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COMMENT

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REVIEWING REFUSAL: LETHAL INJECTION, THE FDA,  
AND THE COURTS

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## INTRODUCTION

Most death row inmates today face execution by lethal injection through a series of compounded lethal drugs. However, this lethal injection method has only become standard practice within the last decade.<sup>1</sup> Traditionally, state correctional facilities conducted executions using manufactured drugs, which national pharmaceutical companies produced at industry-grade standards. Starting in 2010, states began running out of manufactured drugs when pharmaceutical companies placed distribution restrictions on such drugs to ensure that states could not obtain the drugs for use in lethal injections.<sup>2</sup> Furthermore, a court order effectively blocked foreign imports of a misbranded drug that several state correctional departments had turned to for lethal injections.<sup>3</sup> This drug shortage crisis caused states to settle for a solution that would allow lethal injection to continue uninterrupted: sourcing drugs from local compounders.<sup>4</sup>

Compounded lethal drugs are mixed by individuals at local shops according to their own specifications and are widely regarded to be less safe than manufactured drugs.<sup>5</sup> These drugs receive little government oversight in their production. Although the Food and Drug Administration (FDA) has statutory authority to regulate compounded lethal drugs, it has consistently refused to do so.<sup>6</sup> Instead, the federal government has mostly left regulation of compounders to the states.<sup>7</sup> Despite being responsible for licensing and overseeing

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<sup>1</sup> For an overview of lethal injection's origins and development, see Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 *FORDHAM L. REV.* 49, 64-77 (2007).

<sup>2</sup> German Lopez, *How a Shortage of Lethal Injection Drugs Put the Death Penalty Before the Supreme Court*, *VOX* (June 29, 2015), <https://www.vox.com/2015/3/27/8301357/death-penalty-lethal-injection> [<https://perma.cc/5RL5-CY95>].

<sup>3</sup> See *Cook v. FDA*, 733 F.3d 1, 3 (D.C. Cir. 2013).

<sup>4</sup> See Ross Levitt & Deborah Feyerick, *Death Penalty States Scramble for Lethal Injection Drugs*, *CNN* (Nov. 16, 2013), <https://www-m.cnn.com/2013/11/15/justice/states-lethal-injection-drugs> [<https://perma.cc/78YG-YRG2>] (describing how states were resorting to procedures never before used in execution history such as trying new drug combinations or going to compounding pharmacies).

<sup>5</sup> See *Compounding Pharmacies*, DEATH PENALTY INFORMATION CENTER, <https://deathpenaltyinfo.org/compounding-pharmacies> [<https://perma.cc/G5DW-CBQR>] (last visited Apr. 14, 2019) (discussing the dangers associated with compounding pharmacies and lethal injection).

<sup>6</sup> See, e.g., Reply Brief for Appellants at 19, *Cook*, 733 F.3d 1 (Nos. 12-5176, 12-5266) [hereinafter *FDA Brief*] (“[The] FDA . . . decline[s] to take enforcement action in the narrow category of cases in which drugs are destined for use by States in accordance with their lethal injection laws.”); Telephone Interview with Chris McDaniel, Investigative Reporter, BuzzFeed News (Jan. 8, 2019) (“The FDA does not regulate lethal injection. It does not want to regulate lethal injection.”).

<sup>7</sup> See *Compounding and the FDA: Questions and Answers*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm339764.htm> [<https://perma.cc/2X5Z-LKAH>] (last updated June 21, 2018) (“Generally, state boards of

compounders, some states have passed laws that insulate these compounders from regulation by state boards of pharmacy, medicine, and health.<sup>8</sup> In fact, over twenty states have passed secrecy laws or engaged in practices that forbid public disclosure of their suppliers' identities in order to encourage compounders to enter into contracts to supply states compounded lethal drugs.<sup>9</sup>

Non-regulation of compounded lethal drugs has contributed to a disturbing series of botched executions. In 2012, a death-row inmate's heart continued to beat for at least twenty minutes after South Dakota officials injected him with compounded lethal drugs for execution.<sup>10</sup> In 2014, an Arizona death-row inmate died after two hours of "gasping and snorting."<sup>11</sup> Five of the eleven men executed in Texas in 2018 indicated in their final moments that they could feel the compounded drugs burning their bodies inside out.<sup>12</sup>

Non-regulation of compounded lethal drugs also poses profound dangers to the public. A 2018 article in the *Journal of the American Pharmacists Association* observed that an unregulated supply chain of these substandard drugs threatens the general public:

With states increasingly using compounded medicines in executions, there is a greater risk that non-pharmaceutical-grade, substandard or contaminated product will enter the United States market . . . . The secrecy surrounding the execution drug procurement practices of death-penalty states risks undermining channels for the importation of medicines that are otherwise safe and effective. Once an illicit supply channel is established with a supplier, it is extremely challenging to control which drug products move through it and which customers they reach, particularly in a context where the FDA, DEA [Drug Enforcement Administration], and state boards of pharmacy are prevented from

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pharmacy have primary responsibility for the day-to-day oversight of state-licensed pharmacies that are not registered with [the] FDA as outsourcing facilities.”).

<sup>8</sup> See, e.g., VA. CODE ANN. § 53.1-234 (2019) (“The compounding of such drugs pursuant to the terms of such a contract . . . is not subject to the jurisdiction of the Board of Pharmacy, the Board of Medicine, or the Department of Health Professions . . .”).

<sup>9</sup> For a full list, see *State by State Lethal Injection Protocols*, DEATH PENALTY INFO. CTR., <https://deathpenaltyinfo.org/state-lethal-injection> [<https://perma.cc/VR54-R88L>] (last visited Apr. 14, 2019) [hereinafter *State by State Lethal Injection Protocols*].

<sup>10</sup> Laura Sullivan, *Missouri Execution Stalled over Lethal Drugs in Short Supply*, NPR (Feb. 18, 2014), <https://www.npr.org/2014/02/18/279216377/missouri-execution-stalled-over-lethal-drugs-in-short-supply> [<https://perma.cc/CQ33-HT6N>].

<sup>11</sup> Ellen Killoran, *Arizona Botched Lethal Injection: Secrecy, Compounding Pharmacies and the Eighth Amendment*, INT'L BUS. TIMES (July 26, 2014), <https://www.ibtimes.com/arizona-botched-lethal-injection-secrecy-compounding-pharmacies-eighth-amendment-1639770> [<https://perma.cc/YK2W-KPU3>].

<sup>12</sup> Chris McDaniel, *Inmates Said the Drug Burned as They Died. This Is How Texas Gets Its Execution Drugs*, BUZZFEED NEWS (Nov. 28, 2018), [https://www.buzzfeednews.com/article/chrismdaniel/inmates-said-the-drug-burned-as-they-died-this-is-how-texas?fbclid=IwARoqLzEqTvbRaL-VJx\\_UmXT3ravJEyt\\_-lMgESWiu14VtE8YHmmdJToLx8g](https://www.buzzfeednews.com/article/chrismdaniel/inmates-said-the-drug-burned-as-they-died-this-is-how-texas?fbclid=IwARoqLzEqTvbRaL-VJx_UmXT3ravJEyt_-lMgESWiu14VtE8YHmmdJToLx8g) [<https://perma.cc/TRF3-QZ3K>].

performing their usual regulatory duties. These practices also create the risk that substandard execution drugs fall directly into the wider patient population. This has already happened in the manufactured drug context in several documented instances in which lethal injection drugs were diverted into the patient market.<sup>13</sup>

Constitutional litigation is one strategy to urge state or federal governments to regulate compounded lethal drugs. However, if the Supreme Court's past rulings on the constitutionality of lethal injection provide any clue, it is unlikely the Court would find execution by these unregulated, compounded lethal drugs to be unconstitutional.<sup>14</sup> This Comment takes a different path of urging regulation by focusing on administrative litigation against the FDA. Compounded drugs used in lethal injection are, after all, drugs. A core component of the FDA's mission is to regulate drugs. It is the Food and Drug Administration. And yet the FDA refuses to regulate these drugs.

The FDA can refuse to regulate these drugs because the law insulates its inaction from judicial review. While courts regularly conduct arbitrary and capricious review of agency enforcement actions, they are far more reluctant to review agency inaction. In fact, the Supreme Court has created a presumption against judicial review of agency inaction.<sup>15</sup> The basic idea behind this principle is that agencies are far better positioned than courts to know how to allocate regulatory priorities against scarce resources to achieve their statutory duties.<sup>16</sup> So, the reasoning goes, courts should not be in the business of second-guessing agency inaction. This presumption is powerful because it closes the door to litigants at the outset of litigation regardless of how strong their claims are on the merits. Simply put, courts are foreclosed from reviewing FDA inaction.

The presumption against judicial review seems unreasonable when the stakes are so high for death row inmates and the public at large. Although the presumption against judicial review may be a sound principle generally, the FDA's refusal to regulate compounded lethal drugs is the kind of agency inaction that one might think necessitates at least some judicial scrutiny. I therefore propose creating a narrow avenue of judicial review for cases like these. My rule,

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<sup>13</sup> Prashant Yadav et al., *When Government Agencies Turn to Unregulated Drug Sources: Implications for the Drug Supply Chain and Public Health Are Grave*, 58 J. AM. PHARMACISTS ASS'N 477, 479 (2018).

<sup>14</sup> See, e.g., *Glossip v. Gross*, 135 S. Ct. 2726, 2731 (2015) (rejecting petitioner's argument that Oklahoma's off-label use of midazolam in executions carried a demonstrated risk of severe pain, even though it had led to several recent botched executions); see also *Bucklew v. Precythe*, 139 S. Ct. 1112, 1118–19, 1133 (2019) (declining to find that the intended method of execution was unconstitutional because the petitioner failed to provide a sufficiently detailed plan on how he would be executed through an alternative, feasible method associated with a significantly lower risk of severe pain).

<sup>15</sup> See *Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (“[A]n agency's decision not to take enforcement action should be presumed immune from judicial review . . .”).

