

STATUTORY INTERPRETATION — FEDERAL FOOD, DRUG, AND COSMETIC ACT — THIRD CIRCUIT HOLDS THAT THE FDA CAN OBTAIN RESTITUTION ON BEHALF OF CONSUMERS. — *United States v. Lane Labs-USA Inc.*, 427 F.3d 219 (3d Cir. 2005).

How should courts interpret statutory silence regarding a requested remedy? One line of cases adopts the presumption that a federal court's equitable authority is plenary unless Congress indicates otherwise.<sup>1</sup> Another recent line of cases, however, limits judicial power: if a statute explicitly identifies particular remedies, courts should be "chary of reading others into it."<sup>2</sup> Recently, in *United States v. Lane Labs-USA Inc.*,<sup>3</sup> the Third Circuit became the second court of appeals to adhere to the presumption of plenary equitable authority, agreeing with the Food and Drug Administration (FDA) that district courts may order restitution under the Federal Food, Drug, and Cosmetic Act<sup>4</sup> (FDCA) despite the absence of explicit statutory permission.<sup>5</sup> Although the court introduced an unnecessary wrinkle into the doctrinal test, it providently navigated warring precedents.

Andrew Lane is the owner of Lane Labs-USA Inc. (Lane Labs), which markets and distributes health products<sup>6</sup> and generates approximately \$30 million each year in sales.<sup>7</sup> As of 2004, its products included BeneFin, a powder or caplet containing shark cartilage; MGN-3, a dietary fiber made from rice bran and shiitake mushroom extract; and SkinAnswer, a skin cream containing an extract of sand

---

<sup>1</sup> See, e.g., *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291–92 (1960); *Porter v. Warner Holding Co.*, 328 U.S. 395, 397–98 (1946).

<sup>2</sup> *Meghriq v. KFC Western, Inc.*, 516 U.S. 479, 488 (1996) (quoting *Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 14–15 (1981)) (internal quotation mark omitted); see also *United States v. Philip Morris USA Inc.*, 396 F.3d 1190, 1200 (D.C. Cir. 2005) ("Congress' care in formulating such a 'carefully crafted and detailed enforcement scheme provides strong evidence that Congress did *not* intend to authorize other remedies that it simply forgot to incorporate expressly." (quoting *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 209 (2002))). A distinct but analogous line of cases, exemplified by *Alexander v. Sandoval*, 532 U.S. 275 (2001), embraces judicial restraint in the context of implied private rights of action.

<sup>3</sup> 427 F.3d 219 (3d Cir. 2005).

<sup>4</sup> 21 U.S.C.A. §§ 301–397 (West 1999 & Supp. 2005).

<sup>5</sup> *Lane Labs*, 427 F.3d at 220. The Sixth Circuit is the other circuit that has followed the presumption of plenary equitable authority in the context of the FDCA. See *United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 761 (6th Cir. 1999) ("Absent a clear command by Congress that a statute providing for equitable relief excludes certain forms of such relief, this court will presume the full scope of equitable powers may be exercised by the courts."). The Tenth Circuit has since endorsed the *Lane Labs* court's reasoning in holding that a court may order disgorgement of profits under the FDCA. See *United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1061–62 (10th Cir. 2006) (citing *Lane Labs*, 427 F.3d at 220).

<sup>6</sup> *Lane Labs*, 427 F.3d at 220.

