further held that, even if the exclusion provisions were ambiguous, the Secretary's interpretation was reasonable. *Id.* at 108-10. The district court also rejected Appellants' argument that their RCO convictions were strict liability offenses based on their status as corporate officers, and not based on their conduct. Instead, the court concluded that "[i]t strains credulity to argue that despite this admission [that Appellants were "responsible corporate officers"], they were not accused of committing any unlawful acts themselves and were convicted based solely on their status as senior executives, without any culpability or wrongful action on their part at all." *Id.* at 111 (internal quotation marks and emphasis omitted).

The district court also affirmed the 12-year exclusion. In light of its determination that exclusion was proper under subsection (b)(1), the court deemed it unnecessary to address exclusion under subsection (b)(3).

SUMMARY OF ARGUMENT

The Secretary construed 42 U.S.C. § 1320a-7(b)(1) and (3) to exclude Appellants based upon their misdemeanor convictions under the responsible corporate officer doctrine. It is well-established that the improper promotion of which Appellants were convicted is a strict liability offense.

Given the threat to fundamental fairness posited by strict liability offenses, constitutional due process requires strict liability penalties to be relatively small and not cause grave damage to an offender's reputation. Excluding Appellants from participation in federal health care programs for twelve years imposes a large penalty that deprives Appellants of their chosen occupation, significantly erodes their ability to make a living, and causes great harm to their reputations. Because the Secretary imposed exclusion based solely upon Appellants' strict liability RCO convictions, the fact that the penalty is not relatively small and will cause serious reputational harm raises serious constitutional due process concerns about the Government's interpretation of the exclusion statute. To avoid these constitutional problems, the Secretary's statutory construction should be reversed.

ARGUMENT

I. EXCLUSIONS BASED UPON RESPONSIBLE CORPORATE OFFICER CONVICTIONS RAISE SERIOUS CONSTITUTIONAL CONCERNS

The Secretary's enforcement of the exclusion statute based solely upon Appellants' misdemeanor convictions invites an unnecessary confrontation with the Constitution's Due Process Clause. This confrontation stems from the strict liability nature of the responsible corporate officer ("RCO") doctrine according to which Appellants were convicted. Because strict liability offenses violate due process when they result in more than relatively small penalties or cause grave damage to reputation, the Court should interpret the exclusion statute narrowly to not include strict liability RCO convictions.

A. A Misdemeanor Conviction Under The RCO Doctrine Is A Strict Liability Offense

Under the RCO doctrine, corporate executives can be held criminally liable for FDCA violations based solely upon their responsibility and authority over the employee wrongdoer, even though they had no knowledge of or culpability for any wrongdoing. The Supreme Court first announced this doctrine in *United States v. Dotterweich*, 320 U.S. 277 (1943), a case involving the president and general manager of a pharmaceutical company who was convicted of a misdemeanor under the same FDCA provisions as Appellants because misbranded and adulterated drugs were shipped in interstate commerce, *id.* at 278. The Supreme Court upheld the conviction, even though there was no evidence that the president was personally guilty of the charged misconduct, that he actively participated in the misconduct, or that he even knew of the misconduct. *Id.* at 285-86 (Murphy, J., dissenting). Instead, guilt was imputed to the president "solely on the basis of his authority and responsibility as president and general manager of the corporation." *Id.* at 286 (Murphy, J., dissenting).

The Supreme Court revisited the RCO doctrine in *United States v. Park*, 421 U.S. 658 (1975). In that case, the president of a national food store chain was convicted under similar FDCA provisions prohibiting the adulteration of food because food products were exposed to contamination by rodents at a warehouse. *Id.* at 660. In upholding the conviction, the Supreme Court explained that, to establish a prima facie case against a corporate officer, the Government must show that the officer "had, by reason of his position in the corporation, 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." *Id.* at 673-74. The Court reiterated that criminal liability does not turn on knowledge of any wrongdoing. *Id.* at 672-73. To the contrary, liability flows from the officer's failure "to prevent the act complained of." *Id.* at 671. The sole defense is that the officer "was 'powerless' to prevent or correct the violation." *Id.* at 673; *see also id.* (stating that "the Act, in its criminal aspect, does not require that which is objectively impossible"). The Court accordingly upheld the relatively light sentence imposed on the company president: a $250 fine. *Id.* at 660, 666.

