

# Beyond All Bounds of Civility: An Analysis of Administrative Sanctions Against Responsible Corporate Officers

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## I. INTRODUCTION

The corporate business form functions to limit individual liability; in recent years, however, it has been doing just the opposite for some corporate executives.<sup>1</sup> Expanded use of the Responsible Corporate Officer (RCO) doctrine has caused this increased, individual liability.<sup>2</sup> This doctrine, and its subsequent growth, arose from the basic need to hold individuals—generally a malfeasant corporation’s executives—accountable for a corporation’s criminal offenses. Historically, high fines against these entities failed to deter hazardous yet lucrative behavior because the risk of monetary sanctions failed to offset the potential profits.<sup>3</sup> From the corporation’s perspective, these fines and other sanctions were reduced to nothing more than another “cost of doing business”<sup>4</sup> in its accounting books. Administrative agencies and courts have adjusted accordingly and shifted their focus to prosecuting and punishing executives in charge of corporations that violate criminal laws.<sup>5</sup> This Note seeks to illustrate how the increased effort to hold these individuals liable for corporate actions has blurred the basic legal distinction between civil and criminal law. Specifically, it will emphasize how duplicative punishment of RCOs offends the Fifth Amendment’s double jeopardy clause. Part II of this Note will discuss the history of the Responsible Corporate Officer doctrine, which has been employed to hold corporate executives criminally liable for a corporation’s transgressions. It will also introduce the analytical framework courts employ to analyze whether a legal sanction is civil or criminal. Part III will illustrate how courts and regulatory agencies have created a de facto system of duplicative, punitive punishments against RCOs. Finally, Part IV recommends adjustments to the analytical framework courts use to determine the nature of a legal sanction.

## II. BACKGROUND

The Responsible Corporate Officer doctrine’s resurgence illustrates the recent paradigm shift toward individual liability for corporate wrongdoing. The RCO doctrine allows courts to punish individuals who hold positions of responsibility within a corporation, rather than punishing the corporation itself.<sup>6</sup> Importantly, under this doctrine, corporate officers who neither knew of nor played an active role in a corporation’s illegal behavior can be held criminally liable.<sup>7</sup> This Part will provide a brief overview of the RCO doctrine’s evolution since its origins in the 1930s. Then, this Part

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1. See *infra* Part II (discussing how the Responsible Corporate Officer (RCO) doctrine opens corporate executives to expansive individual, criminal liability).

2. See *infra* Parts II.A–B (describing the RCO doctrine as a method to impose individual criminal liability for corporate wrongs).

3. See generally *Improving Efforts to Combat Healthcare Fraud: Testimony Before the H. Comm. on Ways and Means, Subcomm. on Oversight*, OFF. INSPECTOR GEN. (Mar. 2, 2011), [http://oig.hhs.gov/testimony/docs/2011/morris\\_testimony\\_03022011.pdf](http://oig.hhs.gov/testimony/docs/2011/morris_testimony_03022011.pdf) (providing the testimony of Lewis Morris, Chief Counsel to Inspector General, U.S. Dep’t of Health & Human Services) [hereinafter *Testimony of Lewis Morris*].

4. *Id.* at 6.

5. See *infra* Parts II.A–B (describing the RCO doctrine as a method to impose individual criminal liability for corporate wrongs).

6. JAMES D. COX & THOMAS LEE HAZEN, *TREATISE ON THE LAW OF CORPORATIONS* § 8:22 (3d ed. 2014).

7. *Id.*

will introduce how RCO prosecutions and regulatory punishments have eroded the foundational, legal distinction between civil and criminal sanctions.

#### *A. Brief Summary of the Responsible Corporate Officer Doctrine*

Legislators justify the RCO doctrine as a method to bridge the liability gap caused by corporate wrongs.<sup>8</sup> Simply put, it resolves the predicament created by the absence of an identifiable individual who is culpable for a corporation's actions by holding its executives responsible.<sup>9</sup> This doctrine, when paired with the public welfare doctrine, presents a legal paradox by allowing courts to hold individuals criminally liable for corporate wrongs without proving two of the four essential elements of most crimes—*mens rea* and *actus reus*.<sup>10</sup> The following Sections discuss how the recent, strict application of the RCO doctrine against healthcare executives illustrates a significant divergence from the doctrine's humble beginnings.<sup>11</sup>

##### *1. The Origins of RCO*

The history of the RCO doctrine begins with the Supreme Court's interpretation of the Food, Drug, and Cosmetic Act of 1938's (FDCA) public welfare crime<sup>12</sup> in two seminal cases.<sup>13</sup> Among many things, the FDCA prohibits corporations and individuals from introducing adulterated or misbranded food or drugs into interstate commerce.<sup>14</sup> This legislation plays a prominent role in prosecuting corporate crimes in the food and drug industry.

In *United States v. Dotterweich*, the Supreme Court held a pharmaceutical company's president liable for the introduction of mislabeled drugs into interstate commerce.<sup>15</sup> The Court found that the defendant, as president of the company, was "standing in responsible relation to a public danger."<sup>16</sup> Importantly, the Court held Dotterweich liable despite a lack of evidence that he had any knowledge of the mislabeling.<sup>17</sup> The Court reasoned that Congress passed the FDCA to protect the public from certain health hazards; in this case, the public welfare concerns outweighed the need to find any scienter or a direct link between this executive's actions and the corporation's transgressions.<sup>18</sup> The Court concluded: "Such legislation dispenses with the

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8. *Id.*

9. *Id.*

10. *Id.*

11. See *infra* Sections II.A.1–2 (discussing how the RCO doctrine has evolved over time).

12. Food, Drug, and Cosmetics Act of 1938, 21 U.S.C. § 301 (1938) (current version at 21 U.S.C. § 331 (2015)) (stating that any individual who introduced mislabeled or adulterated drugs into commerce is liable for monetary fines and up to three years in prison).

13. *United States v. Dotterweich*, 320 U.S. 277, 281 (1943); *United States v. Park*, 421 U.S. 658, 678 (1975).

14. 21 U.S.C. § 301.

15. *Dotterweich*, 320 U.S. at 278.

16. *Id.* at 281.

17. *Id.* at 285.

18. See *id.* at 281 (discussing how the public good outweighs the burden of proving a scienter requirement in the context of public welfare offenses, stating "the burden of acting at hazard [is] upon a person otherwise innocent but standing in responsible relation to a public danger").

conventional requirement for criminal conduct—awareness of some wrongdoing.”<sup>19</sup> The Court upheld Dotterweich’s sentence of 60 days of probation and a \$750 fine in a five-to-four decision.<sup>20</sup> Not only did this case establish vicarious liability for all executives who were “standing in responsible relation to a public danger,” but it also created a reduced mens rea requirement for RCOs, which is akin to strict liability.<sup>21</sup> Courts refer to this mens rea reduction as the public welfare doctrine.<sup>22</sup>

