

(Slip Opinion)

Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions

May 3, 2019

Articles intended for use in executions carried out by a State or the federal government cannot be regulated as “drugs” or “devices” under the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration therefore lacks jurisdiction to regulate articles intended for that use.

MEMORANDUM OPINION FOR THE ATTORNEY GENERAL

The Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, grants the Food and Drug Administration (“FDA”) the authority to regulate all “drugs” and “devices,” which include any “articles (other than food) intended to affect the structure or any function of the body,” as well as any components of such articles. *Id.* § 321(g)(1)(C)–(D), (h)(3). Your office has asked us whether FDA has authority to regulate articles used in historically accepted methods of execution. Some of those articles—like electric chairs and gas chambers—exist for the sole purpose of effectuating capital punishment. Others—like substances used in lethal-injection protocols and firearms used by firing squads—have other intended uses.

FDA has not historically exercised jurisdiction over articles intended to carry out a lawful sentence of capital punishment. In connection with challenges to FDA’s regulatory inaction, the federal courts have addressed when the agency may lawfully decline to enforce the FDCA against such articles. *See, e.g., Heckler v. Chaney*, 470 U.S. 821 (1985); *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013). Yet they have not squarely addressed whether FDA has administrative jurisdiction in the first place. Congress has repeatedly authorized the death penalty on the assumption that there are lawful means to carry it out, but the regulation of such articles under the FDCA would effectively require their prohibition because they could hardly be found “safe and effective” for such an intended use. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 137–39 (2000). Consistent with the agency’s practice in this area for several decades before 2017, we thus conclude that, when an article’s intended use is to

effectuate capital punishment by a State or the federal government, it is not subject to regulation under the FDCA.¹

I.

The FDCA was first enacted in 1938. Act of June 25, 1938, ch. 675, 52 Stat. 1040. Then, as well as now, the United States and several States authorized the imposition of capital punishment for the most serious offenses. From the time of the FDCA's enactment until very recently, FDA had never claimed authority over the methods by which the federal and state governments carry out executions. That is in no small part because one of the FDCA's fundamental purposes is to ensure that drugs and devices marketed in interstate commerce are safe and effective for their intended uses—a goal that markedly conflicts with the purpose of an execution. In this Part, we summarize the regulatory structure of the FDCA and the history of its intersection with capital punishment.

A.

The FDCA authorizes FDA to regulate drugs and devices. The FDCA defines “drug” to mean:

- (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1) (paragraph breaks added). Congress has made only superficial changes to this definition since 1938. *Compare* Act of June 25, 1938, § 201(g), 52 Stat. at 1041.

¹ In reaching this conclusion, we have solicited and considered the views of FDA and of the Office of the Associate Attorney General.

The FDCA defines “device” as any “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article” that does not “achieve its primary intended purposes through chemical action within or on the body”; is not “dependent upon being metabolized for the achievement” of those purposes; and is:

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals.

21 U.S.C. § 321(h) (paragraph breaks added). The definition of “device” also includes “any component, part, or accessory” of such articles. *Id.*²

As the statutory definitions indicate, whether FDA may regulate an article as a “drug” or “device” often depends not just on that article’s effect on a human or animal body, but also on whether that effect is intended. *Id.* § 321(g)(1), (h). An article may be a “drug” or “device” for some uses but not for others, depending on the manufacturer’s or distributor’s intent. For instance, FDA regulates “medical gases,” but not chemically identical industrial gases. As FDA has explained, “industrial gases . . . are not drugs” because manufacturers and distributors of industrial gases do not intend their products to treat disease or other conditions, or to otherwise affect the structure or function of the body. Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements, 71 Fed. Reg. 18,039, 18,044 (Apr. 10, 2006); *see* 21 C.F.R. §§ 201.161, 211.94(e). In a similar vein, FDA considers hot tubs, saunas, and treadmills as “devices” only when they are “intended for medical purposes.” Physical Medicine Devices; General Provisions and Classification of 82 Devices, 48 Fed. Reg. 53,032, 53,034, 53,044, 53,051–52

² Initially, the FDCA defined “device” as “instruments, apparatus, and contrivances, including their components, parts, and accessories” if they were “intended” either “for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals” or “to affect the structure or any function of the body of man or other animals.” Act of June 25, 1938, § 201(h), 52 Stat. at 1041. In 1976, Congress expanded the definition of “device” to its current scope. Medical Device Amendments of 1976, Pub. L. No. 94-295, sec. 3(a)(1)(A), § 201(h), 90 Stat. 539, 575.

(Nov. 23, 1983); *see* 21 C.F.R. §§ 890.5100, 890.5250, 890.5380. Thus, powered treadmills intended “to redevelop muscles or restore motion to joints” are “devices,” but those sold solely for recreational purposes are not. 48 Fed. Reg. at 53,044, 53,052; 21 C.F.R. § 890.5380. Likewise, FDA considers tape recordings as “devices” when they are “intended for use in the mitigation, treatment, and cure of disease and other medical conditions” (as in hypnotherapy), but not when they are intended “for behavior modification, self-improvement, habit correction, learning techniques, and simple relaxation.” FDA, Compliance Policy Guide § 335.300.