<sup>7</sup> *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 550–51 (D.N.J. 2004).

brier.<sup>8</sup> Lane Labs characterized these three products as effective treatments for cancer and HIV.<sup>9</sup>

Beginning in 1997, the FDA sent multiple warning letters to Lane Labs, asserting that the company was marketing unapproved and misbranded drugs in violation of the FDCA.<sup>10</sup> The agency filed suit against Lane Labs in 1999 and then amended its complaint in 2002 to request a permanent injunction, restitution for consumers, and disgorgement of any remaining profits.<sup>11</sup> After finding that the products were new and misbranded drugs under the FDCA, the district court granted the FDA's motion for summary judgment, issued a permanent injunction against sales of the products without FDA approval, and ordered the requested restitution.<sup>12</sup>

The Third Circuit affirmed.<sup>13</sup> The sole issue on appeal<sup>14</sup> was the district court's authority to order restitution under section 302(a) of the FDCA, which provides district courts with jurisdiction "to restrain violations" of the statute.<sup>15</sup> Writing for a unanimous panel, Judge Rendell<sup>16</sup> interpreted Supreme Court precedent as establishing a two-pronged test to determine whether a district court sitting in equity can award restitution. First, once the court's equitable jurisdiction has been invoked, restitution is available unless "there is a clear statutory limitation" indicating otherwise.<sup>17</sup> Second, even when the first prong is satisfied, restitution is permitted only "where it furthers the purposes of the statute."<sup>18</sup>

In articulating and applying the first prong, the court relied on the interpretive presumption expressed in two Supreme Court cases, *Porter v. Warner Holding Co.*<sup>19</sup> and *Mitchell v. Robert DeMario Jewelry, Inc.*,<sup>20</sup> which held that restitution is available under the Emergency Price Control Act of 1942<sup>21</sup> and the Fair Labor Standards Act of 1938,<sup>22</sup> respectively.<sup>23</sup> Judge Rendell emphasized *Porter's* instruction

---

<sup>8</sup> *Id.* at 551.

<sup>9</sup> *Id.* at 551–52, 568–69.

<sup>10</sup> See *Lane Labs*, 427 F.3d at 221–22.

<sup>11</sup> *Id.* at 222. The suit was filed against Lane as an individual and against Lane Labs as a corporation.

<sup>12</sup> See *Lane Labs*, 324 F. Supp. 2d at 582–83, 586. The court declined, however, to grant the FDA's request for disgorgement. *Id.* at 586. In a separate action, Lane Labs also entered into a consent decree with the FTC to pay a \$1 million fine. See *Lane Labs*, 427 F.3d at 222.

<sup>13</sup> *Lane Labs*, 427 F.3d at 236.

<sup>14</sup> *Id.* at 223 & n.2.

<sup>15</sup> 21 U.S.C. § 332(a) (2000).

<sup>16</sup> Judges Becker and Barry joined Judge Rendell's opinion.

<sup>17</sup> *Lane Labs*, 427 F.3d at 225.

<sup>18</sup> *Id.*

<sup>19</sup> 328 U.S. 395 (1946).

<sup>20</sup> 361 U.S. 288 (1960).

<sup>21</sup> ch. 26, 56 Stat. 23.

<sup>22</sup> 29 U.S.C.A. §§ 201–219 (West 1998 & Supp. 2005).

that “[u]nless a statute in so many words, *or by a necessary and inescapable inference*, restricts the court’s jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied.”<sup>24</sup> Similarly, the court endorsed *Mitchell*’s insistence that when Congress invokes courts’ equitable authority, “it must be taken to have acted cognizant of the historic power of equity to provide complete relief in the light of statutory purposes.”<sup>25</sup> The legislative history of the FDCA, even as presented by the appellants and amicus,<sup>26</sup> did not amount to the requisite necessary and inescapable inference.<sup>27</sup>

The court conceded, however, that the “analytic course” of jurisprudence regarding courts’ authority to order restitution was not “entirely smooth”<sup>28</sup> and required the court to distinguish two countervailing authorities. First, Judge Rendell addressed *Meghrig v. KFC Western, Inc.*,<sup>29</sup> in which the Supreme Court departed from the presumption of plenary equitable authority in deciding that a plaintiff could not recover the costs of cleaning up toxic waste under the Resource Conservation and Recovery Act of 1976<sup>30</sup> (RCRA).<sup>31</sup> The *Meghrig* Court mentioned *Porter* with little comment and instead emphasized that when a statute expressly provides a remedy or remedies, courts should hesitate to infer that additional remedies are available<sup>32</sup> — evocative of the *expressio unius est exclusio alterius* canon of construction.<sup>33</sup> Second, Judge Rendell noted that a recent D.C. Circuit