As articulated by both *Dotterweich* and *Park*, the RCO doctrine does not require the Government to prove that the corporate officer's acts or omissions were unreasonable or negligent. Indeed, three justices dissented in *Park* precisely because the majority refused to require a finding of negligence as a prerequisite to liability. *See id.* at 683 (Stewart, J., dissenting) (refusing to join the majority because "a jury must find—and must be clearly instructed that it must find—evidence beyond a reasonable doubt that he engaged in wrongful conduct amounting at least to common-law negligence"). Therefore, not only does the RCO doctrine require no proof that the officer knew of the facts creating liability, it does not even require proof that a ***reasonable*** officer ***should have known of those facts***. This is reflected in FDA guidelines, which provide that a corporate officer can be liable without proof that the officer "acted with intent or even negligence." FDA Manual, § 6-5-3. In short, an officer can be held criminally liable even though a jury could have found that the officer's acts or omissions were entirely reasonable. The mere occurrence of a violation by an employee necessarily means that the corporate officer failed to prevent the violation, thereby making the officer's "responsibility and authority" the sole basis for liability regardless of the reasonableness or blameworthiness of the officer's conduct. *See id.* ("When considering whether to recommend a misdemeanor prosecution against a corporate official, consider 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."). Because the Government has no obligation to prove that the corporate officer's actions were wrongful or even unreasonable, the RCO doctrine imposes—by definition—strict liability. *See United States v. Cordoba-Hincapie*, 825 F. Supp. 485, 508 (E.D.N.Y. 1993) ("It is, in effect, a *prima facie* strict liability standard because the defendant officer's negligence [is] presumed.").[5]

[5] Countless courts and legal commentators have long recognized that the RCO doctrine provides for strict liability. *See, e.g.*, *Stepniewski v. Gagnon*, 732

That a corporate officer can fortuitously escape liability by proving that the violation was unavoidable or that the officer was powerless to prevent it does not convert the RCO doctrine's standard of liability into something other than strict liability. Because it applies to the reckless as well as the vigilant, this "impossibility defense" simply does not bear on culpability. Moreover, as a practical matter, this defense affords high-level executives such as Appellants no protection given their broad mandate and authority over the company. No matter how dimly foreseeable the problem and no matter how high the costs or unreasonable the burdens to the company, it will always be "objectively possible" for a high-level executive to prevent employee wrongdoing. *See United States v. Starr*, 535 F.2d 512, 516 (9th Cir. 1976) (upholding corporate officer's conviction despite employee's blatant disobedience because the officer failed to anticipate and prevent the employee's insubordination).

(continued…)

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*]."); Amiad Kushner, *Applying the Responsible Corporate Officer Doctrine Outside the Public Welfare Context*, 93 J. 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 . . . .").

Also misplaced is the argument that the RCO doctrine does not impose strict liability by virtue of the Supreme Court's statement in *Park* that the "concept of a 'responsible relationship' to, or a 'responsible share' in, a violation of the Act indeed imports some measure of blameworthiness" and that the "considerations which prompted the imposition of [the corporate officer's] duty, and the scope of the duty, provide the measure of culpability." *Park*, 421 U.S. at 673-74. Far from requiring that the Government actually prove blameworthiness, the Court's only point was that blameworthiness can be imputed from a corporate officer's responsible relationship to the violation. But imputing culpability is not the same as proving it, and the fact that the Court is imputing some measure of blameworthiness does not establish that the RCO doctrine imposes something other than strict liability.