<sup>16</sup> See *id.* at 831–32 (“The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.”).

what I will call “discrete look,” identifies opportunities for judicial review that are sensible and manageable for the courts to engage in, while also keeping these avenues sufficiently narrow to respect the underlying policy rationales of the existing doctrine. Under discrete look, when death row inmates sue the FDA for its failure to regulate compounded lethal drugs, courts can no longer treat the FDA’s inaction as an exercise of unreviewable enforcement discretion.

This Comment first establishes in Part I that the FDA has jurisdiction to regulate compounded lethal drugs. This is an important premise because an agency’s duty to regulate presupposes that it has jurisdiction to regulate in the first place. Part I then moves on to show that under existing case law, the FDA is not subject to judicial review for refusing to regulate compounded lethal drugs. In Part II, I propose a rule, which I label “discrete look,” that would allow judicial review in cases like these. My rule is broad in the sense that it is not bound to the context of lethal injection, but it is narrow in the sense that it requires plaintiffs to meet a test to qualify for judicial review. Part II then applies discrete look to the case of lethal injections to show that the FDA’s inaction in that context would be subject to judicial review. Finally, I discuss the general benefits discrete look brings to administrative law.

## I. REVIEW UNDER CURRENT LAW

Section A of this Part shows that the FDA can regulate compounded lethal drugs. It first explains the statutory framework for FDA jurisdiction. Next, it discusses how two states have responded to claims about FDA jurisdiction. Finally, it addresses objections that Congress did not intend the FDA to have jurisdiction and that jurisdiction would produce an absurd outcome.

Section B first describes the Supreme Court case that created the presumption against judicial review of agency inaction. Then it discusses how the circuit courts have developed this doctrine. It concludes that under existing law, FDA inaction toward compounded lethal drugs is unreviewable.

### A. *The FDA Has Jurisdiction to Regulate Compounded Lethal Drugs*

The FDA can regulate compounded lethal drugs because they are “new drugs.” The Federal Food, Drug, and Cosmetic Act (FDCA) charges the FDA to regulate the interstate activity of new drugs, which the statute defines as any drug “the composition of which is such that such drug is not generally recognized . . . as safe and effective . . . .”<sup>17</sup> For new drugs to enter the market, they must undergo an expensive and lengthy FDA clinical trial process to

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<sup>17</sup> 21 U.S.C. § 321(p)(1) (2018).

establish that they are “safe and effective.”<sup>18</sup> Although the FDA’s statutory framework never expressly says that compounded lethal drugs are new drugs, the statute’s text requires this conclusion for two reasons.

First, a compounded drug is a new drug because of the term’s broad definition. Compounders create new drugs all the time when they compound because the act of compounding requires mixing existing drugs to achieve a unique composition as the end product. As the Fifth Circuit noted in a case turning on this very issue,

If a compounder changes the composition of an approved drug—by mixing or combining an approved drug with something else to create a different substance or by creating special dosage or delivery forms of an approved drug inconsistent with a drug’s labeling—the composition of the individualized concoction created by a compounding pharmacist will not have been previously approved for use. The resulting substance is therefore a ‘new drug.’<sup>19</sup>

Second, the structure of the FDA’s statutory scheme assumes that compounded drugs are new drugs. The 1997 Food and Drug Administration Modernization Act (FDAMA) empowered the FDA to regulate compounders.<sup>20</sup> The relevant provision declared that the FDA’s new drug requirements “shall not apply” to a compounded drug product “if the drug product meets the requirements of this section.”<sup>21</sup> Because the Act allows compounders to be exempt from new drug regulations only if compounders met certain exemption conditions, compounded drugs are by definition new drugs—otherwise, there would be no need for Congress to create the exemption. As the Fifth Circuit observed, it is “‘a cardinal principle of statutory construction’ that a statute be construed such that ‘no clause sentence, or word shall be superfluous, void or insignificant.’”<sup>22</sup> Since the lethal drugs discussed in this Comment are compounded, they must also by definition be new drugs.<sup>23</sup>

Although compounders are exempt from the FDA’s new drug regulations when they meet certain exemption conditions, they fail to meet these exceptions here. The FDA has provided guidance documents that detail these exemption conditions. One guidance document highlighted the first statutory exemption condition as key: “[t]he drug product is compounded for an

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<sup>18</sup> See *id.* § 355(b) (detailing process for new human drugs); *id.* § 360b(b) (detailing process for new animal drugs).

<sup>19</sup> *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 395 (5th Cir. 2008).

<sup>20</sup> Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 503A, 111 Stat. 2296, 2328 (codified at 21 U.S.C. § 353(a) (2018)).

<sup>21</sup> § 353a(a).

<sup>22</sup> *Mukasey*, 536 F.3d at 406 (quoting *Duncan v. Walker*, 533 U.S. 167, 174 (2001)).

<sup>23</sup> *Id.*

identified individual patient based on the receipt of a valid prescription order, or a notation, approved by the prescribing practitioner . . .”<sup>24</sup> A second guidance document elaborated that “a *valid prescription order* for a compounded drug product means a valid prescription order from a licensed physician or other licensed practitioner authorized by state law to prescribe drugs (prescriber).”<sup>25</sup> The guidance explained that statutory conditions to exemption exist “to help ensure that compounding . . . is based on individual patient needs . . . [and that compounders] are not actually operating as conventional manufacturers.”<sup>26</sup>

Here, state correctional facilities are not exempt from the FDA’s new drug regulation because they cannot meet the exemption conditions. Consider the official advisory opinion that Virginia’s Attorney General wrote to Virginia state legislators in 2016 on this very question. In his opinion, the Attorney General examined the exemption conditions in the 1997 Act and admitted that Virginia’s lethal injection system failed to meet the exemption condition that required a valid prescription for an identified individual patient.<sup>27</sup>

Virginia understandably lacks this kind of prescription because the Hippocratic Oath—the ethical creed of the medical profession—specifically upholds that “[t]o please no one will I prescribe a deadly drug . . .”<sup>28</sup> Likewise, the American Medical Association (AMA)’s *Code of Medical Ethics* states that “as a member of a profession dedicated to preserving life when there is hope of doing so, a physician must not participate in a legally authorized execution.”<sup>29</sup> The Code specifies that participation includes “[p]rescribing or administering . . . medications that are part of the execution procedure.”<sup>30</sup>

Interestingly, Georgia is an outlier state in its attempt to create a valid prescription for these drugs. According to a news report, Georgia has contracted a doctor—whose identity is specifically protected by a secrecy law—to write

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<sup>24</sup> U.S. FOOD & DRUG ADMIN., PHARMACY COMPOUNDING OF HUMAN DRUG PRODUCTS UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 3 (2016) [hereinafter PHARMACY COMPOUNDING GUIDANCE] (citing § 353a(a)).

<sup>25</sup> U.S. FOOD & DRUG ADMIN., PRESCRIPTION REQUIREMENT UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 7 (2016).

<sup>26</sup> *Id.* at 5.

<sup>27</sup> Virginia Attorney General Mark R. Herring, Opinion Letter at 6-7, 9 (Apr. 19, 2016) [hereinafter *Herring Opinion*], [https://www.oag.state.va.us/files/Opinions/2016/Miller\\_et\\_al\\_16-014.pdf](https://www.oag.state.va.us/files/Opinions/2016/Miller_et_al_16-014.pdf) [<https://perma.cc/P2TR-72GN>]. However, the Attorney General opined that despite the fact that Virginia’s compounded drugs used for lethal injection did not have a prescription, he did not think that lethal compounded drugs were subject to FDA regulation. *Id.*

<sup>28</sup> *Hippocratic Oath*, FREE DICTIONARY, <https://medical-dictionary.thefreedictionary.com/Hippocratic+oath> [<https://perma.cc/QZ2R-9G76>] (last visited on Apr. 14, 2019).

<sup>29</sup> *Capital Punishment: Code of Medical Ethics Opinion 9.7.3*, AM. MED. ASS’N, <https://www.ama-assn.org/delivering-care/ethics/capital-punishment> [<https://perma.cc/7MAX-7MP5>] (last visited April 14, 2019).

<sup>30</sup> *Id.*

prescription orders for individual inmates on death row.<sup>31</sup> The doctor sends the “prescription order” to the compounder with the name and information of the inmate, listing the inmate as the individual “patient.”<sup>32</sup> However, Georgia’s practice does not undermine the FDA’s jurisdictional reach for two reasons.

First, a state must surmount the challenge of showing that a valid prescription order can even exist for something like compounded lethal drugs. Federal regulations state that in order for a “prescription for a controlled substance to be effective [it] must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”<sup>33</sup> Compounded lethal drugs are not on the list of “controlled substances,” but they seem to share the same, if not greater, qualities for abusive and dangerous use as controlled substances.<sup>34</sup> Although this particular regulation does not bar a prescription order for compounded lethal drugs, it demonstrates that federal regulators reserve valid prescriptions of dangerous substances for medical reasons that arise in everyday practice. In light of the Hippocratic Oath and the AMA’s position against such prescriptions, Georgia’s insistence that it uses a valid prescription order becomes even weaker.

Second, even if Georgia can avoid regulation, its method appears to be the exception and not the rule. I could not locate another state that also uses a “prescription order” for every death row “patient.” Indeed, if Georgia’s strategy were a viable way to be exempt from new drug regulation and a model for other states, Virginia’s Attorney General would not have candidly admitted in an official advisory opinion in 2016 that such a prescription order was “unavailable” and therefore a compounder would facially fail one of the statutory exemption conditions.<sup>35</sup> Thus for purposes of my discussion, I can safely assume that the FDA would still have jurisdiction of compounded lethal drugs in most states.

Still, one might object that Congress did not intend the FDA to have jurisdiction over compounded lethal drugs when it passed the FDAMA. This congressional-intent objection takes two forms. The first argues that Congress’s intent to solve a problem was not broad enough to cover the particular issue now in question. The second argues that Congress would not have intended the

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<sup>31</sup> Bill Rankin, *The Secrets of the Death Penalty*, ATLANTA J.-CONST. (Oct. 24, 2015), <https://www.ajc.com/news/local/the-secrets-the-death-penalty/4MGsZNIPTwgoh9Mg1yolpO/> [<https://perma.cc/2BCX-TNQ8>].

<sup>32</sup> *Id.*

<sup>33</sup> 21 C.F.R. § 1306.04(a) (2018).