Many of the FDCA’s prohibitions are keyed to a product’s intended use. The FDCA prohibits distribution of a “new drug” that FDA has not approved as safe and effective for its intended use. *See* 21 U.S.C. § 355(a), (d)(1), (d)(5); *United States v. Caronia*, 703 F.3d 149, 152–53 (2d Cir. 2012). Similarly, the FDCA prohibits distribution of certain devices that present “a potential unreasonable risk of illness or injury,” unless FDA has approved them as safe and effective for their intended uses. 21 U.S.C. § 360c(a)(1)(C); *see id.* §§ 331(a), 351(f)(1), 360e(a), (d)(2)(A)–(B). The FDCA also bars distribution of “misbranded” drugs and devices, including those whose labeling lacks adequate directions for their intended uses, *id.* § 352(f)(1), or adequate warnings against unsafe dosages or methods of administration for those uses, *id.* § 352(f)(2). Finally, the FDCA provides that FDA “shall” block the importation of drugs and devices that appear to be unapproved for their intended use or misbranded. *Id.* § 381(a)(3).

Even if FDA has approved an article for one intended use, it still may not be imported, sold, or distributed for another, unapproved use. *See Wash. Legal Found. v. Henney*, 202 F.3d 331, 332–33 (D.C. Cir. 2000). FDA’s regulations define the “intended use” of a drug or device with reference to “the objective intent of the persons legally responsible for the labeling” of the article. 21 C.F.R. §§ 201.128 (drugs), 801.4 (devices). That intent “is determined by such persons’ expressions” or from “the circumstances surrounding the distribution of the article.” *Id.* §§ 201.128, 801.4. The regulations emphasize that “[t]he intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.” *Id.* §§ 201.128, 801.4. “[F]or example, a packer, distributor, or seller [may] intend[] an article for different uses than those intended by the person from whom he received the” drug or device, in which case “such packer, distributor, or seller is required to supply adequate

labeling in accordance with the new intended uses.” *Id.* §§ 201.128, 801.4. Likewise, a manufacturer could lawfully distribute an article intending that it be used for an approved purpose, and then later violate the FDCA by distributing the same article intending that it be used for a different, unapproved purpose.

As a general matter, FDA does not regulate the practice of medicine, which includes “off-label” prescribing—that is, when physicians prescribe FDA-approved drugs or devices for non-FDA-approved uses.³ As the Supreme Court has explained in the context of medical devices, “‘off-label’ usage . . . (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001); *see also Caronia*, 703 F.3d at 153. Thus, while the FDCA bars a manufacturer or distributor from selling any drug or device for an unapproved use, physicians may, with limited exceptions, prescribe and administer FDA-approved drugs and devices for unapproved uses.

B.

Capital punishment in the United States predates the Republic. For most of the Nation’s history, the federal government and the States employed the gallows. Starting in the late nineteenth century, States began using the electric chair and, to a lesser degree, the gas chamber. At least since Thomas Edison’s New Jersey laboratory supplied parts for New York’s first electric chair in 1890, prison authorities have used interstate suppliers to procure articles necessary for executions.⁴ Today, every

³ *See* Citizen Petition Regarding the Food and Drug Administration’s Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820, 59,821 (Nov. 18, 1994) (“[O]nce a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens o[f] patient populations that are not included in approved labeling.”) (quoting 12 FDA Drug Bulletin 5 (Apr. 1982)); *see also* 21 U.S.C. § 396.

⁴ *See* Stuart Banner, *The Death Penalty: An American History* 183, 197 (2002) (describing New York’s purchase of electric-chair components, and Nevada’s purchase of hydrocyanic acid for use in the gas chamber from a California source); Scott Christianson, *The Last Gasp: The Rise and Fall of the American Gas Chamber* 6 (2010) (explaining that Eaton Metal Products in Colorado built gas chambers for most of the States that used them); Carol J. Williams, *Maker of Anesthetic Used in Executions is Discontinuing Drug*,

method of execution appears to involve some component that traveled in interstate or foreign commerce.

Beginning in the late 1970s, many States and the federal government adopted lethal injection as the preferred method of execution. Those executions generally used sodium thiopental, a widely administered surgical anaesthetic. Although patients typically received a dose of around 300 milligrams of sodium thiopental during surgical procedures, the dose in a lethal injection was anywhere from “seven to sixteen times higher.” Mark Dershwitz & Thomas K. Henthorn, *The Pharmacokinetics and Pharmacodynamics of Thiopental as Used in Lethal Injection*, 35 *Fordham Urb. L.J.* 931, 932 (2008); *see also Glossip v. Gross*, 135 S. Ct. 2726, 2742 (2015) (noting that the dose of midazolam in Oklahoma’s more recent execution protocol “is many times higher than a normal therapeutic dose”).