More than three decades later, in 1975, the Supreme Court revisited the RCO doctrine in *United States v. Park*.<sup>23</sup> *Park* cemented the proposition that an individual’s criminal liability can depend almost entirely on his or her corporate officer position.<sup>24</sup> Instead of an executive “standing in responsible relation to a public danger,”<sup>25</sup> the Court defined RCOs’ scope of individual, criminal liability to all executives who have “responsibility and authority either to prevent . . . or promptly to correct, the violation complained of.”<sup>26</sup> Some justices cautioned against using such a broad scope of potential, criminal liability for corporate executives.<sup>27</sup> Justice Stewart warned that, while this form of vicarious liability appeared justified when courts handed out insignificant sanctions such as monetary fines, the same cannot be said for greater sanctions:

[T]he standardless conviction approved today can serve in another case tomorrow to support a felony conviction and a substantial prison sentence. However highly the court may regard the social objectives of the Food, Drug, and Cosmetic Act, that regard cannot serve to justify a criminal conviction so wholly alien to fundamental principles of our law.<sup>28</sup>

This plea for caution did not fall on deaf ears. Until recently, criminal sanctions associated with RCO cases were limited to monetary fines.<sup>29</sup> Courts were hesitant to exercise their statutory authority to incarcerate individuals who violated the FDCA without any proof of conscious wrongdoing.<sup>30</sup>

19. *Id.*

20. *Dotterweich*, 320 U.S. at 285. The four dissenting judges voiced concern over applying strict liability to criminal law. *Id.* at 286 (Murphy, J., dissenting) (“[A] fundamental principle of Anglo-Saxon jurisprudence that guilt . . . ought not lightly to be imputed to a citizen who, like the respondent, has no evil intention or consciousness of wrongdoing.”).

21. *Id.* at 281.

22. Amiad Kushner, *Applying the Responsible Corporate Officer Doctrine Outside the Public Welfare Context*, 93 J. CRIM. L. & CRIMINOLOGY 681, 700 (2003).

23. *United States v. Park*, 421 U.S. 658, 678 (1975).

24. *Id.* at 674. The *Park* Court stated, “the charge did not permit the jury to find guilt solely on the basis of respondent’s position in the corporation.” *Id.* Rather, guilt must rest on a “responsible relation to the situation”—a phrase the *Dotterweich* Court held “too treacherous to define.” *Id.*; *Dotterweich*, 320 U.S. at 285. Accordingly, finders of fact will largely rely on an executive’s position and its official responsibilities to find a responsible relation to a crime.

25. *Dotterweich*, 320 U.S. at 281; *Park*, 421 U.S. at 674.

26. *Park*, 421 U.S. at 674.

27. *Id.* at 683 (Stewart, J., dissenting).

28. *Id.*

29. See generally Randy J. Sutton, Annotation, “The Responsible Corporate Officer” Doctrine or “Responsible Relationship” of Corporate Officer to Corporate Violation of Law, 119 A.L.R. 5th 205 (2004) (listing criminal cases under the FDCA employing the RCO doctrine).

30. 21 U.S.C. § 333 (2015) (allowing incarceration for up to one year for violations of the FDCA). It should also be noted that environmental executives were occasionally subjected to incarceration. See generally, e.g., *United States v. Ming Hong*, 242 F.3d 528 (4th Cir. 2001) (upholding a three-year prison sentence for

## 2. Expansion of RCO

In the decades preceding *Park*, prosecutors employed RCO sparingly—with the exception of environmental claims.<sup>31</sup> RCO-related criminal penalties exacted on healthcare executives for FDCA violations were monetary fines.<sup>32</sup> However, recent efforts to strengthen regulatory enforcement are challenging the once well-accepted custom that vicariously liable RCOs should only be subject to monetary fines.<sup>33</sup>

In 2010, a report from the Government Accountability Office (GAO) implored administrative agencies and the Department of Justice (DOJ) to increase efforts to enforce Federal Drug Administration (FDA) regulations and statutes, namely the FDCA.<sup>34</sup> Accordingly, this has and will result in punishing more RCOs.<sup>35</sup> Advocating for greater individual liability for corporate wrongs, Lewis Morris, Chief Counsel for the Department of Health and Human Services (HHS), explained how corporations and RCOs that commit public welfare crimes consider civil penalties and criminal fines a “cost of doing business.”<sup>36</sup> Although the fines handed to corporations and RCOs were far from slaps on the wrist,<sup>37</sup> historical corporate practice has illustrated that businesses will continue to violate laws even after receiving hefty fines.<sup>38</sup> These efforts to expand liability led administrative agencies to develop new protocols for stricter enforcement of public welfare crimes, like the FDCA.<sup>39</sup>

The primary regulatory tool used to enforce public welfare crimes in the healthcare industry is the HHS’s exclusion authority.<sup>40</sup> The exclusion authority allows the Office of the Inspector General (OIG)<sup>41</sup> to withhold federal healthcare program payment to any

environmental RCOs); *see generally, e.g.*, United States v. Frezzo Bros., Inc., 602 F.2d 1123 (3rd Cir. 1979) (sentencing executives to 30 days in jail for discharging pollutants into water).

31. Environmental executives were occasionally subjected to incarceration. *See generally, e.g., Ming Hong*, 242 F.3d 528 (upholding a three-year prison sentence for environmental RCOs); *Frezzo Bros., Inc.*, 602 F.2d 1123 (sentencing executives to 30 days in jail for discharging pollutants into water).

32. *See Sutton*, *supra* note 29, at § 6[b] (describing criminal punishments for FDCA cases).

33. *See Park*, 421 U.S. at 683 (Stewart, J., dissenting) (warning that RCOs should not be incarcerated).

34. *See generally* U.S. GOV’T ACCOUNTABILITY OFF., GAO-10-221, IMPROVED MONITORING AND DEVELOPMENT OF PERFORMANCE MEASURES NEEDED TO STRENGTHEN OVERSIGHT OF CRIMINAL AND MISCONDUCT INVESTIGATIONS (Jan. 2010), <http://www.gao.gov/assets/310/300503.pdf>; Lisa Estrada et al., *Recent Developments in OIG Exclusion: Health Care Corporate Executives in the Crosshairs*, BLOOMBERG BNA (June 14, 2013),

<https://www.arentfox.com/sites/default/files/EstradaGreenbergMaddenOIGExclusion.pdf> (discussing the OIG’s increased use of regulatory punishments against RCOs in the healthcare industry).

35. *Park*, 421 U.S. at 683 (Stewart, J., dissenting).

36. Testimony of Lewis Morris, *supra* note 3, at 6.

37. *See* Katrice Bridges Copeland, *The Crime of Being in Charge: Executive Culpability and Collateral Consequences*, 51 AM. CRIM. L. REV. 799, 801 (2014) (noting how some corporations received penalties as high as \$3 billion).

38. *See* Stacey English, *The rising costs of non-compliance*, THOMSON REUTERS (Dec. 8, 2014), [thomsonreuters.com/en/articles/2014/rising-costs-of-non-compliance.html](http://thomsonreuters.com/en/articles/2014/rising-costs-of-non-compliance.html) (describing the current corporate atmosphere as “a world where supersize fines no longer either shock or deter”).

39. *See* Andrew R. Ellis, *The Responsible Corporate Officer Doctrine: Sharpening a Blunt Health Care Fraud Enforcement Tool*, 9 N.Y.U. J.L. & BUS. 977, 981 (2013) (discussing the new OIG protocol for issuing exclusions).

40. *See id.* (explaining exclusion authority, and stating that the OIG received exclusion authority from the HHS in 1977).