<sup>34</sup> *Cf.*, e.g., 21 U.S.C. § 802(6) (2018) (“The term ‘controlled substance’ means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V . . .”).

<sup>35</sup> See Herring Opinion, *supra* note 27, at 6-7.

statute it created to be interpreted to arrive at an absurd result. Neither is persuasive here.

The first objection amounts to a debate about scope. The U.S. Senate Labor and Human Resources Committee Report indicated that limited FDA regulation was needed to “prevent small-scale manufacturing under the guise of compounding.”<sup>36</sup> Since compounded lethal drugs, the argument goes, are not produced in bulk or commercially available to the public, they do not implicate Congress’s concern about manufacturers in disguise.

This argument about congressional intent, however, does not produce such a narrow result. In passing the 1997 FDAMA to modernize the FDA’s regulatory toolkit, Congress seemed concerned about *any* kind of compounding that was not based on legitimate individual patient needs. The same Senate Committee Report noted that “[t]he exemptions . . . are limited to compounding for an individual patient based on the medical need of such patient for the particular drug compounded.”<sup>37</sup> The Report continued: “To qualify for the exemptions, the pharmacist or physician must be able to cite a legitimate medical need for the compounded product that would explain why a commercially available drug product would not be appropriate.”<sup>38</sup> Further, according to the FDA, even compounders who are exempt from new drug regulations can still be subject to a series of other FDA regulations.<sup>39</sup> These include requirements for sanitary packing conditions, purity and strength levels, and labeling, advertising, and promotion that is not false or misleading.<sup>40</sup> This shows that Congress intended the 1997 FDAMA to empower the FDA to have at least some regulatory authority over all compounders—a wider intent than simply stopping commercial manufacturers in disguise.

Further, statutes can cover specific problems that Congress did not, or could not, anticipate. As the Supreme Court underscored, “statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed.”<sup>41</sup> Congress did not think about lethal compounders when it acted in 1997 because they did not exist: the first recorded use of compounded lethal drugs

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<sup>36</sup> S. REP. NO. 105-43, at 67 (1997).

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* at 67-68.

<sup>39</sup> See PHARMACY COMPOUNDING GUIDANCE, *supra* note 24, at 6-7.

<sup>40</sup> *Id.*

<sup>41</sup> *Oncale v. Sundownder Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998); see also Brett M. Kavanaugh, *Fixing Statutory Interpretation*, 129 HARV. L. REV. 2118, 2143-2144 (2016) (reviewing ROBERT A. KATZMANN, *JUDGING STATUTES* (2014)) (“Chief Judge Katzmann puts it well: ‘it is unreasonable to expect Congress to anticipate all interpretive questions that may present themselves in the future,’ particularly when Congress operates under strict ‘time pressures.’”).

occurred in 2012.<sup>42</sup> But Congress did seem to express a general intent. The FDAMA “enhanced FDA’s mission in ways that recognized the Agency would be operating in a 21st century characterized by increasing technological, trade and public health complexities.”<sup>43</sup> Congress recognized the growth and widespread use of compounding compared to traditional manufacturing. It was concerned about compounders deviating from their socially useful and acceptable purpose—mixing drugs to suit the needs of individual patients—into other areas that would raise generalizable problems worthy of federal regulation. That Congress did not anticipate at the time that exemption conditions would empower it to regulate compounded lethal drugs says little. What matters is that Congress felt comfortable forgoing federal regulation of compounding *only* where the compounding occurred for a narrow and individualized purpose.

The second objection from congressional intent relies on the absurdity doctrine, also known as the “elephant-in-mousehole” principle.<sup>44</sup> In *FDA v. Brown & Williamson Tobacco Corp.*, the Supreme Court rejected the FDA’s attempt to regulate tobacco products, reasoning that despite the statute’s broad definition of “drug” and “device,” the FDA’s statutory scheme and congressional activity sufficiently indicated that Congress had not given the FDA authority over tobacco and tobacco marketing.<sup>45</sup>

The Office of Legal Counsel (OLC) has relied on *Brown* and the absurdity doctrine to claim that the FDA does not have jurisdiction over any articles, including lethal drugs, used in executions.<sup>46</sup> Its argument proceeds as follows:

1. A core mission of the FDA is to ensure that drugs and devices are “safe.”<sup>47</sup> This means that the drug’s or device’s therapeutic attributes outweigh its risk of harm.<sup>48</sup>

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<sup>42</sup> See *Compounding Pharmacies*, DEATH PENALTY INFORMATION CENTER, <https://deathpenaltyinfo.org/executions/lethal-injection/compounding-pharmacies> [https://perma.cc/K5GM-Rh43] (last visited Oct. 21, 2019) [hereinafter *Compounding Pharmacies*].

<sup>43</sup> *Food and Drug Administration Modernization Act (FDAMA) of 1997*, FOOD & DRUG ADMIN., <https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdact/fdama/default.htm> [https://perma.cc/P22N-M8R3] (last updated Mar. 29, 2018).

<sup>44</sup> See *Whitman v. American Trucking Association*, 531 U.S. 457, 468 (2001) (“Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.”).

<sup>45</sup> 529 U.S. 120, 126 (2000).

<sup>46</sup> Whether the Food & Drug Admin. Has Jurisdiction over Articles Intended for Use in Lawful Executions, slip op. at 1, 1-2 (Office of Legal Counsel May 3, 2019), <https://www.justice.gov/olc/opinion/file/1162686/download> [https://perma.cc/FM2Q-BFPJ].

<sup>47</sup> See *id.* at 11 (noting that “[u]nder the FDCA, a ‘new drug’ may not go to market unless FDA determines . . . that the substance is ‘safe’ and ‘effective[.]’”) (quoting 21 U.S.C. § 355(d)(1) (2018)).

<sup>48</sup> *Id.* (“[A] drug is unsafe if its potential for inflicting death . . . is not offset by the possibility of therapeutic benefit.” (quoting *United States v. Rutherford*, 442 U.S. 544, 556 (1979))).

2. Execution drugs and devices are inherently unsafe because they are used for death, not therapy.<sup>49</sup> So if the FDA could regulate them, it would have to ban them outright.<sup>50</sup>
3. The Constitution and federal statutes expressly allow the death penalty.<sup>51</sup>
4. Therefore, it cannot be the case that Congress intended the FDA to have jurisdiction over articles used in executions.<sup>52</sup>

As an initial matter, this Comment does not take a position on whether the FDA should ban lethal injection drugs. This Comment's discussion does not turn on resolving that particular issue, and at any rate the OLC's absurdity theory is unpersuasive for three reasons.

First, even if FDA jurisdiction over compounded lethal drugs required the FDA to ban them outright, this does not necessarily violate Congress's intent. In *Brown*, the Supreme Court pointed to six separate pieces of legislation addressing tobacco use and human health, along with a failed congressional attempt to extend FDA jurisdiction to tobacco, to arrive at the conclusion that "Congress has persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health."<sup>53</sup> By contrast, in this case, Congress has not persistently spoken on the viability of lethal injection as a method of execution—in fact, it has not spoken on the issue at all. Congress has approved of the death penalty, but it has not set up a federal death penalty scheme where *lethal injection* is the exclusive—or even listed—form of execution.<sup>54</sup>

Not only is this case distinguishable from *Brown*, it is also analogous to a case where a court expressly rejected the absurdity objection. In *Cook v. FDA*, the D.C. Circuit Court affirmed the district court's permanent injunction requiring the FDA to forbid the import of sodium thiopental, a critical anesthetic used in executions.<sup>55</sup> In that case, a provision of the FDCA required the FDA to refuse admission of misbranded or unapproved new drugs into the country.<sup>56</sup> The D.C. Circuit ruled that since the imported anesthetic was a misbranded and unapproved new drug, the FDA was

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<sup>49</sup> *Id.* ("[T]here is no way products intended to carry out capital punishment could ever satisfy that [cost-benefit] test . . .").

<sup>50</sup> *Id.* at 12-13 ("In sum, if articles intended for use in capital punishment were regulated as 'drugs' or 'devices,' then the FDCA would prohibit them altogether.")

<sup>51</sup> *Id.* at 10 ("[T]he Constitution and laws of the United States presuppose the continued availability of capital punishment for the most heinous federal and state crimes.")

<sup>52</sup> *Id.* at 26.

<sup>53</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 156 (2000), *superseded by statute*, Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

<sup>54</sup> See 18 U.S.C. §§ 3591-3599 (2018).

<sup>55</sup> 733 F.3d 1, 3 (D.C. Cir. 2013).

<sup>56</sup> *Id.* at 7.

required to seize the drugs rather than allow them to be delivered to state correctional facilities for use in lethal injection.<sup>57</sup> The court recognized the stakes of the case by acknowledging that sodium thiopental was no longer in domestic production.<sup>58</sup> Nonetheless, it affirmed the permanent injunction, which appeared to effectively block the last remaining source of the critical anesthetic.<sup>59</sup> In reaching this conclusion, the court expressly rejected the argument that this was an absurd result, citing Supreme Court precedent for the proposition that “the Court rarely invokes the absurdity test to override unambiguous legislation.”<sup>60</sup>

*Cook* is instructive to this case. There, the unambiguous import statute led to a ban on an unapproved new drug that was critical to lethal injection. Here, the statutory exemption conditions for compounders is equally unambiguous, and therefore a ban on unapproved compounded lethal drugs should be no less consistent with Congress’s intent.

While a ban may be permissible, FDA jurisdiction over lethal compounded drugs would not automatically require it. As the *Cook* court observed, “The FDA may exercise enforcement discretion to allow the domestic distribution of a misbranded or unapproved new drug, as the Supreme Court recognized in *Chaney*.”<sup>61</sup> The FDA could turn that enforcement discretion into ensuring that compounded lethal drugs are safer and more effective, rather than banning them outright. For example, the FDA could enter into agreements with compounders to ensure that their procedures for producing compounded lethal drugs are more comparable to industry-grade standards. This arrangement is consistent with both *Chaney* and this Comment’s argument. Under *Chaney*, the FDA’s enforcement discretion provides it regulatory options besides an outright ban, as *Cook* observed. And as I discuss in Part II of my Comment, the FDA will be doing its job as long as it is engaging in some level of enforcement, including through informal means.