In 1980, death-row inmates petitioned FDA to seize lethal-injection substances from several States, arguing that, although the substances were approved for other uses, their use in executions would violate the FDCA’s prohibitions against the distribution of unapproved new drugs and misbranded drugs. FDA denied the petition, reasoning that it lacked authority to regulate States’ use of FDA-approved drugs in capital punishment. FDA also stated that, even if it had such authority, it would decline to regulate in its enforcement discretion. When the issue reached the Supreme Court, the United States argued more broadly that FDA lacked jurisdiction over articles intended for use in capital punishment. *See Heckler*, 470 U.S. 821; Br. for Pet’r at 13–14, 44–46, *Heckler v. Chaney*, 470 U.S. 821 (1985) (No. 83-1878) (“*Heckler* Pet’r Br.”). The Court found it “implausible . . . that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are ‘safe and effective’ for human execution.” 470 U.S. at 827. Rather than “address the thorny question of the FDA’s jurisdiction,” however, the Court held that FDA’s exercise of enforcement discretion is not subject to judicial review. *Id.* at 828.

L.A. Times (Jan. 22, 2011), <http://articles.latimes.com/2011/jan/22/local/la-me-execution-drug-20110122> (discussing California’s use of sodium thiopental produced in North Carolina); Deborah W. Denno, *Getting to Death: Are Executions Constitutional?*, 82 *Iowa L. Rev.* 319, 354 & n.207 (1997) (explaining that the sole commercial suppliers of electric-chair equipment were in Massachusetts and Arkansas).

In 2009, the sole American manufacturer of sodium thiopental ceased production. *See Glossip*, 135 S. Ct. at 2733. Since then, several States have imported sodium thiopental from foreign suppliers. *Cook*, 733 F.3d at 4. In 2012, however, the U.S. District Court for the District of Columbia held that, although FDA has unreviewable discretion when enforcing the FDCA's domestic prohibitions, FDA's discretion is more limited with respect to the Act's importation provisions. The court issued a permanent injunction requiring FDA to block the importation of sodium thiopental on the grounds that it was unapproved and misbranded. *See Beaty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff'd*, *Cook*, 733 F.3d 1. Neither the parties nor the district court, however, addressed the government's previous argument in *Heckler* that FDA lacks jurisdiction over articles intended for use in capital punishment. *See Beaty*, 853 F. Supp. 2d at 34. Following the *Beaty* injunction, FDA expressly stated in a letter ruling, apparently for the first time, that it had jurisdiction over a substance intended for that use, though, significantly, the State seeking the ruling had conceded the point. *See* Letter from Todd W. Cato, Director, Southwest Import District Office at 5 (Apr. 20, 2017).

As of December 31, 2016, there were over 2,750 inmates with state death sentences. Elizabeth Davis & Tracy L. Snell, Bureau of Justice Statistics, U.S. Dep't of Justice, *Capital Punishment, 2016*, at 3 tbl.1 (2018). And there are now approximately 62 civilian prisoners with federal death sentences. *See* Federal Bureau of Prisons, *Statistics: Sentences Imposed*, https://www.bop.gov/about/statistics/statistics_inmate_sentences.jsp (last updated Apr. 13, 2019). In response to difficulties in obtaining appropriate substances for lethal injection, some States are considering turning to different methods of execution, including the electric chair and nitrogen gas. Tom Barton, *SC Senators Resurrect Bill to Bring Back the Electric Chair, Add Firing Squad*, The State (Jan. 30, 2019), <https://www.thestate.com/news/politics-government/article225312765.html>; Denise Grady & Jan Hoffman, *States Turn to an Unproven Method of Execution: Nitrogen Gas*, N.Y. Times (May 7, 2018), <https://www.nytimes.com/2018/05/07/health/death-penalty-nitrogen-executions.html>.

II.

With this background in mind, we turn to whether FDA may regulate articles intended for use in capital punishment. The Supreme Court recognized some time ago that "Congress fully intended that the [FDCA]'s

coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow.” *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). Nevertheless, in *Brown & Williamson*, the Court recognized one limitation to such coverage in the context of reviewing FDA’s authority to regulate tobacco products.

In *Brown & Williamson*, the Court considered whether FDA had properly determined that tobacco products as customarily marketed could be regulated as “drugs” or “devices” under the FDCA. FDA had conducted a rulemaking in which it concluded that the definitional phrase, “intended to affect the structure or any function of the body,” is “broad in scope and encompass[es] a range of products wider than those ordinarily thought of as drugs or medical devices.” Analysis Regarding the Food and Drug Administration’s Jurisdiction over Nicotine-Containing Cigarettes and Smokeless Tobacco Products, 60 Fed. Reg. 41,453, 41,463 (Aug. 11, 1995); Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619, 44,658 (Aug. 28, 1996). FDA deemed nicotine to be regulable as a “drug” because it was “intended” to have “psychoactive, or mood-altering, effects on the brain” that foster addiction, stimulate and depress the nervous system, and suppress appetite, thus mirroring the effects of tranquilizers, stimulants, weight-loss drugs, and other articles long subject to FDA jurisdiction. 61 Fed. Reg. at 44,631–32.