The strict liability nature of the RCO doctrine is also apparent from the facts of this case. There is no factual assertion in the Agreed Statement of Facts that Appellants engaged in wrongful or unreasonable conduct. The only specific reference to Appellants' connection with employee wrongdoing is that they "were responsible corporate officers of PURDUE," (Agreed Statement of Facts ¶ 45), which the Statement defined as those "who had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce." *Id.* ¶ 11. There is no discussion about what Appellants did or failed to do as corporate officers that might have caused the improper promotion, nor is there any discussion about what Appellants could or should have done to prevent it. Nevertheless, the district court concluded that, because Appellants admitted that they were "responsible corporate officers" with "responsibility and authority" to prevent or correct the improper promotion of OxyContin, it somehow strained credulity for Appellants to argue that they were convicted without any evidence of culpability or wrongful action on their part. *Friedman*, 755 F. Supp. 2d at 111.

Because the RCO doctrine requires no proof of wrongful or even unreasonable conduct and because the Agreed Statement of Facts contains no factual assertion that Appellants actually engaged in wrongful or unreasonable conduct, Appellants' admission to being responsible corporate officers hardly constitutes acceptance of culpability. The district court is simply wrong. As the Supreme Court's precedents and the facts of this case both demonstrate, a conviction under the RCO doctrine requires no evidence of fault. Appellants' guilty pleas signified nothing more than an admission that they were responsible officers at Purdue at a time when (unbeknownst to them) other Purdue employees engaged in improper promotional activity. Holding a high-level executive position has never been deemed "evidence of culpability," in our legal system, and prosecutors never alleged that Appellants' convictions were based on anything more.

B. Due Process Requires Strict Liability Penalties To Be "Relatively Small" And Not Cause "Grave Damage To An Offender's Reputation"

Because strict liability offenses dispense with any requirement that the Government prove a defendant's culpability, they are disfavored. *Staples v. United States*, 511 U.S. 600, 606 (1994). Indeed, "[t]he existence of a *mens rea* is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence." *Dennis v. United States*, 341 U.S. 494, 500 (1951). The traditional common law rule is that scienter is a necessary element of every crime. *United States v. Balint*, 258 U.S. 250, 251 (1922).

The presumption against imposing liability without proof of culpability arises from fundamental conceptions of justice and fairness:

> The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil.

Morissette v. United States, 342 U.S. 246, 250 (1952). To brand and punish a person as a criminal without requiring that the person knew or should have known of the conduct that the law deems to be wrongful is to deny that person the essential human dignity of being judged according to his or her conscious choices and not according to sheer fortuity.[6]

Even though strict liability crimes are morally objectionable and have generally been disfavored, courts have nevertheless permitted the imposition of strict liability for so-called "public welfare offenses," but only where the penalties were "relatively small" and conviction did not cause "grave damage to an offender's reputation." *Morissette*, 342 U.S. at 256. These sanctions are regulatory in nature and do not involve "direct or immediate injury to person or property but merely create the danger or probability of it which the law seeks to minimize." *Id.* The RCO doctrine, as applied in both *Dotterweich* and *Park*, falls within this class of strict liability public welfare offenses. Both cases involved FDCA violations, and the penalties were extremely small. In *Dotterweich*, the defendant officer received a $500 fine and 60 days of probation, *United States v. Buffalo Pharmacal Co., Inc.*, 131 F.2d 500, 501 (2d Cir. 1942), *rev'd*, *United States v. Dotterweich*, 320 U.S. 277 (1943), and in *Park*, the defendant officer received a $250 fine. *Park*, 421 U.S. at 666.

---

[6] *See, e.g.*, Assaf Hamdani, *Mens Rea and the Cost of Ignorance*, 93 Va. L. Rev. 415, 416-17 (2007) (noting the consensus view that strict liability "punishes innocent actors and is thus unjust, unconstitutional, and ineffective"); Henry M. Hart, Jr., *The Aims of the Criminal Law*, 23 Law & Contemp. Probs. 401, 422-23, 430 (1958) (explaining that "there can be no moral justification for [strict liability], and that there is not, indeed, even a rational, amoral justification").