---

<sup>23</sup> The presumption that “Congress will not withdraw the courts’ traditional equitable discretion” is a substantive canon of statutory interpretation. WILLIAM N. ESKRIDGE, JR. ET AL., *CASES AND MATERIALS ON LEGISLATION* 850 (3d ed. 2001). Unlike linguistic canons, through which courts infer congressional intent from statutory text and which are generally policy-neutral, substantive canons correspond to policy preferences that courts ascribe to Congress absent indications to the contrary. *Id.* at 848, 850. Substantive canons come in several formulations bearing different weight. As a category, presumptions can be rebutted more easily than clear statement rules or “super-strong clear statement rules.” *See id.* at 851. Presumptions themselves may vary in weight, serving as “starting point[s] for discussion[s],” mere balancing factors, or tiebreakers. *Id.* at 850.

<sup>24</sup> *Lane Labs*, 427 F.3d at 224 (emphasis added) (quoting *Porter*, 328 U.S. at 398).

<sup>25</sup> *Id.* at 225 (quoting *Mitchell*, 361 U.S. at 291–92).

<sup>26</sup> The Washington Legal Foundation filed a brief as amicus curiae in support of Lane Labs. *See* Brief of the Wash. Legal Found. as Amicus Curiae in Support of Appellants Seeking Reversal, *Lane Labs*, 427 F.3d 219 (3d Cir. 2005) (No. 04-3592) [hereinafter WLF Brief], available at <http://www.wlf.org/upload/LANELABS.pdf>.

<sup>27</sup> *See Lane Labs*, 427 F.3d at 228–29.

<sup>28</sup> *Id.* at 230.

<sup>29</sup> 516 U.S. 479 (1996).

<sup>30</sup> Pub. L. No. 94-580, 90 Stat. 2795 (codified as amended at 42 U.S.C. §§ 6901–6992k (2000)).

<sup>31</sup> *Meghrig*, 516 U.S. at 488.

<sup>32</sup> *See id.*

<sup>33</sup> The canon holds that “to express or include one thing implies the exclusion of the other, or of the alternative.” BLACK’S LAW DICTIONARY 602 (7th ed. 1999); *see also* United States v. Philip Morris USA Inc., 396 F.3d 1190, 1220 (D.C. Cir. 2005) (Tatel, J., dissenting) (describing *Meghrig* as relying on a version of the canon).

case, *United States v. Philip Morris USA Inc.*,<sup>34</sup> interpreted *Meghrig* as lowering the bar for what constitutes a necessary and inescapable inference that Congress intended to restrict courts' equitable power.<sup>35</sup> Nevertheless, she distinguished these cases based on key differences in the factual circumstances and applicable statutes. Judge Rendell noted that *Meghrig* involved a citizen suit rather than a government enforcement action; statutory language that premised relief on a finding of "imminent and substantial" harm"; a remedy that was more legal than equitable in nature; and a more detailed remedial scheme.<sup>36</sup> In addition, she noted that the FDCA's remedial scheme is less detailed than the scheme that the *Philip Morris* court considered.<sup>37</sup>

The opinion also addressed the second prong of the Third Circuit's stated test: the requirement that restitution further the purpose of the statute. Undertaking a searching analysis, the court acknowledged that protecting consumer health and safety is a primary purpose of the FDCA<sup>38</sup> but determined that the text and legislative history of the FDCA, as well as prior judicial interpretations, indicate that Congress also intended the FDCA to protect consumers' financial interests.<sup>39</sup> Accordingly, the court concluded that the second prong was fulfilled.<sup>40</sup>

The *Lane Labs* decision properly resolved the apparent contradictions in Supreme Court precedent by recognizing that the *Porter* and *Mitchell* presumption of plenary equitable authority should guide the case in spite of the competing approach suggested by *Meghrig*. However, the court needlessly grafted *Meghrig*'s skepticism of expansive remedial authority onto the doctrinal test by adding a "statutory purpose" prong that undercuts the logic of the *Porter* approach and may permit novel restrictions on courts' remedial power in the future.