The Supreme Court rejected FDA’s conclusion, holding that the FDCA’s jurisdictional provisions must be read in the context of the entire statute, and of later-enacted laws, to ensure “a symmetrical and coherent regulatory scheme.” *Brown & Williamson*, 529 U.S. at 133. “Viewing the FDCA as a whole,” the Court concluded that it would “contravene[] the clear intent of Congress” to treat tobacco products as subject to FDA regulation. *Id.* at 132, 133. Were tobacco products regulated as “drugs” or “devices,” the FDCA would prohibit their sale, because they could not be “safe” or “effective” for their intended use. *Id.* at 134–37. Yet such “a ban would contradict Congress’s clear intent as expressed in its more recent, tobacco-specific legislation,” which reflected the “collective premise . . . that cigarettes and smokeless tobacco will continue to be sold in the United States.” *Id.* at 137, 139, 143–56. Furthermore, Congress had enacted this tobacco-specific legislation “against the background of the FDA repeatedly and consistently asserting that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed.” *Id.* at 155–

56. The Court concluded: “The inescapable conclusion is that there is no room for tobacco products within the FDCA’s regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit.” *Id.* at 143.⁵

Congress subsequently ratified the Court’s conclusion in the Tobacco Control Act, 21 U.S.C. § 387 *et seq.*, which confirmed that tobacco products as customarily marketed are not regulable as “drugs” or “devices” under the FDCA. *See id.* § 321(rr)(1)–(2). At the same time, Congress granted FDA the authority to impose other regulations on tobacco products. *See id.* § 387a(a) (“Tobacco products . . . shall be regulated . . . under this subchapter and shall not be subject to the [drug-and-device] provisions of subchapter V.”); *Sottera, Inc. v. FDA*, 627 F.3d 891, 898 (D.C. Cir. 2010).

Under *Brown & Williamson*, FDA lacks jurisdiction to regulate articles intended for a use not traditionally regulated by FDA, when those articles cannot be safe and effective for such intended use, and Congress has otherwise made clear its expectation that at least some of those articles shall remain lawful and available for that use. *See Sottera*, 627 F.3d at 896 (interpreting *Brown & Williamson*); *see also Massachusetts v. EPA*, 549 U.S. 497, 530–31 (2007) (explaining that *Brown & Williamson* rested on “the unlikel[ihood] that Congress meant to ban tobacco products” and “an unbroken series of congressional enactments that made sense only if adopted against the backdrop of the FDA’s consistent and repeated statements” disclaiming jurisdiction (internal quotation marks omitted)); *Verizon v. FCC*, 740 F.3d 623, 638 (D.C. Cir. 2014) (similar).

III.

Applying *Brown & Williamson*, we conclude that the FDCA does not allow FDA to regulate an article intended for use in capital punishment in the United States. The FDCA’s regulatory framework for “drugs” and

⁵ The *Brown & Williamson* Court declined to give the agency deference under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984), because “Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion.” 529 U.S. at 160; *see also King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) (similarly concluding that “[w]hether [tax] credits are available on Federal [Health Insurance] Exchanges is . . . a question of deep ‘economic and political significance’” that Congress did not implicitly delegate to the agency) (quoting *Brown & Williamson*, 529 U.S. at 160)).

“devices” cannot sensibly be applied to such articles. If the FDCA applied to electric chairs, gallows, gas chambers, firearms used in firing squads, and substances used in lethal-injection protocols, the statute would effectively ban those articles. Yet the Constitution and laws of the United States presuppose the continued availability of capital punishment for the most heinous federal and state crimes. FDA did not expressly assert the authority to regulate articles intended for use in executions at any time before 2017, and we believe that such an assertion cannot be reconciled with the FDCA and other federal law.

A.

Articles used in capital punishment do literally “affect the structure or any function of the body” by causing all bodily functions to cease. 21 U.S.C. § 321(g)(1)(C), (h)(3). Hanging, gas asphyxiation, a firing squad, lethal injection, and electrocution are all intended to achieve the same effect: they cause death. When a prison official seeks to purchase an article essential to one of these methods of execution, the seller will often know that the item will be used in an execution and is thus “intended” to affect the structure or any function of the body. *Id.*; see 21 C.F.R. § 201.128 (a drug’s “intended use” can “be shown by the circumstances surrounding the distribution of the article”); *id.* § 801.4 (same for devices); *cf. United States v. Kaminski*, 501 F.3d 655, 671 (6th Cir. 2007) (concluding that egg powders were “drugs” because defendants “distributed them to consumers for the express purpose of treating and/or preventing diseases” as evidenced by, among other things, “the methods of sale and distribution”).

Nevertheless, *Brown & Williamson* prevents us from interpreting the FDCA in a manner that would depart from its “symmetrical and coherent regulatory scheme,” 529 U.S. at 133, and interpreting the FDCA to authorize regulation of articles intended for use in executions would do exactly that. See also *Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 139 S. Ct. 361, 368 (2018) (“[S]tatutory language cannot be construed in a vacuum . . . so we must also consider [the term] in its statutory context.” (internal quotation marks and citation omitted)). If such articles were regulated as “drugs” or “devices,” the FDCA would effectively ban them and FDA could seek fines or prosecutions against those involved in their sale or distribution. The FDCA “generally requires the FDA to prevent the marketing of any drug or device where the potential for inflicting death or

physical injury is not offset by the possibility of therapeutic benefit.” *Brown & Williamson*, 529 U.S. at 134 (internal quotation marks omitted). In the case of tobacco products, their short-term physiological effects were greatly outweighed by their demonstrated carcinogenic qualities. *Id.* at 134–35. Thus, if tobacco products had been regulated as “drugs” or “devices,” the FDCA would have effectively rendered them unlawful. *Id.* at 135–37.