41. *Exclusions FAQ*, U.S. DEP’T OF HEALTH & HUM. SERVS., <http://oig.hhs.gov/faqs/exclusions-faq.asp> (last visited Mar. 5, 2017) (“The effect of an exclusion is that no payment will be made by any Federal health

party that employs or contracts with an officer held individually liable for his corporation's wrongs (i.e., an excluded individual).<sup>42</sup> Excluded individuals are virtually unemployable because any healthcare company that works with one will be prohibited from conducting business affecting prevalent government programs like Medicare and Medicaid.<sup>43</sup>

The OIG uses its exclusion authority on a case-by-case basis.<sup>44</sup> Some regulatory violations mandate exclusions, while other, less serious offenses may result in permissive exclusions.<sup>45</sup> The HHS generally hands out exclusions after criminal prosecutions, and the harsh effect of exclusions cannot be understated.<sup>46</sup> Excluded healthcare executives will not be able to find work in the industry in which they have presumably spent their entire careers. Many have labeled the civil punishment a “death sentence” to the careers of RCOs in the pharmaceutical or healthcare industry.<sup>47</sup>

A few recent cases demonstrate the growing severity of penalties RCOs now face. In 2007, the OIG handed down one of its longest exclusions to three pharmaceutical executives who failed to prevent false advertising of their pain medications.<sup>48</sup> Before their exclusions, the executives were sentenced to criminal sanctions of 400 hours of community service and \$5000 fines.<sup>49</sup> Also, they were forced to repay approximately \$34.5 million in profits from the sale of these drugs.<sup>50</sup> On top of these criminal sanctions, the OIG excluded the executives—who signed plea agreements that did not indicate any mens rea—for 20 years.<sup>51</sup>

In *United States v. Synthes*, medical company executives were the first RCOs in the drug industry to face jail time after accepting guilty pleas.<sup>52</sup> Four executives were sentenced from terms of five-to-nine months in prison for their admission that they were RCOs of a corporation that tested bone cement without FDA authorization.<sup>53</sup> In addition to criminal incarceration, the OIG subsequently excluded all executives involved.<sup>54</sup> Not only has Justice Stewart's cautionary dissent about RCO incarcerations become a

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care program for any items or services furnished, ordered or prescribed by an excluded individual or entity.”).

42. *Id.* Although HHS received exclusion authority just two years after *Park* from the Social Services Act, legislation that refined and implemented the authority took place over the course of many years. See Copeland, *supra* note 37, at 817 (discussing the evolution of exclusion authority).

43. U.S. DEP'T OF HEALTH & HUM. SERVS., *supra* note 41.

44. *Id.*

45. See 42 U.S.C. § 1320a-7 (2010) (outlining executive conduct that results in mandatory or permissive exclusion).

46. Copeland, *supra* note 37, at 828 (discussing the collateral effects of exclusions).

47. *Id.* at 800 (quoting Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act is the Wrong Rx*, 12 J. HEALTH CARE L. & POL'Y 119, 137 (2009)).

48. See *Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012) (discussing the corporate misconduct).

49. *Id.*

50. See *id.* at 816–17 (discussing the procedural history of the appeal).

51. *Id.* This extended exclusion was subsequently reduced multiple times on appeal. *Id.* at 818, 828. The defendants' final exclusion length could not be found on the OIG's Exclusions database at <https://exclusions.oig.hhs.gov>.

52. Ellis, *supra* note 39, at 1017.

53. See *List of Excluded Individuals and Entities*, OFF. OF INSPECTOR GEN., [https://oig.hhs.gov/exclusions/exclusions\\_list.asp](https://oig.hhs.gov/exclusions/exclusions_list.asp) (last visited Mar. 5, 2017) (failing to provide lengths of exclusions).

54. *Id.*

reality,<sup>55</sup> but RCOs now also face regulatory sanctions, such as exclusions, solely because of their executive status in a corporation.<sup>56</sup>

*B. The Fine Line Between Civil and Criminal Punishments and Its Relevance to RCOs*

American jurisprudence assigns significant constitutional importance to the basic distinction between a criminal and civil punishment, particularly in the double jeopardy clause of the Fifth Amendment.<sup>57</sup> While courts and regulatory agencies may punish the same conduct with both criminal and civil sanctions, the Supreme Court has held that only successive criminal sanctions violate the double jeopardy clause.<sup>58</sup> Although this seems to be an elementary restatement of black-letter law, administrative agencies' growing ability to dole out punitive civil sanctions has blurred this once-imperative distinction.<sup>59</sup> As civil punishments—particularly exclusions—against RCOs become commonplace, administrative agencies are regularly imposing successive punishments on RCOs.<sup>60</sup> The constitutionality of these regulatory sanctions turns on whether courts determine them to be civil or criminal in nature.<sup>61</sup>

*1. The Mendoza-Martinez Test*

When determining whether a punishment is civil or criminal in nature, courts apply the two-pronged *Mendoza-Martinez* test.<sup>62</sup> Courts first look at a criminal statute on its face to determine whether legislators intended the punishment to be civil.<sup>63</sup> Explicit or implicit legislative intent to create a civil punishment cannot be dispositive.<sup>64</sup> However, if a court finds legislators intended to create a civil punishment, there is a strong presumption against criminality.<sup>65</sup> In these cases, the second step of the test requires the “clearest proof” that a punishment is indeed punitive for a court to deem the sanction criminal.<sup>66</sup> In the second part of the test, courts attempt to discern the true nature of a

55. *United States v. Park*, 421 U.S. 658, 683 (1975) (Stewart, J., dissenting).

56. *See Copeland*, *supra* note 37, at 831–33 (positing that lengthy exclusions constitute de facto criminal punishments).

57. U.S. CONST. amend. V (“[N]or shall any person be subject for the same offense to be twice put in jeopardy of life or limb . . .”). It should be noted that the double jeopardy clause of the Fifth Amendment applies to both state and federal sanctions through the Fourteenth Amendment. *Benton v. Maryland*, 395 U.S. 784, 796 (1969).

58. *Benton*, 395 U.S. at 796; *Hudson v. United States*, 522 U.S. 93, 99 (1997).

59. *See* Kenneth Mann, *Punitive Civil Sanctions: The Middleground Between Criminal and Civil Law*, 101 YALE L.J. 1795, 1862 (1992) (discussing the effect of agency punishments on jurisprudential views of the civil criminal punishment distinction).

60. *See supra* notes 48–54 and accompanying text (providing examples of exclusions that occurred after criminal punishment).

61. *See generally* Gregory Y. Porter, Note, *Uncivil Punishment: The Supreme Court's Ongoing Struggle with Constitutional Limits on Putative Civil Sanctions*, 70 S. CAL. L. REV. 517 (1997) (discussing successive criminal punishments).

62. *See Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168 (1963) (outlining the relevant factors for determining whether a sanction is criminal or civil).

63. *Hudson*, 522 U.S. at 99.

64. *Mendoza-Martinez*, 372 U.S. at 169.

65. *United States v. Ward*, 448 U.S. 242, 249 (1980) (noting “only the clearest proof could suffice to establish . . . unconstitutionality of a statute” in the face of Congress’s clear intention to create a civil penalty).