Using the definition of a necessary and inescapable inference that *Porter* and *Mitchell* adopted, the *Lane Labs* court could have concluded easily that no such inference existed for the purposes of the test's first prong. None of the potential indicators of congressional intent to make restitution unavailable rise to the level of a necessary and inescapable inference or a clear legislative command.<sup>41</sup> An argument

---

<sup>34</sup> 396 F.3d 1190.

<sup>35</sup> See *Lane Labs*, 427 F.3d at 232–33.

<sup>36</sup> See *id.* at 231–32.

<sup>37</sup> See *id.* at 232–33. The court did not opine whether *Philip Morris* correctly interpreted the statute at issue in that case.

<sup>38</sup> *Id.* at 226.

<sup>39</sup> See *id.* at 227–28.

<sup>40</sup> See *id.* at 229–30.

<sup>41</sup> Many commentators describe these indicators. See, e.g., Jeffrey N. Gibbs & John R. Fleder, *Can FDA Seek Restitution or Disgorgement?*, 58 FOOD & DRUG L.J. 129, 142–45 (2003); Erika King & Elizabeth M. Walsh, *The Authority of a Court To Order Disgorgement for Violations of the Current Good Manufacturing Practices Requirement of the Federal Food, Drug, and Cosmetic Act*, 58 FOOD & DRUG L.J. 149, 168 (2003).

that the plain meaning of the word “restrain” as used in section 302(a) includes only “forward-looking” remedies<sup>42</sup> is unpersuasive because the Supreme Court has long recognized the deterrent effect of restitution — a restraint in its own right.<sup>43</sup> A structural argument that the presence of a restitution-like remedy elsewhere in the FDCA means that Congress did not intend to make restitution available under section 302(a) also falls flat: the other remedy provides a refund rather than equitable restitution and confers authority to the FDA rather than to the courts.<sup>44</sup> And although the five-year-long legislative history includes no mention of restitution,<sup>45</sup> *Porter* and *Mitchell* suggest that legislative history alone does not create a clear legislative command.<sup>46</sup> With only *Porter* and *Mitchell* as guides, the *Lane Labs* court could have reached a simple and clear-cut decision.

Deciding the appropriate weight of *Meghrig*’s apparent doctrinal about-face is what presented the *Lane Labs* court with “arguably a close call.”<sup>47</sup> Because *Meghrig* did not overrule *Porter* and *Mitchell*,<sup>48</sup> lower courts are left with seemingly contradictory instructions: the substantive canon from *Porter* and *Mitchell* presumes that courts have

<sup>42</sup> Cf. *United States v. Philip Morris USA Inc.*, 396 F.3d 1190, 1198–99 (D.C. Cir. 2005) (concluding that the phrase “prevent and restrain” as used in 18 U.S.C. § 1964(a) “indicates that the jurisdiction [of the district courts] is limited to forward-looking remedies that are aimed at future violations”).

<sup>43</sup> See, e.g., *Porter v. Warner Holding Co.*, 328 U.S. 395, 400 (1946) (“Future compliance may be more definitely assured if one is compelled to restore one’s illegal gains.”).

<sup>44</sup> Section 518(b) of the FDCA gives the FDA authority to order sellers of noncompliant medical devices to provide refunds to consumers. See 21 U.S.C. § 360h(b) (2000). Whether measured by the plaintiff’s loss or the defendant’s gain, a restitutionary remedy may not always be equivalent to the purchase price. See Colleen P. Murphy, *Misclassifying Monetary Restitution*, 55 SMU L. REV. 1577, 1589–95 (2002).