The same conclusion follows here, because the articles used in capital punishment are intended to cause death—for some articles that is their sole purpose. Under the FDCA, a “new drug” may not go to market unless FDA determines, based on “adequate and well-controlled investigations,” that the substance is “safe” and “effective[]” for the “use . . . prescribed, recommended, or suggested in the proposed labeling thereof.” 21 U.S.C. § 355(d)(1), (5); *see also* 21 C.F.R. § 314.50(d)(5). To approve a substance for use in a lethal-injection protocol, then, FDA would have to find that clinical-trial data established that the substance was “safe” for executions—that is, that the harm inflicted by the product would be “offset by the possibility of therapeutic benefit” to the inmate. *Brown & Williamson*, 529 U.S. at 134. It would not be sufficient to show that the substance is safer or more effective than other means of execution. *Brown & Williamson* dismissed such an interpretation of “safety” as involving a “qualitatively different inquiry” from that required by the FDCA. *Id.* at 140. Instead, FDA must find “that the *product itself* is safe as used by consumers.” *Id.* But there is no way products intended to carry out capital punishment could ever satisfy that test, under which “a drug is unsafe if its potential for inflicting death . . . is not offset by the possibility of therapeutic benefit.” *United States v. Rutherford*, 442 U.S. 544, 556 (1979).

The same would be true if electric chairs, gallows, or firing squads’ firearms were regulated as “devices.” Those articles would require pre-market approval because they “present[] a potential unreasonable risk of illness or injury.” 21 U.S.C. § 360c(a)(1)(C)(ii)(II). And FDA could approve them only if the applicant provided “reasonable assurance” that they were “safe” and “effective” for the intended use of carrying out capital punishment, *id.* § 360e(d)(1)(A), (2)(A)–(B), after “weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use,” *id.* § 360c(a)(2)(C). Again, FDA

could not possibly approve “devices” that are intended to effectuate executions as “safe” and “effective.”⁶

Nor would it matter whether an article intended for use in capital punishment was designed solely for that purpose or had other, FDA-approved uses.⁷ Either way, whenever manufacturers or distributors intended that an article be used in capital punishment, the FDCA would prohibit distributing it for that use. For example, FDA has approved midazolam for use as a sedative and anesthetic in certain procedures. But if a manufacturer or distributor of midazolam sold it to prison officials specifically for use in capital punishment, the drug’s “intended use” would be different from any approved use. *See* 21 C.F.R. § 201.128. A drug’s labeling must bear adequate directions for use for all of its intended uses; otherwise it is misbranded. *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.128. Accordingly, the manufacturer or distributor would violate the FDCA’s new drug prohibition where the product’s labeling suggested its use in capital punishment. Drugs intended for use in lethal injection that were FDA-approved only for other uses would also be misbranded because their FDA-approved labeling would, by definition, lack adequate warnings against unsafe dosages or methods of administration for use in capital punishment. *See* 21 U.S.C. § 352(f)(2).⁸ In sum, if articles intended for

⁶ Applications to market drugs and devices both require the submission of well-controlled clinical investigations. 21 U.S.C. §§ 355(d), 360c(a)(2), (3)(A)–(B); 21 C.F.R. § 860.7(c). Given that the articles at issue here are intended to cause death during lawful executions, it is difficult to envision how the articles could be studied in clinical investigations involving humans.

⁷ The FDCA’s practice-of-medicine exception does not extend to articles used in executions. That exception applies only when an article is “prescribe[d] or administer[ed]” to treat a “condition or disease within a legitimate health care practitioner-patient relationship.” 21 U.S.C. § 396 (devices); *see* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 *Food & Drug L.J.* 71, 77–78 (1998) (discussing history behind section 396, which shows it was enacted to extend to devices the practice-of-medicine exception that already applied to drugs).

⁸ The law-enforcement exception in 21 C.F.R. § 201.125 exempts a drug from the requirement in section 502(f)(1) of the FDCA that labeling include “adequate directions for use.” 21 U.S.C. § 352(f)(1). That exception, however, does not extend to section 502(f)(2), which requires “adequate warnings . . . against unsafe dosage or methods or duration of administration.” *Id.* § 352(f)(2). Thus, even if executions qualified as an excepted law-enforcement use, substances used in executions would be misbranded under subsection (f)(2).

use in capital punishment were regulated as “drugs” or “devices,” then the FDCA would prohibit them altogether.