66. *Id.*

sanction by balancing the following seven factors:

Whether the sanction involves [1] an affirmative disability or restraint, [2] whether it has historically been regarded as a punishment, [3] whether it comes into play only on a finding of scienter, [4] whether its operation will promote the traditional aims of punishment—retribution and deterrence, [5] whether the behavior to which it applies is already a crime, [6] whether an alternative purpose to which it may rationally be connected is assignable for it, and [7] whether it appears excessive in relation to the alternative purpose assigned are all relevant to the inquiry . . . .<sup>67</sup>

However, courts have readily accepted that these factors are “neither exhaustive nor dispositive.”<sup>68</sup> This declaration provides courts seemingly limitless discretion, allowing them to pick and choose the factors to emphasize or trivialize in a given case.<sup>69</sup>

## 2. A More Precise View of Judicial and Regulatory Sanctions: The Tripartite Framework

Although current jurisprudence only recognizes the distinction between civil and criminal punishments,<sup>70</sup> legal sanctions can be classified in three distinct groups: criminal, punitive civil, and remedial civil.<sup>71</sup> This tripartite framework more accurately reflects the increased role regulatory enforcement plays in today’s society because civil sanctions handed down by administrative agencies now extend beyond simple monetary fines.<sup>72</sup> Therefore, this framework distinguishes between remedial civil punishments, which seek to compensate an injured party—generally with a monetary payment—and punitive civil sanctions, which attempt to punish and deter.<sup>73</sup> Punitive civil sanctions should be considered criminal for the purposes of this Note because the double jeopardy clause expressly prohibits imposition of two punitive sanctions on the same individual for the same conduct.<sup>74</sup>

### III. ANALYSIS

This Part investigates whether courts and regulatory agencies have overstepped their constitutional limits by imposing successive punitive sanctions on corporate executives. First, this Part briefly introduces the constitutional issue presented by duplicative regulatory and judicial sanctioning of RCOs and explains why it may violate the Fifth Amendment’s double jeopardy clause.<sup>75</sup> Then, this Part will illustrate how courts have

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67. *Mendoza-Martinez*, 372 U.S. at 168–69.

68. *Ward*, 448 U.S. at 249.

69. See generally *infra* Part III.B (analyzing cases where courts haphazardly follow the *Mendoza-Martinez* guidelines—namely *Manocchio v. Kusserow*, 961 F.2d 1539 (11th Cir. 1992) and *Hudson v. United States*, 522 U.S. 93 (1997)).

70. See *Hudson*, 522 U.S. at 98 (explaining that the double jeopardy clause prohibits duplicative criminal penalties).

71. Mann, *supra* note 59, at 1861; Carol S. Steiker, *Punishment and Procedure: Punishment Theory and the Criminal-Civil Procedural Divide*, 85 GEO. L.J. 775, 813 (1997).

72. Mann, *supra* note 59, at 1861–64.

73. *Id.* at 1864–65.

74. U.S. CONST. amend. V; see also *Hudson*, 522 U.S. at 99 (positing that civil punishments which are punitive will be considered criminal for purposes of the double jeopardy clause).

75. U.S. CONST. amend. V; see *infra* Part III.A (expanding on these ideas).

manipulated the flexible *Mendoza-Martinez* framework in the past to perpetuate a system of duplicative, punitive criminal and civil punishments.<sup>76</sup> This Part will conclude by analyzing whether HHS exclusions should be considered criminal or civil sanctions under the *Mendoza-Martinez* framework.<sup>77</sup> This analysis hopes to demonstrate how this test fails to properly determine the nature of vicarious liability crimes with minimal mens rea requirements like FDCA violations.

*A. How RCO's Resurgence Presents a Duplicative Punishment Problem*

The abbreviated summaries of recent RCO cases in the healthcare industry provided in Section II.A.2 demonstrate one unavoidable truth: the days of *Dotterweich* and *Park* are long gone.<sup>78</sup> The fines faced by RCOs in the past<sup>79</sup> pale in comparison to the exclusions that now supplement courts' criminal sanctions against RCOs.<sup>80</sup> These increased efforts to enforce public welfare crimes have created a de facto system of successive punishment where RCOs face both criminal prosecution and civil sanctions from agencies.<sup>81</sup> Although undeniably sound public policy—keeping society safe from dangerous products—motivates regulatory and criminal sanctions, courts and agencies are toeing a dangerous line of imposing successive, punitive, and therefore unconstitutional, punishments for the same conduct.<sup>82</sup>

Analyzing the duplicative punishment of RCOs through the tripartite framework introduced in Section II.B.2 emphasizes the unconstitutional nature of combining exclusions with criminal sanctions. Agencies and courts must be aware of when to employ each type of punishment—remedial civil, punitive civil, and criminal—and how they relate to each other. Each type of punishment affects the need for alternative or supplemental sanctions.<sup>83</sup> For example, “[t]he growth of punitive civil sanctions directly affects criminal law. It lessens the need to use criminal law to sanction wrongs and permits a more flexible response to wrongful conduct.”<sup>84</sup>

Seventh Circuit Judge Richard Posner sees a similar relationship between punitive civil sanctions and criminal sentences. His theory posits that criminal sanctions should be limited to insolvent wrongdoers or to corporate executives who are so wealthy that they are insensitive to monetary fines.<sup>85</sup> On the other hand, courts and agencies should impose

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76. See *infra* Part III.B (summarizing how two different courts employed the *Mendoza-Martinez* test).

77. See *infra* Part III.C (analyzing *Mendoza-Martinez* in relation to exclusions).

78. See *supra* notes 48–54 and accompanying text (describing the strict penalties faced by defendants in *Friedman* and *Synthes*).

79. *Contra*. *United States v. Dotterweich*, 320 U.S. 277, 281 (1943) (fining defendants \$750) and *United States v. Park*, 421 U.S. 658, 683 (1975) (fining defendants \$250) with *Copeland*, *supra* note 37, at 801 (noting some corporations received penalties as high as \$3 billion).

80. See, e.g., *supra* notes 48–54 and accompanying text (providing examples of exclusions that occurred after criminal punishment).

81. See *supra* note 79 (comparing instances of such penalties).

82. See generally *Porter*, *supra* note 61 (discussing the Supreme Court's inconsistent dealings with successive criminal punishments).