<sup>45</sup> *Developments in the Law—The Federal Food, Drug, and Cosmetic Act*, 67 HARV. L. REV. 632, 719 (1954). Indeed, some argue that the drafters actually wanted restitution to be unavailable; the history suggests they intended section 302(a) to provide a remedy less severe than seizure of products, see *King & Walsh*, *supra* note 41, at 158 (citing H.R. REP. NO. 75-2139, at 4 (1938)), a remedy that is “small potatoes” compared to restitution, WLF Brief, *supra* note 26, at 8.

<sup>46</sup> The Court was not persuaded by statements in the legislative histories of the statutes at issue in *Mitchell* and *Porter*. See *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 293–95 (1960); *Porter*, 328 U.S. at 402 n.5. *Lane Labs* also argued that the FDA’s failure to seek restitution for long periods of time — the FDA did not seek restitution for the first thirteen years of the FDCA’s existence, and a senior FDA official did not list restitution among available remedies in a 1992 scholarly publication — rendered the remedy unavailable. See *Lane Labs*, 427 F.3d at 226 (citing Marie A. Urban, *The FDA’s Policy on Seizures, Injunctions, Civil Fines, and Recalls*, 47 FOOD & DRUG L.J. 411 (1992)). The Supreme Court, however, has rejected a similar line of reasoning. See *id.* (“[A]uthority granted by Congress . . . cannot evaporate through lack of administrative exercise.” (omission in original) (quoting *Bankamerica Corp. v. United States*, 462 U.S. 122, 131 (1983)) (internal quotation marks omitted)).

<sup>47</sup> *Lane Labs*, 427 F.3d at 223.

<sup>48</sup> The Supreme Court continues to cite *Porter* and *Mitchell* as good law. See, e.g., *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 496 (2001); *Miller v. French*, 530 U.S. 327, 340–41 (2000).

plenary authority to award equitable remedies, but *Meghrig* expresses reluctance to award remedies that Congress has not identified.

Two solutions seem plausible: either *Meghrig* is sui generis, or *Meghrig*'s aversion to nonexplicit remedies should factor into the necessary and inescapable inference calculus. The Third Circuit lent support to the former solution<sup>49</sup> and found numerous bases on which to distinguish *Meghrig*. Although the D.C. Circuit's use of the latter alternative may achieve greater doctrinal harmony by incorporating both cases into the analysis, it would likely produce the same outcome under the FDCA in light of the *Meghrig* Court's inductive approach. The *Meghrig* Court did not apply a substantive presumption in the style of *Mitchell* or *Porter*; instead, it drew conclusions from unique statutory features.<sup>50</sup> Because the FDCA lacks the detailed remedial schemes and explicit language presented in the statutes at issue in *Meghrig* and *Philip Morris*,<sup>51</sup> any general disfavor of expansive remedial power in *Meghrig*'s wake would lack sufficient traction to produce a different conclusion. Thus, even if *Meghrig* is not sui generis, the *Lane Labs* court was correct in finding no necessary and inescapable inference proscribing restitution under the FDCA.<sup>52</sup>

Although the court providently prioritized *Porter* and *Mitchell*, it added an unnecessary wrinkle. Specifically, by introducing a second prong into the analysis while purporting to hew closely to *Porter*'s test,

---

<sup>49</sup> *Lane Labs*, 427 F.3d at 232 n.4 (“[I]t could be said that *Meghrig* . . . is sui generis.”).

<sup>50</sup> See *Meghrig v. KFC Western, Inc.*, 516 U.S. 479, 483–85 (1996) (relying on, among other factors, RCRA's limitation of remedies to violations that create “imminent and substantial endangerment” and inferring from the backward-looking remedies provided in RCRA's companion statute — the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 — that “Congress . . . knew how to provide for the recovery of cleanup costs” when it wished to do so).