The second reason the OLC opinion is unpersuasive is because one could argue that not all compounded lethal drugs necessarily fail the FDA’s definition of “safe.” As the *Cook* court noted, many states conduct lethal injection using a three-drug cocktail, the first of which “induces anesthesia.”<sup>62</sup> The anesthetic arguably performs a therapeutic function—namely, rendering the person unconscious so that their body does not experience any pain from

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<sup>57</sup> *Id.* at 10-11.

<sup>58</sup> *Id.* at 4, 10-11.

<sup>59</sup> *Id.* at 1, 4.

<sup>60</sup> *Id.* at 9 (quoting *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 459 (2002) (internal brackets omitted)).

<sup>61</sup> *Id.* at 9-10.

<sup>62</sup> *Id.* at 4.

the second drug, which paralyzes the body, and the third drug, which stops the heart.<sup>63</sup> The administration of the anesthetic “is critical because absent ‘a proper dose . . . render[ing] the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of [the second drug] and pain from the injection of [the third drug].”<sup>64</sup> Insofar as the anesthetic can pass the cost-benefit requirement to be considered “safe,” the second premise of the OLC opinion falters and the FDA does not have to ban the anesthetic, thus avoiding the allegedly absurd result. At the very least, then, the FDA has some jurisdiction over some compounded lethal drugs.<sup>65</sup>

The third reason the OLC opinion is unpersuasive is because this case does not implicate the same concerns as *Brown*. The *Brown* majority had good reason to deny the FDA from running with an admittedly broad definition of “device” to regulate an entire industry, after decades of Congress’s own involvement in the field. However, that is not the case here. This case presents an issue the FDA is intimately familiar with: drugs that are injected into the human body to affect its functions—a quintessential area of the FDA’s expertise. Nor would FDA regulation catch lethal compounders off guard. Compounders as an industry have operated under FDA regulation since the 1997 FDAMA. When the first known execution by compounded lethal drugs happened 15 years later in 2012, compounders were voluntarily creating a new product knowing that it would enter into an existing regulatory scheme.<sup>66</sup>

To summarize, the FDA can regulate compounded lethal drugs because they are “new drugs.” Compounders cannot be exempt from the FDA’s new drug regulations because they are not creating lethal drugs for an identified individual patient based on the receipt of a valid prescription order. Objections to this conclusion focused on congressional intent are ultimately unpersuasive, as Congress’s intent is broad enough to address this issue. And including

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<sup>63</sup> *Id.*

<sup>64</sup> *Id.* (quoting *Baze v. Rees*, 553 U.S. 35, 53 (2008)) (ellipses and first alteration in original).

<sup>65</sup> I refer to the anesthetic, which arguably performs a therapeutic function when used in a three-drug cocktail, as a compounded lethal drug for two reasons. First, this facilitates ease of reference without affecting the legal analysis: a compounded anesthetic is still a new drug that is subject to FDA regulation absent satisfying the FDA’s exemption conditions. Second, the anesthetic used in lethal injections comes in dosages significantly higher than that used in medicinal contexts. *See, e.g.*, *Gray v. McAuliffe*, No. 3:16CV982-HEH, 2017 WL 102970, at \*9 (E.D. Va. Jan. 10, 2017) (“The VDOC will use 500 mg of midazolam as its first-stage drug in the three-drug lethal injection protocol. Midazolam is used as a sedative. It is a central nervous system and respiratory depressant . . . [M]uch smaller amounts of midazolam are used for medicinal or therapeutic purposes.”); *Reid v. Johnson*, 333 F. Supp. 2d 543, 546–47 (E.D. Va. 2004) (“The first drug, sodium thiopental is a barbiturate sedative. Two grams of sodium thiopental [used in execution] is approximately five to eight times the dosage that would be used to render a 176 pound individual unconscious for general surgery.”). Thus I can safely assume that compounders are creating this anesthetic for the purpose of lethal injection, which makes grouping the drugs together appropriate.

<sup>66</sup> *See Compounding Pharmacies*, *supra* note 42.

compounded lethal drugs within the FDA's jurisdiction would not lead to an absurd result.

This Section demonstrated that the FDA has jurisdiction to regulate compounded lethal drugs. Having established this basic premise, this Comment next turns to explore whether the FDA can be subject to judicial review for refusing to regulate compounded lethal drugs under that jurisdiction.

### B. *FDA Inaction Is Unreviewable Under Existing Law*

The landmark Supreme Court case *Heckler v. Chaney* established the presumption against judicial review of agency inaction.<sup>67</sup> In that case, plaintiffs were death row inmates asking the FDA to halt their execution by lethal injection and to seize such drugs.<sup>68</sup> Plaintiffs claimed that the drugs were new and misbranded drugs, and alternatively “suggested that the FDCA’s requirements for approval of ‘new drugs’ applied . . . .”<sup>69</sup> The Supreme Court refused to address the case on the merits and instead announced that “an agency’s decision not to take enforcement action should be presumed immune from judicial review . . . .”<sup>70</sup> The Court observed that many reasons justify the general “unsuitability” of judicial review:

[A]n agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency’s overall policies, and, indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.<sup>71</sup>

There is, however, a way to rebut this presumption of unreviewability. In a footnote, *Chaney* acknowledges that the presumption could be overcome where the agency has “consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities.”<sup>72</sup>

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<sup>67</sup> 470 U.S. 821 (1985).

<sup>68</sup> *Id.* at 823-24.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 832.

<sup>71</sup> *Id.* at 831-32.

<sup>72</sup> *Id.* at 833 n.4 (internal quotation marks omitted) (citing *Adams v. Richardson*, 480 F.2d 1159 (D.C. Cir. 1973) (en banc)).

*Chaney* did not elaborate on what abdication would look like, but the circuit courts have provided a clearer picture of this exception.<sup>73</sup> The circuit courts that have developed the abdication doctrine can be grouped into two categories. The first line of circuits (“Line 1”) conducts the abdication analysis by looking to what the agency has done with respect to regulation. The second line of circuits (“Line 2”) conducts the abdication analysis by examining what the agency has said with respect to regulation. The two lines appear to be mutually exclusive, meaning that each articulates its own requirement of what must be met to allow for judicial review.

In Line 1 cases, courts look to what the agency does. Courts have refused to find abdication so long as agencies maintain some level of enforcement activity over the issue identified in the statutory charge. This principle aligns closely with the observation of the *Chaney* Court that “[t]he agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities.”<sup>74</sup>

In operationalizing the concept of enforcement, Line 1 courts find no abdication where agencies choose to settle with the regulated party,<sup>75</sup> resort to informal enforcement measures to effectively induce compliance,<sup>76</sup> or decide not to bring an enforcement action after a good-faith investigation.<sup>77</sup> Enforcement thus encompasses the agency’s initial steps of looking into a problem and deciding whether to take further action.<sup>78</sup> Importantly, the court conducts the abdication analysis by examining if there is at least some level of

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<sup>73</sup> None of the three Supreme Court cases since *Chaney* that discuss judicial review of agency inaction directly address nonenforcement decisions. The first case prohibits review of an agency’s refusal to implement a programmatic proposal. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004). This is relevant to the discrete look rule I propose later, which would limit judicial review to an agency’s refusal to take enforcement action against a private party’s violations. The second case is not on point because it specifically limits its discussion of agency inaction to the context of rulemaking. *See Massachusetts v. EPA*, 549 U.S. 497, 500 (2007). The third case is also not on point because there the agency’s statute contained specific mandatory procedures that the Court said made review possible, whereas the cases this Comment covers are not about procedural compliance. *See Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1656 (2015).

<sup>74</sup> *Chaney*, 470 U.S. at 831-32.

<sup>75</sup> *See, e.g., Garcia v. McCarthy*, 649 F. App’x 589, 591 (9th Cir. 2016) (“[A]n agency’s decision to settle falls under the penumbra of agency inaction that has traditionally been subject to a rebuttable presumption against judicial review.”).

<sup>76</sup> *See, e.g., Block v. SEC*, 50 F.3d 1078, 1084 (D.C. Cir. 1995) (“Thus, we cannot agree that the Commission has refused to implement § 2(a)(19); the agency has merely chosen thus far to enforce it informally rather than formally. So far, it appears, the Commission has found that sufficient to induce compliance with the law.”).

<sup>77</sup> *See, e.g., Greer v. Chao*, 492 F.3d 962, 967 (8th Cir. 2007) (“Among other actions, OFCCP officials visited Eaton, discussed conditions with coworkers, and interviewed managers. These investigatory steps are sufficient to indicate that the Secretary discharged her statutory obligations.”).

<sup>78</sup> *See id.* at 965 (quoting *Giacobbi v. Biermann*, 780 F. Supp. 33, 37 (D.D.C. 1992)) (“[T]he investigation itself, like the final decision whether or not to take enforcement action, is within the enforcement arena and therefore, committed to agency discretion.” (internal quotations omitted)).

enforcement *across* cases. An agency may weigh its priorities and choose not to enforce in particular cases while enforcing in other cases.<sup>79</sup> A low level of enforcement does not amount to abdication of statutory duty, because the agency has discretion to choose the level of enforcement so long as it has not “totally abdicated its statutory responsibility.”<sup>80</sup>

Here, judicial review of FDA inaction toward compounded lethal drugs is unavailable under Line 1. The court will look to see if there is some level of enforcement of the statutory charge. The FDA’s statutory charge, as relevant here, is to regulate new drugs.<sup>81</sup> That is a very broad mandate. Compounded lethal drugs fall under new drug regulation, as argued earlier, and therefore comprise a subset of new drugs.<sup>82</sup> Suppose, for the sake of argument, that the FDA’s enforcement level of new drugs is dangerously low or even nonexistent. The FDA could simply increase its overall new drug enforcement level while still leaving compounded lethal drugs completely alone. A court following Line 1 will find that the FDA has some level of enforcement toward new drugs and thus cannot be subject to judicial review.