83. See *Mann*, *supra* note 59, at 1863 (discussing the relationship between different classifications of sanctions).

84. *Id.*

85. See Richard A. Posner, *An Economic Theory of the Criminal Law*, 85 COLUM. L. REV. 1193, 1205 (1985) (explaining that civil sanctions are commonly ineffective because of solvency limits).

punitive civil sanctions primarily as deterrence.<sup>86</sup>

Agencies and courts have turned a blind eye to the relationship between criminal and punitive civil sanctions.<sup>87</sup> The dual-punishment inflicted on RCOs blurs the distinction between civil and criminal penalties; this current practice aims “to achieve the state’s regulatory purpose unimpeded by the ‘technical’ limits imposed by criminal law or criminal procedure. This results in the erosion of formal distinctions between ‘criminal’ and ‘civil’ actions.”<sup>88</sup> This “erosion” bears constitutional significance, especially if incarceration of RCOs becomes more commonplace.<sup>89</sup>

### B. Shortcomings of the *Mendoza-Martinez* Analysis

This Part illustrates how courts have manipulated the seven factors of the *Mendoza-Martinez* test<sup>90</sup>—which determines whether a sanction is civil or criminal—to perpetuate the unconstitutional legal fiction of pairing criminal sanctions with punitive regulatory punishments. As stated above, the test consists of two parts.<sup>91</sup> First, courts search for legislative intent to create a civil or criminal punishment.<sup>92</sup> Then, courts look to the “neither exhaustive nor dispositive”<sup>93</sup> factors for an indication of a penalty’s criminal or civil nature.<sup>94</sup> Courts only deem a sanction criminal if the factors show it should be declared so by the “clearest proof.”<sup>95</sup> This balancing test’s discretionary nature allows courts to selectively choose the factors that emphasize a sanction’s civility.<sup>96</sup>

For example, the Eleventh Circuit investigated whether an exclusion constituted a punitive punishment in *Manocchio v. Kusserow*.<sup>97</sup> In this case, the court imposed a \$1000 fine and three years of probation after a doctor pleaded guilty to making a fraudulent Medicare claim for \$62.50.<sup>98</sup> Subsequently, the Department of Health and Human Services excluded him for five years.<sup>99</sup> The Eleventh Circuit dismissed

86. Mann, *supra* note 59, at 1830 (“[T]he purpose of these sanctions is to impose a cost on wrongdoers that promotes compliance with the law.”).

87. See, e.g., *United States v. Synthes, Inc.*, Criminal No. 09-403-02, 2010 WL 4977512 (E.D. Pa. Dec. 7, 2010) (imposing jail sentences of five to nine months and excluding the same individuals).

88. Abraham S. Goldstein, *White-Collar Crime and Civil Sanctions*, 101 YALE L.J. 1895, 1895 (1992) (discussing administrative sanctions in general).

89. The constitutionality of incarcerating RCOs has been challenged primarily through Fifth and Eighth Amendment arguments. See generally Brief for The Nat’l Ass’n of Mfrs. & the CATO Inst. as Amici Curiae Supporting Appellants and Reversal, *United States v. DeCoster*, 828 F.3d 626 (8th Cir. 2016) (Nos. 15-1890, 15-1891) (challenging incarceration on cruel and unusual punishment and due process grounds). This Note seeks to highlight the commonly overlooked route to challenging incarceration of RCOs through the double jeopardy clause of the Fifth Amendment.

90. See *supra* Part II.B (introducing the *Mendoza-Martinez* analysis).

91. *Id.*

92. *Id.*

93. *United States v. Ward*, 448 U.S. 242, 249 (1980).

94. *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 209 (1963).

95. *Id.*

96. Similar tests that have multiple, optional factors have met heavy criticism. *Exacto Spring Corp. v. Commissioner*, 196 F.3d 833, 835 (7th Cir. 1999) (“[I]t is nondirective. No indication is given of how the factors are to be weighed in the event they don’t all line up on one side . . . [Such a test] invites the making of arbitrary decisions based on uncanalized discretion or unprincipled rules of thumb.”).

97. *Manocchio v. Kusserow*, 961 F.2d 1539, 1541 (11th Cir. 1992).

98. *Id.* at 1539.

99. *Id.* at 1541 (providing an exclusion pursuant to 42 U.S.C. § 1320a-7). *Manocchio* had already received

Manocchio’s claim against the secretary of the HHS to strike down the exclusion as an unlawful, successive, criminal penalty.<sup>100</sup>

While investigating whether the five-year exclusion was punitive—and therefore unconstitutional when paired with another criminal sanction—the court concluded that legislators intended to create a civil sanction.<sup>101</sup> However, the Social Security Act, which created the HHS’s exclusion authority, contains no text that explicitly labels the regulatory sanction as a civil or criminal penalty.<sup>102</sup> The court also concluded that, “[w]hile his exclusion from the Medicare system for five years undoubtedly carries the ‘sting of punishment,’ the purpose his exclusion serves is still remedial.”<sup>103</sup>

At its core, the Fifth Amendment was intended to prevent citizens from suffering the “sting of punishment” twice for the same conduct.<sup>104</sup> However, the court tactfully minimizes this sentiment by focusing on the remedial purpose of exclusions.<sup>105</sup> Furthermore, it is worth noting that the court reached these conclusions without explicitly considering any of the seven *Mendoza-Martinez* factors.<sup>106</sup> This exemplifies how the test fails to properly focus a court’s analysis and restrain judicial discretion.

The Supreme Court’s decision in *Hudson v. United States*—which affirmed the *Mendoza-Martinez* factors as the proper test for deciding a punishment’s criminal or civil nature—illustrates how the test fails to reign in judicial discretion.<sup>107</sup> This opinion undermines the *Mendoza-Martinez* test by manipulating its loose guidance.<sup>108</sup> In this case, a banker who had already faced criminal sanctions for misappropriating funds appealed the Office of Comptroller of Currency’s (OCC) subsequent decision to debar him based on the same conduct.<sup>109</sup> After holding that the OCC statute did not explicitly label the debarment punishment civil in nature, the Supreme Court held that the mere fact that an administrative agency gave the penalty was “prima facie evidence that Congress intended to provide for a civil sanction.”<sup>110</sup> The Court then allowed this circular logic<sup>111</sup> to frame its analysis of the *Mendoza-Martinez* factors.

Moving to the second prong of the *Mendoza-Martinez* test, the Court concluded that debarment does not constitute an affirmative restraint.<sup>112</sup> It reasoned “debarment has

criminal sanctions of a fine and probation. *Id.*

100. *Id.*

101. *Manocchio*, 961 F.2d at 1541.

102. *See generally* 42 U.S.C. § 1320a-7 (2015) (containing no mention of civil or criminal nature of exclusions).

103. *Manocchio*, 961 F.2d at 1542.

104. U.S. CONST. amend. V.

105. *Manocchio*, 961 F.2d at 1542.

106. *See generally id.* (failing to even allude to the existence of any uniformly used test that decides the nature of a sanction).

107. *Hudson v. United States*, 522 U.S. 93, 104 (1997) (referring to the *Mendoza-Martinez* test as the *Ward* test).

108. *Id.* at 104–05.

109. *Id.* at 97–98.

110. *Id.* at 103.

111. It seems counterintuitive that any inquiry into the nature of a penalty should rely on the governing body that handed down such a punishment. A test that intends to prevent regulatory agencies from giving criminal punishments cannot allow the fact that a punishment is given by an agency to be “prima facie” evidence that such a sanction is civil. *See id.* at 115 (Breyer, J., concurring) (arguing legislative intent should not be dispositive in determining a sanction’s nature and against the clearest proof standard).

112. *Hudson*, 522 U.S. at 104.

historically been viewed as punishment.”<sup>113</sup> However, the court decided it was not an affirmative restraint because it is “certainly nothing approaching the ‘infamous punishment’ of imprisonment.”<sup>114</sup> Then, the Court reasoned that the defendant’s scienter was considered during debarment but not required for the punishment.<sup>115</sup> Finally, the Court admitted two of the seven factors indicated the sanction was indeed punitive: (1) the conduct was also punishable by criminal sanctions (in this case there was a previous indictment), and (2) debarment served a common criminal law goal of deterrence.<sup>116</sup>

This case illustrates how courts commonly manipulate the “neither exhaustive nor dispositive” factors of the test. Rather than simply applying the test’s standard of whether the sanction imposes an affirmative restraint,<sup>117</sup> the Court trivializes the disability debarment placed on the defendant by comparing it to incarceration.<sup>118</sup> In addition, the Court created a presumption of civility by declaring the mere fact that an agency gave the sanction a prima facie indicator that it was a civil sanction. Commonly overlooked framing devices such as these demonstrate how easily a court can make a punitive characteristic of a sanction appear civil.