Given the threat to fundamental fairness posited by strict liability offenses, courts consider the extent of the penalty and the gravity of the impact on the defendant's reputation in determining whether convictions under the RCO doctrine violate the Due Process Clause. *See United States v. Heller*, 579 F.2d 990, 994 (6th Cir. 1978) ("if Congress attempted to define a *Malum prohibitum* offense that placed an onerous stigma on an offender's reputation and that carried a severe penalty, the Constitution would be offended"). The leading case addressing the constitutional implications of strict liability public welfare offenses is *Holdridge v. United States*, 282 F.2d 302 (8th Cir. 1960) (Blackmun, J), which concluded that the elimination of a *mens rea* requirement did not violate due process where, among other things, "the penalty is relatively small" and the "conviction does not gravely besmirch." *Id.* at 310. *See also United States v. Unser*, 165 F.3d 755, 762-64 (10th Cir. 1999) (applying *Holdridge*); *Tart v. Commonwealth of Massachusetts*, 949 F.2d 490, 502-03 (1st Cir. 1991) (same); *United States v. Wulff*, 758 F.2d 1121, 1125 (6th Cir. 1985) (same). Conversely, a strict liability public welfare conviction violates due process—or at lease raises serious due process concerns—if the penalty is not relatively small or if the conviction causes grave harm to the defendant's reputation.

C. Appellants' Exclusion Raises Serious Due Process Concerns

By excluding Appellants from participation in federal health care programs for twelve years, the Government has imposed a penalty that deprives Appellants of their chosen occupation and significantly erodes their ability to make a living. This exclusion raises serious due process concerns because it imposes a penalty on Appellants for their strict liability convictions that vastly exceeds the relatively minor punishments imposed in *Dotterweich* and *Park*.[7]

Exclusion is hardly a "small" punishment, especially for Appellants who are corporate executives that have spent the large part of their professional lives in the pharmaceutical and health care industries. Under federal law, companies that employ excluded individuals as officers, directors, agents, or managing employees may themselves be excluded from participation in federal health care programs. 42 U.S.C. § 1320a-7(b)(8). These companies may also be fined if they employ excluded individuals to provide services that are reimbursable through a federal health care program. *Id.* § 1320a-7a(a)(6). The effect of these provisions is to exclude Appellants from executive positions within pharmaceutical or health care

[7] Contrary to the district court's assertion that this argument amounts to a collateral challenge to Appellants' RCO convictions, WLF does not question the legality of those convictions. The constitutional problem arises, not from the convictions standing alone, but from the Secretary's interpretation of the exclusion statute as allowing for career-ending exclusions based upon strict liability RCO convictions.

companies that participate in federal health care programs. As a practical matter, this amounts to a *de facto* exclusion from the entire industry because virtually all such companies participate in federal health care programs. As the Secretary advised in the Notices of Exclusion, "[t]he scope of this exclusion is ***broad and has a significant effect on [Appellants'] ability to work in the health care field***." Pls' Mot. for S.J. at 21, Dkt. 21, No. 1:09-cv-02028-ESH (emphasis added). Because exclusion sweeps so broadly, the Secretary has admitted that "[i]n many instances, the practical effect of an OIG exclusion is to preclude employment of an excluded individual in any capacity by a health care provider that receives reimbursement, ***indirectly or directly***, from any Federal health care program." Publication of the OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, 64 Fed. Reg. 52791, 52793 (Sep. 30, 1999) (emphasis added).

Notwithstanding the Secretary's representation about the adverse impact of exclusion on Appellants' ability to work in the health care field, the district court nevertheless concluded that "the consequences of exclusion are not nearly as dire as [Appellants] contend" because they "remain free to seek private employment at a company that does not rely on federal or state funds." *Friedman*, 755 F. Supp. 2d at 112 n.20. This conclusion, however, is extraordinarily dismissive of the pervasive—and ever-growing—role the Government plays in the health care and pharmaceutical sectors. Appellants will be hard-pressed to find any comparable employment in a health care or pharmaceutical company that does not rely "directly or indirectly" on federal or state funding. In reality, therefore, the Secretary's exclusion is tantamount to a ban on their future employment as executives, officers, or managers in the health care field.