In Line 2 cases, courts look to what the agency says. Courts have refused to find abdication so long as agencies have not articulated a general nonenforcement policy.<sup>83</sup> The case that established this rule, *Crowley Caribbean Transport, Inc. v. Pena*, involved a shipping company that contested the Maritime Administrator’s grant of a shipping waiver to a competitor.<sup>84</sup> The D.C. Circuit examined the Administrator’s correspondence letters with both parties and found the Administrator’s waiver grant to be a “single-shot non-enforcement decision.”<sup>85</sup> The court found that the waiver did not articulate a general policy and therefore the particular instance of nonenforcement was not subject to judicial review.<sup>86</sup> The court observed that many agency documents, such as “side comments, form letters, litigation

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<sup>79</sup> See, e.g., *Raymond Proffitt Found. v. U.S. Army Corps of Eng’rs*, 343 F.3d 199, 211 (3d Cir. 2003) (“The Corps has decided, however, to continue to emphasize flood control as the primary objective of this particular facility, something the WRDA certainly permits it to do.”).

<sup>80</sup> *Madison-Hughes v. Shalala*, 80 F.3d 1121, 1131 (6th Cir. 1996).

<sup>81</sup> See 21 U.S.C. § 355(a) (2018) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) [of this section] is effective with respect to such drug.”).

<sup>82</sup> See *supra* text accompanying notes 17–23.

<sup>83</sup> See, e.g., *Salmon Spawning & Recovery All. v. U.S. Customs & Border Prot.*, 550 F.3d 1121, 1129 n.5 (Fed. Cir. 2008) (holding that abdication was not an issue in this case because plaintiffs did not allege any express policy of non-enforcement); *Riverkeeper v. Collins*, 359 F.3d 156, 170–71 (2d Cir. 2004) (holding that the Nuclear Regulatory Commission (NRC)’s refusal to implement the plaintiff’s proposed nuclear safety measures was unreviewable because the agency did not articulate a policy expressly abdicating any relevant statutory authority).

<sup>84</sup> 37 F.3d 671, 672 (D.C. Cir. 1994).

<sup>85</sup> *Id.* at 676.

<sup>86</sup> *Id.*

documents, and informal communications,” would not be reliable indicators for the court to “tease[] out” a general nonenforcement policy.<sup>87</sup> According to the court, documents on this disfavored list indicate “the sort of mingled assessments of fact, policy, and law that drive an individual enforcement decision” of the nature that *Chaney* intended courts not to touch.<sup>88</sup>

The D.C. Circuit provided two categories of agency documents that it would consider as general policies. One category consists of agency policies articulated through the full rulemaking process.<sup>89</sup> The other category consists of agency policies articulated in the form of a “universal policy statement.”<sup>90</sup> Further, while *Crowley* did not entirely rule out the possibility that agency documents from the disfavored list could articulate a general policy,<sup>91</sup> such a category currently seems to be a null set: in the thirty years since *Crowley* was decided, I could not find a single court that has inferred a general nonenforcement policy from a document on *Crowley*’s disfavored list.

Here, under Line 2, the FDA’s inaction toward compounded lethal drugs will also not be subject to judicial review. The FDA has not articulated a general nonenforcement policy. And either out of intentional desire to avoid judicial review or simply the inertia of not needing to announce a policy of inaction, the FDA will likely continue to remain silent. Even if it had zero level of enforcement, the agency would not be subject to review because the court can only look at what the FDA has said about its nonenforcement policies. The best evidence that plaintiffs have of a general nonenforcement policy is the FDA’s long-standing position that it declines to take enforcement action “in the narrow category of cases in which drugs are destined for use by States in accordance with their lethal injection laws.”<sup>92</sup> But this policy statement was made in a litigation document, which is on *Crowley*’s disfavored list. Supposing that the court would allow the rare inference of a general policy from litigation documents, the FDA could preempt this possibility by simply omitting this language from its documents going forward. Furthermore, as with Line 1, Line 2 seems to analyze policies at the general level of the statutory charge. Thus, it is not clear that even a general nonenforcement policy toward compounded lethal drugs would persuade a court that the FDA was abdicating its duty of regulating new drugs.

This Section demonstrates that under the reasoning of either Line 1 or Line 2, FDA inaction is unreviewable. Yet it seems incomplete to rest abdication analysis either exclusively on what an agency has done or what it has said at the

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<sup>87</sup> *Id.* at 677.

<sup>88</sup> *Id.*

<sup>89</sup> *Id.* at 676 (citing *Nat’l Wildlife Fed’n v. EPA*, 980 F.2d 765 (D.C. Cir. 1992)).

<sup>90</sup> *Id.* (citing *Edison Elec. Inst. v. EPA*, 996 F.2d 326 (D.C. Cir. 1993)).

<sup>91</sup> *Id.* at 677.

<sup>92</sup> *FDA Brief*, *supra* note 6, at 19.

general level of the statutory charge. This Comment next discusses the problems with this case law and creates a new rule to fix those flaws.

## II. REVIEW UNDER DISCRETE LOOK

I have shown that a challenge to FDA inaction is unreviewable under existing case law. In this Part, I generalize the flaws of the existing law and propose a solution by introducing the discrete look rule. I then discuss how the rule works in practice.

### A. *Discrete Look Described*

Abdication analysis under the current circuit case law provides at best a tiny peephole of judicial review. First, when courts look at agency inaction, they only look at it in relation to the general level of the statutory charge. They refuse to look below the statutory charge to any particular issue, or “subset,” of the statutory charge, even if the agency is completely refusing to enforce that subset. Second, when courts look at agency inaction, they look either to what an agency has done to determine if some level of enforcement exists or to what an agency has said about its enforcement policies, but not both. It will be the rare case indeed where an agency engages in no level of enforcement of its statutory charge or where an agency has announced a general nonenforcement policy. Most agency refusal patterns are not that broad in scope or that conspicuous in nature. So the existing framework results in hardly any judicial review in practice. The high stakes of this case for death row inmates and the public at large challenge the workability of this rigid presumption against judicial review.

This Comment proposes a new rule to remedy these problems by opening a narrow avenue for judicial review. Under this rule, abdication analysis can occur at not just the general level of the statutory charge (the “statutory level”), but also at any *discrete subset* of the statutory charge (the “discrete level”). That is, a court can look at agency refusals to enforce a discrete subset that falls within an agency’s broader statutory charge—a practice I have been calling “discrete look.” Further, this Comment proposes a hybrid rule that merges Line 1 and Line 2 so that they are no longer mutually exclusive; meeting either will be sufficient to allow judicial review.

One might worry that a rule about discrete nonenforcement could be so sweeping as to be unworkable or burdensome on the courts. Thus, this proposed rule has two further constraints. First, the rule only applies to agency refusals to take enforcement action against a private party’s violations. This prevents agencies from being harassed for refusing to implement private proposals on how best to go about doing their job. Second, the rule only applies when an

agency's refusal to enforce occurs against the backdrop of a unitary regulatory scheme—that is, when no other regulator can step in to take action.

To summarize, the discrete look rule requires a court to conduct arbitrary and capricious review of an agency's (1) discrete (2) nonenforcement (3) of violations (4) within a unitary regulatory scheme.

### 1. Discrete

Establishing a discrete subset requires passing a two-step test. First, the desired target of regulation must fall within a subset of a statutory charge that the agency is tasked to regulate. Courts should conduct this subset analysis using *Chevron* deference toward the agency because the agency has the expertise and policy tools to interpret the scope of its statutory duty.<sup>93</sup> Under *Chevron*, the court defers to an agency's interpretation of ambiguity in the statute so long as the agency's interpretation is reasonable.<sup>94</sup> For example, an agency tasked with regulating vegetables might refuse to regulate tomatoes because it finds "vegetable" to be an ambiguous word and reasonably interprets it to exclude tomatoes. In that case, tomatoes are not a discrete subset of all vegetables, because tomatoes are not reasonably understood by the agency to be a subset in the first place. As a result, the agency's lack of enforcement toward tomatoes should not be subject to judicial review.

Second, the desired object of regulation must be discrete. The Merriam-Webster Dictionary defines "discrete" as "constituting a separate entity: individually distinct" or "taking on or having a finite . . . number of values."<sup>95</sup> Thus, courts should consider whether the subset in question can be thought of as "individually distinct" from the other subsets that fall within the statutory charge. The Supreme Court's refinement of "discrete" in its equal protection jurisprudence may be a useful guide. In the famous "Footnote Four" of *United States v. Carolene Products Co.*, the Court observed that certain legislation could give rise to a higher level of scrutiny than rational basis review when it prejudiced "discrete and insular minorities."<sup>96</sup> Professor Bruce Ackerman helpfully defined the Court's understanding of "discrete" as referring to

members [that] are marked out in ways that make it relatively easy for others to identify them. For instance, there is nothing a black woman may plausibly do to hide the fact that she is black or female. Like it or not, she will have to

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<sup>93</sup> See generally *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

<sup>94</sup> *Id.* at 845.

<sup>95</sup> *Discrete*, MERRIAM-WEBSTER.COM DICTIONARY, <https://www.merriam-webster.com/dictionary/discrete> [<https://perma.cc/H5HR-GWAR>] (last visited on Apr. 14, 2019).

<sup>96</sup> 304 U.S. 144, 152-53 n.4 (1938).

deal with the social expectations and stereotypes generated by her evident group characteristics.<sup>97</sup>

If evident minority characteristics associated with discrimination are the mark of discreteness in the constitutional context, courts can ask what makes subsets “evident” in the administrative law context. For example, is the subset one that has emerged recently? If so, judicial review could help clarify the agency’s relationship to it. Does the subset carry sizeable economic consequences? If so, that may make review a worthwhile expenditure of judicial resources. Does the subset implicate the agency’s ability to faithfully carry out its mission? All subsets theoretically do, but those that especially do should merit more attention. These questions are a starting point with room for refinement rather than an exhaustive list. Over time, because agencies are repeat players in the courts, parties can develop a working expectation of what is “discrete” that maps onto the unique specialties of each agency. The point here is that a discrete subset, by definition, would stand out enough to be worth judicial review.