### C. *Mendoza-Martinez Application to Exclusions*

As illustrated in Part III.B,<sup>119</sup> courts rarely feel bound by the plain language and meaning of the *Mendoza-Martinez* factors. This Part demonstrates that a proper *Mendoza-Martinez* analysis indicates that lengthy exclusions constitute punitive sanctions that should not be paired with criminal sanctions. Additionally, this Part displays how courts fail to account for inherent differences between public welfare crimes and typical criminal sanctions when determining the nature of a punishment by highlighting a few problematic prongs of the test. The following sections mimic a court’s application of the *Mendoza-Martinez* test to an exclusion.<sup>120</sup>

#### I. *Legislative Text*

The plain text of the Social Security Act does not explicitly label exclusions as a civil sanction.<sup>121</sup> However, in the past, courts have interpreted legislative silence as

113. *Id.*

114. *Id.* (quoting *Flemming v. Nestor*, 363 U.S. 603, 617 (1960)).

115. *Id.* at 104–05.

116. *Id.* at 105.

117. The first factor considered in the second prong of the *Mendoza-Martinez* test is “[w]hether the sanction involves an affirmative disability or restraint.” *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168 (1963).

118. *Hudson*, 522 U.S. at 104.

119. See *supra* Part III.B (summarizing how courts have failed to properly follow the *Mendoza-Martinez* test).

120. As a reminder, the test consists of two prongs. The first prong of the test investigates whether the face of the legislative text that creates the regulatory punishment states that the sanction is intended to be civil in nature. *Mendoza-Martinez*, 372 U.S. at 168–69. If there is a finding of legislative intent toward a sanction’s civil nature, the second-prong, which consists of seven equally weighted factors, must present the “clearest proof” for a punishment to be considered criminal. *Id.* Section III.C.1 represents the first prong, while Sections III.C.2–7 represent the second prong factors (Section III.C.7 consolidates the considerations of “whether an alternative purpose to which [the sanction] may rationally be connected is assignable for it, and whether [the sanction] appears excessive in relation to the alternative purpose assigned . . .” *Id.*).

121. See generally 42 U.S.C. § 1320a-7 (2015) (failing to provide any description of a criminal or civil

indicia of intention to create a civil penalty.<sup>122</sup> This reasoning is quite untenable; a proper analysis of a sanction's nature should focus on how a penalty actually affects individuals, rather than a contrived theory of legislative intent based on silence.<sup>123</sup>

In *Hudson v. United States*—where the Supreme Court affirmed the use of the *Mendoza-Martinez* test<sup>124</sup>—Justices Stevens and Breyer wrote concurring opinions that urged the Court to eliminate the first part of its two-part analysis.<sup>125</sup> Justice Breyer opined that the majority's analysis gave too much deference to legislative text, stating: “Unlike the Court I would not say that ‘only the clearest proof’ will ‘transform’ into a criminal punishment what a legislature calls a ‘civil remedy.’”<sup>126</sup> Regardless of how much emphasis a court places on a sanction's legislative text, the Social Security Act—which created the HHS's exclusionary authority—does not explicitly define it as a civil sanction.<sup>127</sup> The following factors should not have to present the “clearest proof”<sup>128</sup> to overcome a contrived presumption of civility because such an assumption allows courts to largely ignore the harsh, practical effects punishments have on individuals.

## 2. Affirmative Disability or Restraint

Exclusions constitute a form of affirmative disability or restraint, which is the first of the seven factors considered in the second prong of the *Mendoza-Martinez* analysis.<sup>129</sup> Exclusions, just like debarment of a lawyer or banker, completely preclude an individual from working in any healthcare organization dealing with federal healthcare programs.<sup>130</sup> Although these restrictions certainly are not comparable to incarceration, one of criminal law's most extreme restraints, they closely mimic a criminal court's ability to place occupational restrictions on guilty defendants as a term of probation.<sup>131</sup> However, it must be noted that *Hudson*'s improper juxtaposition of any affirmative restraints to incarceration has gained significant traction, and several courts have cited it as precedent.<sup>132</sup> Although a functionalist analysis indicates otherwise, precedent dictates that an exclusion does not constitute an affirmative restraint.

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nature for the exclusion authority).

122. *See, e.g.*, *Manocchio v. Kusserow*, 961 F.2d 1539, 1541 (11th Cir. 1992) (concluding that legislators intended the punishment to be civil despite no explicit mention of this in the statute). In practice, when Congress fails to express a preference, courts have held that Congress intended the sanction to be civil despite the fact that *Ward* indicates that courts may infer congressional preference for a criminal sanction. *Id.*

123. *Id.*

124. *Hudson v. United States*, 522 U.S. 93, 104 (1997) (referring to the analysis as the *Ward* test).

125. *Id.* at 115 (Breyer, J., concurring); *id.* at 110 (Stevens, J., concurring).

126. *Id.* at 115 (Breyer, J., concurring). Justice Breyer went on to opine that “[t]he ‘clearest proof’ language is consequently misleading.” *Id.* at 115–16.

127. *See generally* 42 U.S.C. § 1320a-7 (2015) (failing to provide any description of criminal or civil nature of the exclusion authority).

128. *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 209 (1963).

129. *Hudson*, 522 U.S. at 104.

130. U. S. DEP'T HEALTH & HUM. SERVS., *supra* note 41.

131. 18 U.S.C. § 3563 (2008).

132. *See, e.g.*, *Herbert v. Billy*, 160 F.3d 1131, 1137–38 (6th Cir. 1998) (holding that a revocation of a driver's license carries the sting of punishment but is civil in nature); *Cox v. Commodity Futures Trading Comm'n*, 138 F.3d 268, 272–73 (7th Cir. 1998) (“The *Hudson* court understood this factor [affirmative restraint] to mean that the sanction in question smacks of the infamous punishment of imprisonment.”).

### 3. Historically Regarded as a Punishment

The question of “whether [exclusions] ha[ve] historically been regarded as a punishment”<sup>133</sup> presents an interesting inquiry. Since Congress first implemented the exclusion authority in 1977, courts and the OIG have viewed the sanction as a civil punishment.<sup>134</sup> However, these perspectives overlook two important considerations. First, the perceptions of exclusions as civil punishments have been formed during an era where courts and agencies have blurred the distinction between civil and criminal sanctions.<sup>135</sup> Second, one must consider the commonly overlooked collateral consequences faced by excluded individuals.<sup>136</sup> Not only will these employees struggle to find work during their exclusion’s term, but also the sanction permanently damages their reputation within the industry.<sup>137</sup>

### 4. Scierter Requirement

The scierter requirement highlights perhaps the most notable red flag in applying the *Mendoza-Martinez* analysis to public welfare, vicarious liability RCO cases. In criminal proceedings, the RCO doctrine combined with the public welfare doctrine allows for vicarious criminal liability with no, or minimal, mens rea finding for the individual being punished.<sup>138</sup> Accordingly, the OIG does not have any scierter requirements when handing out exclusions.<sup>139</sup> This factor should be excluded from the analysis of a strict liability sanction’s nature. In strict liability criminal proceedings, courts do not require a scierter finding to impose punitive criminal sanctions, and therefore, an individual’s mindset should be immaterial in deciding the nature of a sanction given for strict liability crimes.<sup>140</sup> This inquiry has no place in an investigation of the nature of exclusions—which “are based upon the individual’s role or interest in a company that is excluded or is convicted of certain offenses”—just like criminal sanctions in RCO criminal proceedings.<sup>141</sup>

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133. *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168–69 (1963).