<sup>51</sup> See *Lane Labs*, 427 F.3d at 232–33 (comparing the text and remedial schemes of the three statutes). In addition to the distinguishing factors that Judge Rendell identified, the FDCA, unlike RCRA, has no companion statute providing backward-looking remedies for similar violations.

<sup>52</sup> Additionally, two “soft” factors may weigh in favor of restitution's availability. First, according to *Porter*, courts have greater remedial flexibility in government enforcement actions, which are more attuned to the public interest than private controversies. See *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946). Second, according to some judges and scholars, the FDCA requires especially expansive interpretation. See, e.g., *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 165 (2000) (Breyer, J., dissenting); *United States v. An Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 798 (1969) (“[R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health . . .”); William N. Eskridge, Jr., & John Ferejohn, *Super-Statutes*, 50 DUKE L.J. 1215, 1215–16, 1256–57 (2001) (suggesting that the FDCA may be a “super-statute,” meaning that it should receive more expansive construction than ordinary legislation, because it “penetrate[s] public normative and institutional culture in a deep way”).

the Third Circuit unnecessarily complicated the doctrine.<sup>53</sup> The *Porter* Court itself did not require that restitution further a statutory purpose. To the extent that the Court considered statutory purpose at all, it presumed that restitution's deterrent effect would promote compliance and thus advance the legislature's purpose.<sup>54</sup> A recent Tenth Circuit decision followed *Porter's* approach,<sup>55</sup> and other circuit courts have ascribed even less weight to statutory purpose, interpreting *Porter* and *Mitchell* as establishing only a single-pronged test.<sup>56</sup>

The tension between the two prongs bears noting. Whereas the first prong highlights a desire to allow courts broad power to ensure justice under a statute, the second suggests that each potential remedy within the equitable grant must correspond to an ex ante statutory objective.<sup>57</sup> Methodologically, the first presumes that plenary equitable power exists, whereas the second hinges remedial power on positive indicators of authorization, requiring a full investigation into legislative intent.

At bottom, the second prong suggests a suspicion that the substantive canon will be blind to practical considerations<sup>58</sup> or too permis-

---

<sup>53</sup> Because *Meghrig* applies only to the first prong of the doctrinal test, once a court has concluded that no necessary and inescapable inference exists, the question of statutory purpose draws solely from *Porter*, *Mitchell*, and their progeny.

<sup>54</sup> *Porter*, 328 U.S. at 400. As a secondary justification, the *Porter* Court also noted a more specific policy implication: that "the statutory policy of preventing inflation is plainly advanced if prices or rents which have been collected in the past are reduced to their legal maximums." *Id.* *Mitchell* did discuss statutory purpose, but only as a response to unusual circumstances. The *Mitchell* Court had to probe legislative intent to establish that a recent amendment to the statute at issue had not eliminated the availability of restitution. See *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 293-94 (1960).

<sup>55</sup> *United States v. Rx Depot, Inc.*, 438 F.3d 1052, 1054-57 (10th Cir. 2006).

<sup>56</sup> See, e.g., *United States v. Universal Mgmt. Servs., Inc.*, 191 F.3d 750, 761 (6th Cir. 1999); *SEC v. First City Fin. Corp.*, 890 F.2d 1215, 1230 (D.C. Cir. 1989) ("Disgorgement, then, is available simply because the relevant provisions of the [statute] . . . vest jurisdiction in the federal courts."); *Commodity Futures Trading Comm'n v. Co Petro Mktg. Group, Inc.*, 680 F.2d 573, 583 (9th Cir. 1982) (restricting the inquiry into statutory purpose to the observation that "disgorgement may serve to deter future violations"); *Interstate Commerce Comm'n v. B & T Transp. Co.*, 613 F.2d 1182, 1186 (1st Cir. 1980) (holding that the equitable power to award restitution existed but remanding to the district court to determine "whether and how it should exercise its equitable power . . . 'to provide complete relief in light of the statutory purposes'" (quoting *Mitchell*, 361 U.S. at 292)); *Commodity Futures Trading Comm'n v. Hunt*, 591 F.2d 1211, 1223 (7th Cir. 1979) (restricting the inquiry into statutory purpose to the observation that "to allow a violator to retain the profits from his violations would frustrate the purposes of the regulatory scheme").