## 2. Nonenforcement

A court should analyze nonenforcement on the discrete level in the same way that it currently analyzes nonenforcement on the statutory level. How much enforcement is enough? I suggest that this necessarily is a fact-specific inquiry. One instance of enforcement in the past year on an issue that rarely comes up seems to pass. However, one instance of enforcement in the past year on a common issue with hundreds of missed enforcement opportunities that the agency refuses to deal with would probably not pass. While “some” literally means “greater than zero,” “some level” still implies a degree rather than an absolute count. Another way to think about it is to ask if the agency demonstrates either total nonenforcement or severe under-enforcement to the practical effect of nonenforcement.<sup>98</sup> However difficult this question may be, it would not be too demanding for courts, as they are comfortable conducting this kind of line-drawing inquiry in other contexts.<sup>99</sup>

Further, the nonenforcement analysis should combine the reasoning of Line 1 and Line 2. That is, the court should look to what an agency is doing *and* what it is saying, on the discrete level. Thus, the court should ask two questions. First, is there a general nonenforcement policy of the discrete

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<sup>97</sup> Bruce A. Ackerman, *Beyond Carolene Products*, 98 HARV. L. REV. 713, 729 (1985).

<sup>98</sup> See Jentry Lanza, Comment, *Agency Underenforcement as Reviewable Abdication*, 112 NW. U. L. REV. 1171, 1193-1208 (2018) (explaining why severe underenforcement should be treated as nonenforcement for purposes of allowing judicial review).

<sup>99</sup> See, e.g., *Texas v. United States*, 809 F.3d 134, 171-73 (5th Cir. 2015) (finding that the barebones percentage of applicants denied deferred action amounted to evidence that officials did not make decisions with discretion), *aff'd by an equally divided Court*, 136 S. Ct. 2271 (2016).

subset? Second, is the agency lacking “some level” of enforcement of the discrete subset? Answering “yes” to either question will trigger discrete look.

The fusion of Line 1 and Line 2 approaches is a straightforward and sensible rule for courts to use. As it stands, neither Line is satisfactory on its own in closely tracking instances of agency nonenforcement behavior. Line 1 is more robust because it allows the court to look at what an agency is doing. However, one weakness of Line 1 is illuminated when an agency may be confronted with a new issue—too new for it to have some level of enforcement. The agency can persuasively argue that it is not abdicating its duty; rather, the issue is so new that the agency has not even had an opportunity to refuse enforcement. Line 2 can address this “temporality” problem by looking to what an agency says, which provides the clearest indication of nonenforcement behavior. However, its flaw is that its determination of abdication rests solely on what an agency says. In effect, the agency can control whether it will be subject to judicial review. Together, a hybrid rule will allow courts to supplement Line 1 analysis with the rarer instances of Line 2 analysis. Compared to the status quo of mutually exclusive Lines, this fusion helpfully expands instances of judicial review.

### 3. Violation

Plaintiffs should only be allowed to challenge agency inaction when the agency is refusing to take enforcement action against a private party’s violation. Limiting this rule to violations directly addresses the concerns of *Norton v. Southern Utah Wilderness Alliance*.<sup>100</sup> In that case, plaintiff challenged the Bureau of Land Management (“BLM”)’s refusal to ban off-road vehicles in designated areas, arguing that BLM needed to enforce this ban to fulfill its statutory duty of wilderness preservation.<sup>101</sup> However, nothing in the text of BLM’s statutory charge required it to ban off-road vehicles. The Court held that BLM had broad discretion to decide how to achieve wilderness preservation, making BLM’s rejection of plaintiff’s “programmatic” proposal unreviewable.<sup>102</sup> The Court worried that to allow judicial review of an agency’s rejection of a programmatic proposal “would ultimately become the task of the supervising court, rather than the agency, to work out compliance with the broad statutory mandate, injecting the judge into day-to-day agency management.”<sup>103</sup>

A violation is qualitatively different from a programmatic proposal. A violation by definition has contradicted the regulatory scheme; a proposal is simply one suggestion for how an agency should handle its regulatory scheme.

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<sup>100</sup> 542 U.S. 55 (2004).

<sup>101</sup> *Id.* at 60-61.

<sup>102</sup> *Id.* at 64, 67.

<sup>103</sup> *Id.* at 66-67.

Agencies are tasked with addressing violations, but it is up to them to decide which proposals to adopt. An agency can consistently reject a line of policy suggestions, because as the expert in the field, it can choose how to best achieve its enforcement duties. By contrast, an agency that consistently refuses to enforce a line of violations does not look like it is doing its job.

#### 4. Unitary Regulatory Scheme

Even after plaintiff satisfies the first three elements of this test, courts should only allow review if plaintiff has no other recourse through an overlapping regulatory scheme. An agency may choose not to act for a variety of valid reasons, one of which is that it made a calculation that its inaction is not the final word in the context of a broader regulatory scheme. Although agencies specialize, few issues today are covered or solvable by only one agency. One of the main functions of the Office of Information and Regulatory Affairs (“OIRA”) is to smooth out inter-agency policies to ensure that they work together.<sup>104</sup> The same can be said for the executive branch’s international regulatory scheme.<sup>105</sup> Regulatory schemes are thus intricate and complex. One agency’s inaction may actually be in purposeful horizontal coordination with another agency’s action. When performing this analysis, courts should ask if there really is an overlapping regulatory scheme.<sup>106</sup> Sometimes it may appear so because of general subject-matter similarities, but if Congress only gave one agency the regulatory tools such that no other agency can provide similar relief for similar claims, then the regulatory scheme is unitary.

Regulatory overlap may also exist vertically across federal and state governments. A federal agency may choose not to act because it determines that a state engages in its own regulatory activity in that field, and therefore federal action would be redundant and wasteful. However, vertical overlap is less likely to be satisfactory. This is because state action may vary in its purposes and scope from federal action and might not actually cover the field the agency has a duty to regulate. Further, a lawsuit may feature multiple plaintiffs, some of whom come from states with regulatory schemes while others do not, in which case the vertical overlap would have “holes” requiring federal action to fill. To address these concerns, the court should simply

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<sup>104</sup> *Office of Management and Budget, Information and Regulatory Affairs*, THE WHITE HOUSE (last visited Apr. 14, 2019), <https://www.whitehouse.gov/omb/information-regulatory-affairs/> [<https://perma.cc/JK8A-BSQR>].

<sup>105</sup> See generally Exec. Order No. 13609, 77 Fed. Reg. 26,413 (May 1, 2012) (dividing authority amongst and ensuring coordination among numerous federal agencies in the natural defense space).

<sup>106</sup> One court did so in a recent case. See *Riverkeeper, Inc. v. Collins*, 359 F.3d 156, 161 nn.4-5 (2d Cir. 2004) (considering the relationship other agencies may have in fulfilling the regulatory scheme).

presume that no vertical regulatory overlap exists. The federal agency can rebut this presumption by providing the court with sufficient evidence of state regulatory activity in every state from which plaintiffs sue. As with horizontal regulatory overlap, the federal agency here has the most knowledge of what regulatory activity already exists in states. If it not acting because it sees that states are already doing something, then surely it can point the court to what it is that the states in question are doing.

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Discrete look borrows procedurally from the Court's burden-shifting mechanism in *Celotex Corp. v. Catrett*.<sup>107</sup> In summary judgment, the movant need only to point to an absence of a dispute of material fact to get the motion considered. The non-movant then responds with affirmative evidence of a dispute of material fact. The court then decides the motion. This is not an empty standard, but it is understandably lenient.

Likewise, here the plaintiff must show a negative. The first way to do so is to point to a general nonenforcement policy. The second is to show that the agency's enforcement level has not reached the "some level" standard discussed above. For new issues, the first way alleviates the temporality problem. If that avenue is not available, plaintiffs can try to persuade the court that an issue is ripe for abdication analysis by pointing to the number of years or potential number of cases that have elapsed since the time the agency was first on notice about the issue. Coordinated litigation can also demonstrate a pattern of refusals to enforce. If hundreds of death row inmates file individual complaints before the FDA and receive refusals to enforce, then that leaves a record of nonenforcement.

If the plaintiff satisfies the negative showing, the agency must then respond. It can provide an affirmative showing of some level of enforcement, contest any allegations of a general nonenforcement policy, or argue under *Chevron* that the subset is not part of an ambiguous statutory charge. Finally, it can provide a persuasive explanation of how an overlapping regulatory scheme justifies the agency's inaction in this particular case. The court must then decide whether to allow judicial review. If so, the review is what the court normally conducts for agency action: arbitrary and capricious review, which includes fact-finding, full briefing by both parties, hearings with cross-examination, discovery, expert witnesses, and more.<sup>108</sup> If the court finds that

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<sup>107</sup> 477 U.S. 317 (1986).

<sup>108</sup> For examples of how courts conduct arbitrary and capricious review, see generally *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009); *Motor Vehicles Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29 (1983).

the agency's inaction is arbitrary and capricious, it can order the agency to increase the level of enforcement of the discrete subset. In more egregious or straightforward cases, it can also grant the specific relief plaintiff requests.

This Section proposed the discrete look rule and discussed how courts could apply it in practice. The rule offers a constrained and targeted form of judicial review in cases that might require some kind of judicial scrutiny. The next Section specifically applies discrete look to potential cases in which death row inmates would sue the FDA for refusing to regulate compounded lethal drugs.

### B. *Discrete Look Applied*

This Section applies discrete look to the issue specifically addressed in this Comment: the use of lethal compounded drugs in state executions of inmates. This Section shows that a typical case brought by inmates against the FDA challenging the lack of regulation of these drugs in executions would satisfy the four elements of discrete look. As such, FDA inaction toward compounded lethal drugs should be subject to judicial review.

#### 1. Discrete

First, compounded lethal drugs are clearly a subset of new drugs that the FDA is tasked to regulate. Applying *Chevron*, a court will likely find that “drug” is not ambiguous from the statutory text. The FDA may argue that compounded lethal drugs are not really “drugs” to begin with, because drugs are meant to heal, not kill people. This is a weak argument, because it turns out that the FDCA defines the term: “The term ‘drug’ means . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . .”<sup>109</sup> Since compounded lethal drugs clearly aim to affect a human being’s body, they are unambiguously a subset of new drugs. The phrase “compounded lethal drugs” is an apt description rather than a misnomer.