134. U.S. DEP’T OF HEALTH & HUM. SERVS., *supra* note 41.

135. This analysis hopes to resurrect the once-important distinction between civil and criminal sanctions and, in doing so, must acknowledge that current perceptions of civility are based on the legal fiction that any regulatory punishment is civil. This unfair presumption was displayed above in the Supreme Court’s declaration that the fact that an administrative agency gives a penalty is “prima facie evidence that Congress intended to provide for a civil sanction.” *Hudson v. United States*, 522 U.S. 93, 103 (1997).

136. *See Copeland, supra* note 37, at 828–31 (providing an in depth analysis of real consequences faced by excluded individuals).

137. *Id.*

138. *See supra* Part II.A (discussing the origins of the RCO doctrine).

139. *See* OFF. OF INSPECTOR GEN., GUIDANCE FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(B)(15) OF THE SOCIAL SECURITY ACT 2 (2010), [https://oig.hhs.gov/fraud/exclusions/files/permissive\\_excl\\_under\\_1128b15\\_10192010.pdf](https://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf) (“With respect to officers and managing employees, the statute includes no knowledge element. Therefore, OIG has the authority to exclude every officer and managing employee of a sanctioned entity.”).

140. *See COX & HAZEN, supra* note 6 and accompanying text (stating that RCOs can be held criminally liable with no mens rea finding).

141. OFF. OF INSPECTOR GEN., *supra* note 139, at 1.

### 5. Promotion of Traditional Aims of Punishment

When investigating whether exclusions “promote the traditional aims of punishment,” courts should adjust their analysis to the context of public welfare crimes like FDCA violations.<sup>142</sup> Courts have consistently determined that criminal law traditionally aims to deter and provide retribution, while civil sanctions primarily provide compensation.<sup>143</sup> The *Dotterweich* court—which established the RCO doctrine—declared RCO prosecution focuses on “the interest of the larger good,” or keeping society safe from harmful products.<sup>144</sup> This illustrates that public welfare crimes are unique because they primarily aim to promote public welfare rather than inflict harm on a wrongdoer. In recent years, RCO enforcements have undoubtedly focused on deterrence to achieve this utilitarian goal.<sup>145</sup> In 2011, Gregory Demske, the OIG’s Assistant Inspector General for legal affairs, stated that there was concern “about criminal conduct and that our remedy in civil cases is not sufficient to protect programs going forward and provide a deterrent.”<sup>146</sup> This quote speaks volumes about how the OIG has used exclusions and criminal sanctions as a deterrent.

### 6. Is the Behavior Already a Crime?

Because regulatory sanctions imposed on RCO defendants commonly follow a criminal trial, the behavior exclusions punish is obviously already a crime.<sup>147</sup> Many times, agencies will depend on criminal plea deals to establish a factual record before deciding appropriate sanctions.<sup>148</sup> In fact, the Social Security Act lists situations that the OIG should impose both mandatory and permissive exclusions.<sup>149</sup> These situations include: conviction of program-related crimes, crimes relating to patient abuse, health care fraud, or crimes related to substances.<sup>150</sup> The OIG exclusively gives mandatory exclusions—the only exclusions that can last more than five years—to defendants already convicted of criminal activity.<sup>151</sup> Therefore, the exclusion penalty should be considered a criminal sanction because it exclusively punishes behavior that can be criminally prosecuted.

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142. *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168–69 (1963).

143. *Id.* at 168.

144. *United States v. Dotterweich*, 320 U.S. 277, 281 (1943).

145. See Jeffrey E. Rogers, *Guilt By Position: Re-Emergence of the RCO Doctrine*, LAW360 (Aug. 14, 2012, 1:14 PM), <http://www.law360.com/articles/367251/guilt-by-position-re-emergence-of-the-rco-doctrine> (describing the “increasing number of criminal prosecutions and administrative exclusions founded upon the RCO doctrine”).

146. *The OIG and Excluding Execs: Demske Explains*, EXPERT BRIEFINGS (June 7, 2011, 12:31 PM), <http://www.expertbriefings.com/news/the-oig-and-excluding-execs-demske-explains>.

147. See generally Jennifer B. Davis, *New Use of Old Tools: Career-Ending OIG Exclusion and FDA Debarment*, UPDATE MAG., Sept. 2010, at 56–58 (providing examples of FDA debarment procedures).

148. See Copeland, *supra* note 37, at 816 (discussing how collateral consequences of pleading guilty in a criminal trial commonly include regulatory enforcement).

149. 42 U.S.C. § 1320a-7 (2015).

150. *Id.*

151. *Understanding Program Exclusions*, HEALTH CARE FRAUD PREVENTION & ENFORCEMENT ACTION TEAM & OFF. OF INSPECTOR GEN., <http://oig.hhs.gov/compliance/provider-compliance-training/files/HandoutExclusionTips508.pdf> (last visited Mar. 5, 2017).

### 7. Alternative Purpose

The final inquiries of the *Mendoza-Martinez* test ask whether there is an alternative purpose for the sanction and whether the sanction appears excessive in relation to that alternative purpose.<sup>152</sup> This provides a proper conclusion to this analysis because it illustrates how these factors were formulated to analyze a traditional crime with the dual aims of retribution and deterrence. At first glance, it may appear that exclusions exist for the alternate purpose of maintaining public welfare or assuring safety in the food and drug industries.<sup>153</sup> However, this seemingly alternate purpose for sanctions is identical to the rationale behind criminal sanctions in the public welfare context.<sup>154</sup> This alignment illustrates that courts and regulatory agencies are simply two means aimed at the same end and seems to violate the double jeopardy clause.<sup>155</sup> Rather than continuing to hand down duplicate sanctions, courts and regulatory agencies should decide whether exclusions or criminal fines against executives more effectively accomplish the desired goal of public welfare crimes.

## IV. RECOMMENDATION

As regulatory agencies and courts continue to perpetuate a system of duplicative, punitive punishments against RCOs, a line must be drawn; courts should attempt to reign in regulatory agencies' ambivalence to the important distinction between civil and criminal punishments. While the *Mendoza-Martinez* analysis certainly should be adjusted to properly determine whether regulatory sanctions for public welfare crimes constitute civil or criminal punishments, this Note does not seek to reinvent the wheel.<sup>156</sup> A few well-tailored changes could create a reliable test that allows courts to consistently determine a punishment's criminal or civil nature. This Part will provide recommendations for general improvements to the *Mendoza-Martinez* analysis and additional tailoring required for public welfare offenses like those in the FDCA.