In the past, FDA has avoided such regulatory consequences by declining to regulate the domestic sale and distribution of articles intended for use in executions as a matter of enforcement discretion. But the D.C. Circuit recently upheld a district court order enjoining FDA from permitting the importation of foreign-manufactured sodium thiopental, on the grounds that it was misbranded and unapproved. *Cook*, 733 F.3d 1. And the question now is whether FDA’s regulatory authority encompasses articles intended for use in lethal injection or other methods of capital punishment, not whether FDA may use its enforcement discretion to alleviate the regulatory consequences. FDA equally had discretion not to enforce the FDCA against domestic tobacco sales that, in FDA’s view, would have violated the FDCA’s prohibitions on misbranding or unapproved new drugs or devices. What mattered in *Brown & Williamson* was that the FDCA would have rendered the sale of tobacco products per se unlawful, not that FDA could have tempered that ban by selectively sparing particular manufacturers from civil and criminal penalties. *See, e.g.*, 529 U.S. at 136 (“[T]he Act admits no remedial discretion once it is evident that the device is misbranded.”). The prospect that articles intended for use in capital punishment could be sold or distributed at FDA’s sufferance does not alter the fact that the FDCA, by its terms, would effectively require a ban of such articles if they were regulated under the FDCA as “drugs” or “devices.”

B.

Even if the FDCA could be interpreted to authorize regulation of articles intended for use in executions without requiring them to be banned, any attempt to do so would create serious tension with other provisions of the Act. We do not conclude that, in order for FDA to have jurisdiction over an article as a “drug” or “device,” every drug- or device-related provision of the FDCA must apply neatly to the article’s intended use. But the sheer number of FDCA provisions here that would make no sense as applied reinforces the conclusion that FDA lacks jurisdiction over articles intended for use in capital punishment. For example, with respect to articles intended for use in capital punishment, FDA could not assess “[t]he seriousness of the disease or condition that is to be treated with the drug” or “[t]he expected benefit of the drug with respect to such disease

or condition.” 21 U.S.C. § 355-1(a)(1)(B)–(C). Execution drugs address no “condition” suffered by, and produce no “benefit” for, the end user; instead, they exclusively inflict harm upon that user. For the same reason, when reviewing a new drug application for an article intended for use in capital punishment, FDA could not provide for review of scientific disputes by a “panel[] of experts” that includes members with “expertise in *the particular disease or condition* for which the drug . . . is proposed to be indicated.” *Id.* § 355(n)(1), (3)(D) (emphasis added); *see also id.* § 360bbb-1; 8 C.F.R. § 10.75(b)(2). In the context of an execution, there is no applicable “disease or condition.”

Further, with respect to articles intended for use in capital punishment, “patient experience data”—which includes “information about patients’ experiences with a disease or condition,” such as “patient preferences with respect to treatment of such disease or condition”—would never be available. 21 U.S.C. § 360bbb-8c(b)(1), (c)(2). Other FDCA provisions treat death as a serious side effect that triggers mandatory reporting and FDA oversight. *See, e.g., id.* § 355(k)(3)(C)(i)(II) (requiring drug manufacturers to “report[] . . . on all serious adverse drug experiences,” including death); 21 C.F.R. § 314.80 (detailing exhaustive reporting requirements for each “adverse drug experience,” including those resulting in death). These provisions cannot sensibly be read to allow an article’s intended use to be the causing of death in an execution.

Other provisions presuppose that an approved device may not be intended to effectuate an execution. A manufacturer’s application for FDA approval “shall include” a “description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure,” 21 U.S.C. § 360e-1(a)(2)(A), which suggests that a device must be intended to *improve* a patient’s circumstances. FDA must also submit any new device to a panel of experts with “adequate expertise . . . to assess . . . the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose.” *Id.* § 360c(b)(1), (5)(B)(i)(I). But again, it would make no sense to apply those provisions to articles for use in executions, which are not intended to produce any benefit for the end user.

Congress has treated certain articles intended to cause death as falling outside FDA’s jurisdiction. For instance, the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) expressly gives the Environmental Protection Agency rather than FDA jurisdiction over “pesticides,” which include “any substance . . . intended for preventing, destroying, repelling,

or mitigating any pest” but exclude “any article that is a ‘new animal drug’ within the meaning” of the FDCA. 7 U.S.C. § 136(u). FIFRA thus suggests that Congress generally views substances intended to harm or kill pests (such as mosquitos and rats, *see id.* § 136(t)) as outside FDA’s jurisdiction.

Over the years, FDA has disclaimed jurisdiction over several other articles intended to kill or harm humans or animals. In 1969, for instance, FDA’s Chief Counsel testified that even though “pistols and bullets are intended to affect the function or structure of the body in the same way” as mace, the agency “concluded that the products could not properly be classified as drugs under the definition” in the FDCA. *Public Sale of Protective Chemical Sprays: Hearings Before the Consumer Subcomm. of the S. Comm. on Commerce*, 91st Cong. 37 (1969) (statement of William Goodrich). FDA reiterated that position when asserting jurisdiction over tobacco products in 1996, explaining that it “has never construed the structure-function provision to include products such as guns, airbags, and chemical sprays,” despite their intended effects on the structure or function of the body. 61 Fed. Reg. at 44,684. That same rationale extends to articles intended for use in executions.⁹