Second, compounded lethal drugs form a discrete subset. They are “individually distinct” because of their unique characteristics. For starters, the subset is new, as compounded lethal drugs have only emerged since 2012.<sup>110</sup> Second, it would be helpful for the courts to clarify the relationship the FDA has to compounded lethal drugs. Third, compounded lethal drugs carry sizeable economic consequences because not only do they sustain the administration of lethal injection in the states, their proliferation into illicit supply chains can trigger all sorts of disruptive and costly effects for

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<sup>109</sup> 21 U.S.C. § 321(g)(1) (2018).

<sup>110</sup> See *Compounding Pharmacies*, *supra* note 42.

regulators.<sup>111</sup> Moreover, this subset implicates the public reliance on the agency to faithfully carry out its mission. The FDA's mission, according to its website, is to “protect[] the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices . . . .”<sup>112</sup> A court does not need to reach far to see that compounded lethal drugs, both as they are used to kill people and as distributed into illicit supply chains, strongly implicate the FDA mission. Thus, if any subset of new drugs stands out as discrete under these questions, compounded lethal drugs must surely be it.

## 2. Nonenforcement

The FDA has not expressly articulated a general nonenforcement policy, and it is not likely that a court would start inferring general policies from documents on *Crowley's* disfavored list. Even if it did, the FDA could still avoid judicial review on this front by avoiding articulating anything resembling a general policy in its nonenforcement letters, litigation documents, and the like.

The better option for litigants is to argue that the FDA has not engaged in some level of enforcement of compounded lethal drugs. According to a 2016 GAO study, from 2012 through 2016 the FDA completed 265 inspections of small compounders and other drug compounders.<sup>113</sup> The GAO report made no mention of FDA regulation of compounded lethal drugs. The primary news story tying the FDA to lethal injection was about a compounder in Missouri called Apothecary that shut down in 2016 after the FDA and state inspectors found a host of unsanitary practices.<sup>114</sup>

The FDA can argue that it engaged in some level of regulating compounded lethal drugs when its inspections of Apothecary led to the seizure of some compounded lethal drugs. It can also argue that its general enforcement action (inspecting a compounder for violations) *included* enforcement of a discrete subset (seizing compounded lethal drugs).

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<sup>111</sup> Yadav, *supra* note 13, at 479 (“The secrecy surrounding the execution drug procurement practices of death-penalty states risks undermining channels for the importation of medicines that are otherwise safe and effective.”).

<sup>112</sup> *What We Do*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/what-we-do/> [https://perma.cc/4GVL-CF4A] (last updated Mar. 28, 2018).

<sup>113</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-17-64, DRUG COMPOUNDING: FDA HAS TAKEN STEPS TO IMPLEMENT COMPOUNDING LAW, BUT SOME STATES AND STAKEHOLDERS REPORTED CHALLENGES 40 (2016).

<sup>114</sup> See Chris McDaniel, *Pharmacy That Mixed Execution Drugs Is Being Sold After Admitting Numerous Violations*, BUZZFEED NEWS (Apr. 21, 2016, 10:45 PM), <https://www.buzzfeednews.com/article/chrismdaniel/pharmacy-that-mixed-execution-drugs-is-being-sold-after-disc> [https://perma.cc/H77K-95NN].

However, the Apothecary inspection is unpersuasive evidence of “some level” of enforcement for two reasons. First, it provides only one episode when the FDA interacted with compounded lethal drugs. That hardly appears to establish a minimum level of enforcement, given the established presence of compounders as the main supplier of lethal drugs since 2012.<sup>115</sup> Second, the FDA’s regulatory connection with compounded lethal drugs appeared fortuitous. The FDA’s impetus for investigation seemed to stem from a host of violations (unrelated to compounded lethal drugs) rather than the fact that Apothecary also happened to compound lethal drugs on the side.<sup>116</sup> The FDA’s inspection letter to Apothecary<sup>117</sup> focused primarily on the fact that the compounder did not have individual prescription orders for individually-identified patients and did not maintain a clean environment for compounding.<sup>118</sup> As further evidence that the FDA targeted Apothecary for its general compounding practices, the compounder ended up admitting guilt to an astounding 1,892 violations of state pharmacy guidelines.<sup>119</sup> The inspection letter never mentions lethal injection. To be clear, the motive or expectation of the regulator does not necessarily control how “some level” of enforcement is counted. However, given that Apothecary is a stand-alone case, the motive of the FDA in its regulatory action helps to make sense of what *kind* of regulatory action it was taking.

Alternatively, the FDA can argue that it has engaged in some level of regulating compounded lethal drugs by pointing out that it has at least one such compounded drug on its list of banned substances.<sup>120</sup> High dosage potassium chloride, which appears on this list, can be used as the third and final drug in lethal injections that stop the heart.<sup>121</sup> This is also a weak argument. For states that use three drugs in lethal injection, potassium chloride is only the last

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<sup>115</sup> See *Compounding Pharmacies*, *supra* note 42.

<sup>116</sup> The same can be said for Greenpark, a compounding pharmacy that an undercover news story revealed was supplying compounded lethal drugs to Texas. See McDaniel, *supra* note 12. Compared to Apothecary, Greenpark is even more tenuous evidence of FDA regulation because (1) there is no evidence that the FDA seized compounded lethal drugs from it and (2) the FDA identified only a handful of sanitary issues, suggesting that the inspection was something like a routine checkup.

<sup>117</sup> Warning Letter from Amy Barringer, Acting Dallas Dist. Dir., Pub. Health Serv., Food & Drug Admin. to Thomas Marti, President, The Apothecary Shoppe (Aug. 19, 2016), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/apothecary-shoppe-llc-474607-08192016> [<https://perma.cc/V6U5-6XEY>].

<sup>118</sup> *Id.*

<sup>119</sup> McDaniel, *supra* note 114.

<sup>120</sup> See 21 C.F.R. 216.24 (2018) (banning the compounding of “[a]ll solid oral dosage form drug products containing potassium chloride that supply 100 milligrams or more of potassium per dosage unit”).

<sup>121</sup> Atul Gawande et al., *Physicians and Execution—Highlights from a Discussion of Lethal Injection*, NEW ENG. J. MED. (Jan. 31, 2008), <https://www.nejm.org/doi/full/10.1056/nejmpo800378> [<https://perma.cc/56KW-DD46>].

drug.<sup>122</sup> None of the other drugs commonly used in lethal injection appear on the banned list. For example, midazolam, which renders the inmate unconscious, has been the predominant choice in three-drug executions in the past few years.<sup>123</sup> Midazolam is not on the FDA's banned list, even though the dosage levels with which compounders produce it is only useful for the purposes of execution.<sup>124</sup> Potassium chloride's appearance on the FDA's banned compounding list—conspicuously alone—may be more attributable to the FDA's general concern about the drug's potency at high dosages rather than a specific concern about its use in lethal injection.

The FDA can try a temporality argument, but it will likely fail. The first recorded instance of lethal injection by compounded lethal drugs occurred in 2012.<sup>125</sup> The court would likely think that enough time and opportunities have passed for enforcement such that the FDA has had the opportunity to demonstrate a pattern of nonenforcement. Since 2012, at least several dozen executions have used compounded lethal drugs, implying that many more compounded drugs have been produced and distributed without any regulatory oversight by the FDA.<sup>126</sup> Enough time has elapsed to demonstrate that the FDA has consistently refused to regulate here.

### 3. Violation

The FDA's discrete nonenforcement here is toward a violation and not a programmatic proposal. As shown above, compounded lethal drugs are new drugs, and compounders are not exempt from new drug regulations because they do not have valid individual prescription orders. By producing and distributing these drugs outside of the FDA's lengthy and costly new drug approval process, compounders violate the FDA's new drug regulations.

### 4. Unitary Regulatory Scheme

On the federal level, the FDA's website recognizes that the "FDA's responsibilities are closely related to those of several other government agencies."<sup>127</sup> From the FDA's descriptions of these agencies' duties, however,

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<sup>122</sup> *Id.*

<sup>123</sup> See, e.g., *Execution List 2018*, DEATH PENALTY INFO. CTR., <https://deathpenaltyinfo.org/executions/2017> [<https://perma.cc/5EZJ-F3E9>] (last visited Oct. 21, 2019).

<sup>124</sup> See, e.g., *Gray v. McAuliffe*, No. 3:16CV982-HEH, 2017 WL 102970, at \*9 (E.D. Va. Jan. 10, 2017) ("The VDOC will use 500 mg of midazolam as its first-stage drug in the three-drug lethal injection protocol. Midazolam is used as a sedative. It is a central nervous system and respiratory depressant . . . much smaller amounts of midazolam are used for medicinal or therapeutic purposes.")

<sup>125</sup> See *Compounding Pharmacies*, *supra* note 42.

<sup>126</sup> *Id.*

<sup>127</sup> *What Does FDA Regulate?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/aboutfda/transparency/basics/ucm194879.htm> [<https://perma.cc/8QLN-Q9ZW>] (last updated Mar. 28, 2018).

only the Drug Enforcement Administration (“DEA”) shares jurisdiction with the FDA on the subject of drugs.<sup>128</sup> The DEA is tasked with regulating five categories of controlled substances that are listed by statute.<sup>129</sup> Compounded lethal drugs do not fall within that list.<sup>130</sup> This issue is therefore outside of the DEA’s jurisdiction. Without other federal agencies in play, the FDA’s inaction is in a unitary regulatory scheme, unless the states are involved.

On the state level, a regulatory vacuum, rather than a regulatory overlap, exists. The same article in the *Journal of the American Pharmacists Association* that warned against illicit supply chains also noted that “[t]hese execution secrecy laws and policies, which have been implemented by twenty-three of thirty-one states with the death penalty, effectively—and in some cases explicitly—exempt the suppliers of lethal injection drugs from oversight by state boards of pharmacy.”<sup>131</sup> The growth of laws amongst the states that shield compounders from identification and regulation shows how void the regulatory scheme has become and consequently how urgent the need is for the FDA to regulate in this space. Even if a few of the states with the death penalty may be engaging in some regulatory oversight of their compounders, discrete look would treat this as a unitary regulatory scheme, at least for litigation that includes plaintiffs from states with an exemption law.