### A. General Adjustments to the Mendoza-Martinez Analysis

#### 1. Eliminate the "Clearest Proof" Standard

Courts can exercise proper deference to Congress without completely altering the analysis of a sanction's nature by eliminating the clearest proof standard. Currently, courts give excessive deference to Congress. The test's emphasis on legislative intent mandates that any available indicia of a punishment's true nature must provide the "clearest proof" to overcome the slightest finding that legislators intended to create a civil

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152. *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168–69 (1963).

153. *Transcript for Audio Podcast: OIG Outlook 2013: Chief Counsel to the IG, Gregory E. Demske*, OFF. OF INSPECTOR GEN. OF DEP'T OF HEALTH & HUMAN SERVS., <http://oig.hhs.gov/newsroom/podcasts/2012/outlook/demske-trans.asp> (last visited Mar. 5, 2017) ("The exclusion is a remedy to protect the programs going forward . . .").

154. *See* Copeland, *supra* note 37, at 805 (describing the goal of enforcing public welfare crimes).

155. *Compare id. with* Rogers, *supra* note 145 (noting there are similar goals for regulatory civil proceedings against corporate officers and criminal prosecutions for the same acts by the same individuals).

156. *See generally infra* Parts IV.A–B (outlining adjustments that should be made to the *Mendoza-Martinez* framework).

sanction.<sup>157</sup> Legislative intent should play a role in how a court views a sanction. However, if a court frames its entire analysis on *ex ante* intentions, it may fail to adequately address agencies' misapplication of regulatory powers.<sup>158</sup> This problem could be largely avoided by analyzing legislative intent as a factor that courts weigh equally with the other prongs of the *Mendoza-Martinez* analysis. Additionally, this adjustment would prevent courts from declaring a sanction civil after a cursory analysis that focuses solely on legislative text or one legislator's statement during a congressional hearing.<sup>159</sup>

## 2. *Direct Comparisons with Criminal Punishments for Behavior that is Already a Crime*

Courts should strictly scrutinize regulatory punishment for conduct already punishable under criminal law and compare civil sanctions handed down by agencies to typical criminal punishments for such behavior. Civil sanctions for behavior that constitutes an actionable—often times already adjudicated—crime should be directly compared to its criminal equivalent.<sup>160</sup> Courts should narrow their inquiries to the specific conduct being punished when there is a corresponding body of criminal law. For example, “civil” exclusions should be compared to criminal sanctions for FDCA violations—which punish the very same wrongful behavior—instead of drawing on abstract generalizations about criminal law like the *Mendoza-Martinez* factors dictate.<sup>161</sup> Using direct comparisons will help narrow a court's inquiry and reduce improper analogies like the *Hudson* court's comparison of any affirmative disability to incarceration.<sup>162</sup>

### *B. Certain Factors Should be Adjusted for Public Welfare Crimes*

Courts should exclude certain *Mendoza-Martinez* factors because they are not applicable to public welfare sanctions.<sup>163</sup> To start, the scienter factor should be removed from the *Mendoza-Martinez* list.<sup>164</sup> RCO prosecutions do not consider an officer's *mens rea* when imposing criminal sanctions; rather, the RCO doctrine finds *mens rea*, if any, in lower level employees and imputes this mindset to the responsible executive.<sup>165</sup> Because an individual's scienter is not a factor for criminal sanctions, it should not be a factor for

157. *United States v. Ward*, 448 U.S. 242, 249 (1980).

158. *Hudson v. United States*, 522 U.S. 93, 117 (1997) (Breyer, J., concurring) (“[A] statute that provides for a punishment that normally is civil in nature could nonetheless amount to a criminal punishment as applied in special circumstances. And I would not now hold to the contrary.”).

159. Porter, *supra* note 61, at 550 (“[W]hen Congress fails to express a preference, courts have held that Congress intended the sanction to be civil, despite the fact that Ward indicates that courts may infer by implication a congressional preference for a criminal sanction.”).

160. *See supra* notes 48–56 and accompanying text (providing examples of exclusions that occurred after criminal punishment).

161. The *Mendoza-Martinez* factors compare the sanction in question to generalizations about what “has historically been regarded as a punishment” and the “traditional aims of punishment.” *Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168–69 (1963).

162. *Hudson*, 522 U.S. at 104 (comparing any affirmative restraint to incarceration).

163. *See supra* Sections III.C.4–5, 7 (discussing how certain *Mendoza-Martinez* prongs should not apply to public welfare crimes).

164. *See supra* Section III.C.4 (analyzing the problems with the scienter requirement).

165. *See United States v. Park*, 421 U.S. 658, 674 (1975) (stating that RCOs are criminally liable because they have “responsibility and authority either to prevent . . . or promptly to correct, the violation complained of”).

determining whether a sanction is civil or criminal.<sup>166</sup>

Also, courts should contextualize vague inquiries focused on traditional criminal sanctions within the unique public welfare crime framework. Enforcement of public welfare offenses inherently serves the following two purposes: (1) punitive action against wrongful corporate officials and (2) protection of the public against harmful products and drugs.<sup>167</sup> These dual-aims could be confused as an alternative purpose for sanctioning or promotion of a goal outside the traditional aims of punishment and, therefore, indicia that a sanction is civil.<sup>168</sup> However, when placed in the proper context, courts will likely find that civil sanctions associated with public welfare crimes serve the same purposes as criminal punishment for the same behavior.<sup>169</sup>

Finally, the affirmative restraint or disability prong<sup>170</sup> should be reframed for public welfare crimes within the readily available history of RCO criminal prosecutions. Essentially, this can be conceptualized as an application of the recommendation provided in Section IV.A.2. Direct comparisons between criminal and “civil” punishments faced by RCOs would illustrate how OIG exclusions may be more punitive than a court’s criminal sanctions handed for the same offenses. When one acknowledges the long-term ramifications an exclusion has on an individual’s career and reputation, “the collateral consequence of a prolonged period of exclusion is far more devastating than the direct criminal consequences of conviction.”<sup>171</sup>

#### V. CONCLUSION

Administrative agencies and courts play an integral role in protecting individuals from the massive harms corporations can impose on society, specifically those in the healthcare industry. While this Note does not challenge the efficacy or rationale behind renewed emphasis on punishing individuals instead of fining corporations, it does question the basic fairness of severe, duplicative, punitive punishments. Disintegration of the line between criminal and civil sanctions will allow courts and regulatory agencies to consistently violate individuals’ constitutional rights. Accordingly, courts must devise a new framework that, unlike the *Mendoza-Martinez* test, accurately defines a punishment’s effect on individuals and restrains judicial discretion.

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166. *Id.*; *see supra* Section III.C.4 (analyzing the problems with the scienter requirement).

167. *See supra* Section III.C.5 (discussing whether exclusions promote traditional aims of criminal law).

168. *Id.*

169. *See supra* Section III.C.7 (discussing alternative purposes for exclusions).

170. *See Kennedy v. Mendoza-Martinez*, 372 U.S. 144, 168 (1963) (identifying “[w]hether the sanction involves an affirmative disability or restraint” as a relevant inquiry for determining the nature of a sanction).

171. Copeland, *supra* note 37, at 831.