While the Government contends otherwise, the "civil" label is irrelevant for due process purposes. *See id.* at 112 (failing to see why the result in this case, "which only involves the imposition of a *civil* exclusion penalty," should be different than the results in *Dotterweich* and *Park*). The exclusion can fairly be deemed an additional punishment for Appellants' convictions given that those misdemeanor convictions were the ***sole basis*** for the decision to exclude Appellants. Of course, if the Government believed that Appellants acted in a culpable manner that (independent of the fact of their convictions) warranted their exclusion from federal health care programs, it was entitled to open an investigation and, based on the evidence gathered, to issue an exclusion order. The Secretary undertook no such investigation, but instead chose to rely solely on the fact of Appellants' misdemeanor pleas. Under those circumstances, the "civil" exclusion order can only be deemed an additional sanction for Appellants' RCO offense.

In addition, by stripping Appellants of their ability to pursue their present career path, thereby effectively terminating their careers, the Government action—however it might be labeled—implicates an important constitutional liberty interest. *See O'Donnell v. Barry*, 148 F.3d 1126, 1141 (D.C. Cir. 1998) ("Government action that has the effect of 'seriously affect[ing], if not destroy[ing]' a plaintiff's ability to pursue his chosen profession" infringes a liberty interest) (quoting *Greene v. McElroy*, 360 U.S. 474, 492 (1959)). It would be a perverse circumvention of the constitutional limitations on strict liability crimes if the Government were able to increase the consequences after the criminal penalty had already been meted out simply by imposing additional so-called "civil" penalties. The Government cannot impose penalties by artifice or subterfuge that would otherwise be unconstitutional if rendered as a part of the original criminal sentence. To conclude otherwise would eviscerate the constitutional due process protections that have been erected to protect the unwitting from the harshness of strict liability prosecutions.

Exclusion also raises constitutional concerns because of the irreparable injury it causes Appellants' reputations. The central purpose of the exclusion statute is "to improve the ability of [HHS] to protect [federal 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); *see also Joann Fletcher Cash*, DAB 1725 (2000) (exclusion statute "seeks to protect the funds of Federal health care programs and the programs' beneficiaries and recipients from untrustworthy providers"). Because Appellants were convicted on a strict liability basis without proof or an admission of wrongful or even negligent conduct on their part, there is no evidence that they are a threat to federal health care programs or beneficiaries. Nevertheless, the Secretary insists that the purposes of exclusion are served by excluding Appellants from future participation in those programs. But if this argument is to be credited, then there can be little doubt that enforcement of exclusion will do substantial, if not irreparable, damage to Appellants' reputations since exclusion is premised on the need to protect against fraud and abuse, as well as incompetent care. By excluding Appellants, the Secretary effectively represents to the public that Appellants are responsible for fraud or abuse to federal health care programs or for the incompetent or inappropriate treatment of program beneficiaries. That is precisely the sort of grave reputational harm that, when arising from a strict liability conviction, raises serious constitutional concerns.[8] The Secretary cannot have it

[8] The Secretary has argued earlier in this litigation that reputational injury implicates no constitutionally protected interests and, therefore, cannot be a basis for a due process claim. This argument incorrectly assumes that Appellants' reputations are the only interests at stake. Although "reputation by itself" is not a

both ways by arguing, on one hand, that excluding Appellants will protect federal health care programs and beneficiaries from abuse and then arguing, on the other hand, that exclusion will not seriously injure Appellants' reputations. If exclusion is necessary to protect federal health care programs and beneficiaries from fraud, abuse, or incompetence, then it necessarily entails reputational injury to the excluded individuals. Indeed, because the exclusion in this case is a career-ending penalty, Appellants will have no realistic opportunity to repair the damage. This damage is a far cry from the "relatively small" sanctions that *Morissette* contemplated would be imposed on those convicted of RCO offenses.