⁹ Since 1977, FDA has asserted jurisdiction over articles intended for animal euthanasia. FDA first asserted jurisdiction over Beuthanasia-D. *See United States v. Articles of Drug Beuthanasia-D Regular*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,265 (D. Neb. Aug. 1, 1979). A district court agreed that FDA had jurisdiction, both because Beuthanasia-D’s two active ingredients were listed in the United States Pharmacopoeia (a different component of the FDCA’s definition of “drug”), *id.* ¶ 39,129 (citing 21 U.S.C. § 321(g)(1)(A) (1972)), and because “euthanasia—the cessation of all bodily functions— . . . constitute[s] an effect on the function, if not the structure, of the animal’s body,” *id.* ¶ 39,130 (citing 21 U.S.C. § 321(g)(1)(C) (1972)). In 1980, FDA issued a two-paragraph guidance statement, opining that “products intended for animal euthanasia . . . conform to the definition of a drug” under the FDCA “since they are clearly intended to affect the function of the body by inducing death.” FDA, Compliance Policy Guide § 650.100 (Oct. 1, 1980). FDA’s guidance in this area predates *Brown & Williamson*, and no court has revisited the matter. Although it may be difficult to view animal-euthanasia articles as “safe” for their intended use (at least where such articles are used on healthy but unwanted animals), FDA has regulated such articles since 1977; it has approved five applications for these articles; its regulation does not raise constitutional concerns; and we are aware of no legislation that suggests FDA’s assertion of jurisdiction over articles intended for animal euthanasia is contrary to the intent of Congress. Additionally, animal euthanasia has long been an accepted part of veterinary practice, whereas capital punishment has not been a part of medical practice. Therefore, whether or not animal euthanasia may be distinguishable from executions, we do not view FDA’s practice of regulating the former

C.

The FDCA cannot be read as authorizing FDA to effectively ban capital punishment, because that reading would contravene or render moot a host of federal statutes that presuppose the lawfulness of capital punishment. In *Brown & Williamson*, the Court held that FDA was not authorized to prohibit tobacco products because Congress had repeatedly confirmed that such products would remain available. That reasoning applies equally well to articles intended for use in capital punishment. The Constitution and numerous federal statutes presuppose that capital punishment will remain available and that the federal government will defer to States over methods of execution. Interpreting the FDCA to bar the importation, sale, and distribution of articles intended for use in executions would conflict with that settled understanding. By contrast, the conclusion that articles intended for use in executions cannot be regulated under the FDCA would be consistent with how FDA has traditionally exercised its authority; and it would avoid the serious federalism concerns that would arise from a contrary interpretation.

1.

As the Supreme Court recently observed, the Constitution expressly “allows capital punishment.” *Bucklew v. Precythe*, 139 S. Ct. 1112, 1122 (2019). Indeed, “the Fifth Amendment, added to the Constitution at the same time as the Eighth, expressly contemplates that a defendant may be tried for a ‘capital’ crime and ‘deprived of life’ as a penalty, so long as proper procedures are followed.” *Id.* Federal law, accordingly, has authorized the imposition of the death penalty since 1790, when the First Congress mandated that several federal crimes, including treason and murder on federal land, be punished by death. Act of Apr. 30, 1790, ch. 9, §§ 1, 3, 33, 1 Stat. 112, 112, 113, 119. By 1938, federal statutes authorized the death penalty for dozens of offenses. And, in the decades since the FDCA’s enactment, Congress has acted numerous times to make additional federal crimes punishable by death.¹⁰ In providing that the

as sufficient to overcome the force of the arguments against FDA’s authority to regulate the latter.

¹⁰ See, e.g., Act of June 8, 1940, ch. 286, 54 Stat. 255, 255–56 (authorizing capital punishment if anyone is killed by the willful derailment of any train in interstate commerce); Uniform Code of Military Justice, Act of May 5, 1950, ch. 169, 64 Stat. 107,

death penalty is an available punishment for dozens of federal crimes, Congress has presupposed there would be a lawful means for carrying out such a sentence.

From 1790 until 1937, federal law prescribed hanging as the method of execution. Act of Apr. 30, 1790, § 33, 1 Stat. at 119; *Andres v. United States*, 333 U.S. 740, 745 n.6 (1948). Congress then mandated that each federal execution be carried out in “the manner prescribed by the laws of the State within which the sentence is imposed,” or, if that State did not have the death penalty, in accordance with the laws of another State designated by the sentencing court. Act of June 19, 1937, ch. 367, 50 Stat. 304, 304 (repealed 1984). At the time, nearly 30 States were using cyanide gas or the electric chair, but the States adopted at least six different methods of execution between then and the early 1980s. See Deborah A. Denno, *Getting to Death: Are Executions Constitutional?*, 82 Iowa L. Rev. 319, 439–64 (1997). After that provision was repealed in 1984, federal regulations required the government to propose to the sentencing court that any death sentence be carried out by lethal injection. 28 C.F.R. § 26.2(a)(2). Unless the court ordered otherwise, they required the Director of the Federal Bureau of Prisons to “determine[]” which “substance or substances” to use. *Id.* § 26.3(a)(4).