This Section showed how this case satisfies discrete look and therefore can be subject to judicial review. The next Section explains the broader implications discrete look has for administrative law.

### C. Discrete Look Justified

This Section discusses the general benefits of allowing targeted judicial review under discrete look in administrative law and refutes the notion that it asks too much of the courts. It also demonstrates that discrete look beats alternative approaches to judicial review that would impose too much of a burden on the courts.

Where an agency has decided that it will not enforce discrete subsets of a statutory charge, the courts should have the ability to conduct arbitrary and capricious review, in the same way that a court would do so for affirmative enforcement actions. We should not think of agency duties as either all-or-nothing on the level of the statute, but rather as an assortment of responsibilities

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<sup>128</sup> *Id.* (“The Department of Justice’s Drug Enforcement Administration (DEA) works to enforce the controlled substances laws and regulations of the United States, including as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances.”).

<sup>129</sup> *See* 21 U.S.C. § 802(6) (2018) (“The term ‘controlled substance’ means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V . . .”).

<sup>130</sup> *Id.*

<sup>131</sup> *Yadav, supra* note 13.

that Congress included under a statute for the agency to regulate. Courts should have the power to question an agency's job performance when it consistently refuses to enforce some issues under its jurisdiction.<sup>132</sup>

Discrete look benefits the public, the agency, and Congress. Litigation using discrete look can force an agency to provide an affirmative showing of some level of enforcement or an explanation of the overlapping regulatory scheme. This allows the public to better understand an agency's enforcement priorities on discrete issues that may otherwise be swallowed by broader statutory charges. Increased knowledge of agency inaction also empowers lobbying for change and accountability through the political process. Most concretely, plaintiffs in these cases are often members of the public asking for regulation. They benefit from having an opportunity to see some kind of regulation that directly affects their interests.

The agency benefits, too. An agency might be the expert, but that does not mean it is always doing the best resource allocation and priority-setting. Having to explain its reasons helps the agency identify inconsistencies and inaccurate assumptions in its enforcement priorities. Even the specter of litigation could incentivize the agency to give its enforcement levels a second look. Because an agency will have a duty to show some levels of enforcement, it may choose to preemptively publish reports of its discrete enforcement levels, or at least keep internal files in anticipation of litigation. An agency may also try to gain a better understanding of its own overlapping regulatory schemes and when certain issues belong to a unitary scheme. Just as judicial review provides external pressure to an agency to consider its reasons for action, so here would it incentivize the agency to consider its reasons for inaction.

Discrete look also benefits Congress. Congress is frequently silent because it faces collective action problems and scattered priorities, but its silence should not always be understood as affirmative approval of agency inaction.<sup>133</sup> Without further instruction, an agency might exercise discrete nonenforcement because it does not *really* think that Congress mandated it to regulate the subset. If litigation causes frequent shifts in resource allocation between X, Y, and Z, this can be a strong signal to Congress to provide more funding or clarify the agency's mandate. Indeed, if some enforcement priorities become tethered to who happens to have won in court, Congress

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<sup>132</sup> Cf. *Heckler v. Chaney*, 470 U.S. 821, 833 n.4 (1985) (explaining that the presumption against judicial review of agency inaction can be overcome when the agency "consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities" (citing *Adams v. Richardson*, 480 F.2d 1159 (D.C. Cir. 1973) (en banc))).

<sup>133</sup> Cf. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 155 (2000) ("Indeed, this is not a case of simple inaction by Congress that purportedly represents its acquiescence in an agency's position.").

may be alerted to conduct a more programmatic assessment about enforcement priorities.

Despite its benefits, one might ask if discrete look is worth the trouble for the courts. A judge may think that this rule would be too intrusive a test to ask courts to perform. In principle, if courts are already hesitant to find abdication on the face of a statute, they could be even more reluctant to look into the weeds to examine whether an agency is enforcing each discrete subset. Courts might think that it is not their job to probe beneath the surface of a statute where Congress has not delineated the subject matter in more detail in the statute itself. Practically, courts might be concerned about what makes a subset discrete. Absent some clear limiting principle, the courts could find themselves knee-deep in the sort of agency micromanagement that the Supreme Court in *Chaney* wanted the judicial branch to avoid. Three responses assuage these concerns.

First, the unwillingness of circuit courts to find abdication may say less about how deferential courts are to agencies and more about how easy it is for agencies to satisfy the existing test. It is easy for the agency to maintain a barebone level of enforcement at the statutory level. Statutory charges are by nature broad, allowing the agency to easily meet a minimum level of enforcement. This could possibly account for the enormous difficulty of plaintiffs' ability to get review. Once the court can look to the discrete level, however, an agency can no longer rely on the fact that it is still minimally enforcing the statute generally. It cannot simply increase enforcement levels in any subset it wishes in order to raise its overall enforcement level. The court's analysis becomes more piercing because it looks solely to what an agency has done or not done with respect to the discrete subset in question. As a result, the point of reference has narrowed. Under discrete look, abdication analysis is likely to have stronger teeth because agencies will predictably have gaps within their statutory charge that they are not filling at all.

Second, discrete look only asks a court to probe deeper into an existing framework. Courts will still ask if there is some level of enforcement or a general nonenforcement policy. However, the inquiry is not limited at the statutory level but extends toward the more granular perspective of the discrete subset. The status quo under *Chaney's* Lines already asks courts to see if there is some level of enforcement or a general nonenforcement policy. The only further task that discrete look requires courts to perform is operationalizing what makes a subset discrete. This involves asking standard-based questions, which courts are familiar with doing in other contexts.

Further, analysis at the discrete level is not entirely new to the judiciary. While no Line 1 or Line 2 circuit court has performed abdication analysis on the discrete level, at least one district court has. In *PETA v. USDA*, the

District Court for the District of Columbia examined whether the USDA was abdicating its statutory charge under the Animal Welfare Act (“AWA”).<sup>134</sup> The plaintiffs sued the USDA for its decade-long refusal to regulate bird abuse.<sup>135</sup> Had the court followed Line 1, it could have simply concluded that the USDA did maintain some level of enforcement against animal abuse generally and ended the inquiry there. But the court chose to analyze agency nonenforcement as it related specifically to birds.<sup>136</sup> *PETA* is not a direct example of discrete look, however, because birds were specifically defined as one of the animals to be regulated under the AWA, whereas here compounded lethal drugs are not specifically defined as a type of new drug. But the court’s exercise of probing deeper—specifically to birds as opposed to animals in general—is still instructive.

Third, discrete look would not overly burden the courts or agencies with lawsuits. Plaintiffs must make certain threshold showings before requiring the agency to respond. And even then, the court may still refuse judicial review if the agency refutes this showing, persuades the court that the regulatory scheme is not unitary, or questions whether the subset truly belongs to the whole. These hurdles mean that frivolous cases will not clog the court’s docket because they can be disposed of quickly without reaching the stage of arbitrary and capricious review.

As a final thought, discrete look is a modest refinement of *Chaney* compared to alternative proposals that would get plaintiffs into court. This Comment rejects eliminating *Chaney*’s presumption of unreviewability altogether by suggesting, for example, that courts should review agency inaction in the same way as agency action.<sup>137</sup> That would flood the courts and paralyze the agencies in their day-to-day decision-making. This Comment also rejects allowing judicial review of all agency inaction with extra deference to the agency, as Justice Marshall suggested in his concurrence in *Chaney*.<sup>138</sup> That would still drown the courts with lawsuits, because courts could not dismiss cases at the threshold question of judicial reviewability.

The problem with these alternative proposals is that they burn the forest to get the tree. Discrete look is calculated: it looks at a consistent pattern of agency nonenforcement over time or a general nonenforcement policy, rather

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<sup>134</sup> 7 F. Supp. 3d 1, 5-6 (D.D.C. 2013).

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> See, e.g., Lisa Schultz Bressman, *Judicial Review of Agency Inaction: An Arbitrariness Approach*, 79 N.Y.U. L. REV. 1657, 1657 (2004) (suggesting that courts should “eschew any special prohibitions on judicial review of agency inaction, and instead subject agency inaction to the same principles of judicial review that apply to agency action”).

<sup>138</sup> See *Heckler v. Chaney*, 470 U.S. 821, 840 (1985) (Marshall, J., concurring) (“I write separately to argue for a different basis of decision: that refusals to enforce, like any other agency actions, are reviewable . . . but that such refusals warrant deference . . .”).

than every individual instance of nonenforcement. Discrete look is also targeted: it focuses on discrete subsets of a statutory charge, recognizing that agencies can abdicate their duties by consistently not enforcing a discrete subset. That makes litigation more focused and less prone to endless discovery. Thus, discrete look preserves the basic policy motivations behind *Chaney* while giving courts power to conduct some form of judicial review.

This Section described the contribution of discrete look to administrative law. Discrete look is a modest rule that benefits various actors in the administrative context, and it is the kind of probing that courts are competent to perform.

#### CONCLUSION

When death row inmates sue the FDA for its inaction toward compounded lethal drugs, the court should grant judicial review. The FDA has to make tough calls about its enforcement priorities, but consistently choosing not to enforce a discrete subset of new drugs should not be a choice that is immune from judicial review. Because Congress set up a framework that empowers the FDA to regulate compounded lethal drugs, the agency should not be able to refuse to enforce the law without expecting some judicial review.

There will always be hard cases about what counts as “some” level of enforcement, about temporality, and about what makes a subset discrete. But hard questions do not eliminate the need for general principles. Discrete look does not make the question any harder as it largely adapts the existing case law into a more sensible standard. Finally, it suffices to say that when the FDA has essentially no level of enforcement over a subset that could hardly stand out more, this is not a hard case.

While the death penalty is a controversial issue, botched executions and illicit supply chains are not controversial. They are harms that merit regulation, or at least judicial review for a lack of regulation. Whatever salience this topic has outside the courts, it comes in very standard administrative law terms. Here, as in the rest of administrative law, it is still the “province and duty” of the courts to remind the agency “what the law is.”<sup>139</sup>

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<sup>139</sup> *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).