(continued…)

protected interest, *Siegert v. Gilley*, 500 U.S. 226, 233 (1991) (citing *Paul v. Davis*, 424 U.S. 693, 708-09 (1976)), when it is coupled with other, more tangible liberty or property interests, then due process guarantees are triggered. *See Old Dominion Dairy Prods., Inc. v. Sec'y of Def.*, 631 F.2d 953, 966 (D.C. Cir. 1980) (contractor's loss of government employment and the foreclosure of other employment opportunities, both of which resulted from an agency finding that the contractor lacked integrity and responsibility, are liberty interests recognized by the Due Process Clause). *Cf. Davis*, 424 U.S. at 706 ("[T]he Court has never held that the mere defamation of an individual, whether by branding him disloyal or otherwise, was sufficient to invoke the guarantees of procedural due process *absent an accompanying loss of government employment*." (emphasis added)). In this case, the reputational harm to Appellants accompanies their career-ending exclusion from participation in all federal health care programs, both of which are consequences of a criminal conviction. Collectively, these interests suffice to invoke due process protection. In any event, due process concerns are clearly implicated when, as here, the government is inflicting its reputational injury in connection with its imposition of sanctions on criminal defendants.

II. THE SECRETARY'S STATUTORY CONSTRUCTION SHOULD BE REVERSED

It is well established that "where an otherwise acceptable construction of a statute would raise serious constitutional problems," the statute should be construed "to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 466 (1989) (internal quotation marks omitted). Because the Secretary imposed exclusion based solely upon Appellants' strict liability RCO convictions, the fact that the penalty is not relatively small and will cause serious reputational harm raises serious constitutional due process concerns about the Government's interpretation of the exclusion statute. To avoid these constitutional problems, the Secretary's statutory construction should be reversed; exclusion should not be based upon RCO convictions.

Additionally, WLF agrees with Appellants that the Secretary's interpretation decision to exclude Appellants is based on an unreasonable construction of Subsections (b)(1) and (b)(3) of the exclusion statue. Because an RCO conviction imposes vicarious liability on corporate officers for the misconduct of their subordinates, Appellants' RCO convictions necessarily bear a legally manufactured relationship to their employee's acts. But these convictions do not "relate to" that improper promotion in the sense that Appellants had any culpability for it. Given that Appellants had no culpable connection to their employees' improper promotion, it is factually disingenuous to say that Appellants' strict liability convictions "relate to" that misconduct in any meaningful way.

WLF also agrees with Appellants' argument that Subsection (b)(3) is only intended to exclude individuals for crimes related to the Controlled Substances Act and similar state laws, not to crimes under the FDCA. But even if it were, the potential confrontation with constitutional due process guarantees should tip the balance in Appellants' favor, and the relevant exclusion provisions should be construed to not permit exclusion for strict liability RCO convictions.

CONCLUSION

For the foregoing reasons, the district court's decision should be reversed with instructions to vacate the decision of the Departmental Appeals Board.

Respectfully submitted,

/s/ Richard A. Samp
Richard A. Samp
Daniel J. Popeo
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 200036
202-588-0302

Michael A. Carvin
Daniel R. Volkmuth
JONES DAY
51 Louisiana Ave., NW
Washington, DC 20001-2110
202-879-3939

Counsel for *Amicus Curiae*
Washington Legal Foundation

Dated June 29, 2011

CERTIFICATE OF COMPLIANCE

I am an attorney for amicus curiae Washington Legal Foundation. Pursuant to Federal Rule of Appellate Procedure 29(d) and 32(a)(7)(C), I hereby certify that the foregoing brief of amicus curiae is proportionally spaced, has a typeface of 14 points, and contains 6170 words, excluding the parts of the brief exempted by Rule 32 of the Federal Rules of Appellate Procedure.

/s/ Richard A. Samp
Richard A. Samp

CERTIFICATE OF SERVICE

I hereby certify that on this 29th day of June, 2011, I caused true and correct copies of the forgoing Corrected Copy BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLANTS URGING REVERSAL to be served via electronic mail upon all counsel of record, by operation of the Court's ECF system.

/s/ Richard A. Samp
Richard A. Samp