<sup>57</sup> Moreover, because the nexus between the remedy and statutory purpose determines the court's authority to award the remedy as a general matter, rather than in a given case, the second prong presumes a static statutory purpose, a subject of controversy among scholars. Numerous theories of statutory interpretation favor a dynamic view of statutory purposes. See, e.g., GUIDO CALABRESI, *A COMMON LAW FOR THE AGE OF STATUTES* 31-43 (1982); WILLIAM N. ESKRIDGE, JR., *DYNAMIC STATUTORY INTERPRETATION* (1994).

<sup>58</sup> One criticism of a single-pronged test is that it might produce too many restitution awards. See, e.g., *United States v. Carson*, 52 F.3d 1173, 1182 (2d Cir. 1995) (suggesting an evidentiary requirement linking the gains in question to illegal conduct in order to permit a range of remedies

sive.<sup>59</sup> However legitimate these concerns may be as a theoretical matter,<sup>60</sup> the Supreme Court has not embraced them in the context of courts' equitable authority. Although the additional prong may in many cases amount to no more than a box to check, in others it may provide a way to circumvent the substantive canon and develop a more restrictive approach to courts' remedial power.

In the end, the *Lane Labs* court skillfully navigated precedents urging judicial restraint on the one hand and embracing the longstanding presumption of plenary equitable authority on the other. Although the court's doctrinal misstep in probing legislative purpose may have unnecessarily complicated the analysis, this misstep did not alter the result: the Third Circuit retained its presumption of plenary equitable authority absent a necessary and inescapable implication to the contrary, and the FDA added a powerful weapon to its enforcement arsenal.

---

less broad than "any remedy that inflicts pain"). However, two crucial checks should assuage this floodgates concern. First, agency expertise acts as a filter: the agency's prayer for a given remedy signals its conclusion that the remedy is appropriate, both in light of the overall statutory purpose and in the context of the particular case. Cf. Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91 VA. L. REV. 93, 95 (2005) (arguing that the expertise and interest of executive agencies warrant deference regarding the creation and scope of private rights of action). But see, e.g., James O. Freedman, *Crisis and Legitimacy in the Administrative Process*, 27 STAN. L. REV. 1041, 1056-63 (1975) (arguing that agencies lack the expertise and political independence associated with idealized notions of administrative decisionmaking). Even if the question of the court's authority is beyond an agency's interpretive jurisdiction, a policy judgment regarding an enforcement strategy falls within the realm of agency expertise to which courts accord at least some deference, depending on its form. See *United States v. Mead Corp.*, 533 U.S. 218, 234-35 (2001). Second, courts retain full equitable discretion over whether to grant the remedy in any given case. Cf., e.g., *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982) ("The grant of jurisdiction to ensure compliance with a statute hardly suggests an absolute duty to do so under any and all circumstances, and a federal judge sitting as chancellor is not mechanically obligated to grant an injunction for every violation of law.>").

<sup>59</sup> A *Porter*-based, single-pronged test would seem to make restitution available under any similarly worded statute that does not create a necessary and inescapable inference that proscribed the remedy. Restitution could still be unavailable if, unlike the *Porter* Court, a court concluded that restitution would not serve as a deterrent.

<sup>60</sup> Skepticism of the utility and providence of canon usage abounds. For the seminal treatment suggesting that canons are easily manipulated, see Karl N. Llewellyn, *Remarks on the Theory of Appellate Decision and the Rules or Canons About How Statutes Are To Be Construed*, 3 VAND. L. REV. 395 (1950). For a sharp critique of canons as useless for their purported task of divining congressional intent, see RICHARD A. POSNER, *THE FEDERAL COURTS* 276-86 (1985).