Today, capital sentences imposed under the Federal Death Penalty Act of 1994 are again required to be implemented “in the manner prescribed by” either (i) “the law of the State in which the sentence is imposed,” or (ii) if that State does not have the death penalty, the law of another State designated by the sentencing court. 18 U.S.C. § 3596(a). The Army’s executions are by “intravenous administration of a lethal substance, or substances, in a quantity sufficient to cause death.” Army Regulation 190-55, U.S. Army Corrections System: Procedures for Military Executions § 3-1, -2 (Jan. 17, 2006).

135–40 (articles 85, 90, 94, 99, 100, 101, 102, 104, 106, 110, 113, 118, and 120, establishing 13 military offenses punishable by death); Organized Crime Control Act of 1970, Pub. L. No. 91-452, sec. 1102, § 844(d), 84 Stat. 922, 957 (authorizing capital punishment if death results from the use of explosives to maliciously destroy government property); Anti-Drug Abuse Act of 1988, Pub. L. No. 100-690, § 7001(a), 102 Stat. 4181, 4387–88 (codified at 21 U.S.C. § 848(e)) (authorizing capital punishment for intentional killing while engaging in criminal enterprises or drug felonies); Federal Death Penalty Act of 1994, Pub. L. No. 103-322, §§ 60001–60026, 108 Stat. 1796, 1959–82 (codifying procedures for federal death sentences and authorizing capital punishment for 60 offenses under 13 existing and 28 new federal statutes).

This extensive backdrop of legislative and regulatory action precludes any suggestion that the FDCA prohibits the importation, sale, or distribution of articles intended for use in executions; to the contrary, these statutory and regulatory schemes unambiguously assume the continued availability of such articles. Before and after the FDCA's enactment, Congress extended the federal death penalty and required the federal government to adopt States' preferences as to methods of execution. Such provisions would be nonsensical if the FDCA had rendered it a crime to distribute in interstate commerce, including through importation (*see* 21 U.S.C. § 321(b)), the very articles that States and the federal government need to effectuate capital sentences. By expressly recognizing States' discretion to select methods of execution (subject to constitutional limits), Congress precluded any role for FDA in supplanting States' judgments about those methods.

2.

In addition, as in *Brown & Williamson*, “[t]he consistency of the FDA’s prior position” concerning the absence of regulatory jurisdiction over methods of execution, coupled with a corresponding history of non-enforcement, “provides important context” for interpreting federal death-penalty legislation postdating the FDCA. 529 U.S. at 157. Just as FDA “asserted authority to regulate tobacco products as customarily marketed” only late in its history, *id.* at 146, FDA does not appear to have asserted jurisdiction to regulate articles intended for use in executions before 2017.

Between 1981 and 1985, FDA directly addressed its jurisdiction in the proceedings associated with *Heckler*, 470 U.S. 821. The challenge in *Heckler* involved state lethal-injection protocols, which required the unapproved use of drugs that were FDA-approved for other purposes. Although the *Heckler* Court found it “implausible . . . that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are ‘safe and effective’ for human execution,” *id.* at 827, the Court ultimately declined to resolve the “thorny question of the FDA’s jurisdiction” in that circumstance, *id.* at 828. Instead, the Court held that FDA’s decision not to enforce the FDCA was unreviewable. *Id.* at 837–38. Even so, we find instructive FDA’s own statements about its jurisdiction in the Supreme Court and in the underlying administrative proceeding.

In 1981, FDA rejected a petition from death-row inmates asking FDA to adopt a procedure for the seizure and condemnation of drugs destined or held for use in executions. *See* Letter for David E. Kendall, from Arthur Hull Hayes, Commissioner of Food and Drugs at 1 (July 7, 1981) (“*Heckler* Petition Response”). The inmates contended that the States’ acquisition of FDA-approved drugs for capital punishment constituted misbranding because the drugs lacked adequate directions or warnings for that use. *Id.* at 1–2. FDA denied the petition in the first instance because “the use of lethal injection by State penal systems is a practice over which FDA has no jurisdiction.” *Id.* at 2. FDA concluded that the States’ off-label use of FDA-approved drugs in lethal-injection protocols was sufficiently analogous to the practice of medicine, including physicians’ lawful off-label use of FDA-approved drugs, to fall outside the FDCA’s ambit. *Id.* at 3–4. But FDA also emphasized that its lack of jurisdiction flowed from “a consideration of the proper role of the Federal Government with respect to the conduct of State criminal justice systems.” *Id.* at 2. FDA further recognized that, “[b]ecause . . . the [FDCA] does not provide us with authority to declare unlawful the use by State governments of drugs for lethal injection,” concerns about the safety of lethal-injection protocols would “more appropriately [be] addressed to the State legislatures.” *Id.* at 4.¹¹

¹¹ FDA did contend that, “[u]nder the Supremacy Clause,” “a State could not legitimize the unlawful shipment of an unapproved new drug in interstate commerce or prevent its misbranding after shipment in interstate commerce by authorizing its use,” including for purposes of execution. *Heckler* Petition Response at 3. But that reflected a general observation that state law cannot trump the FDCA’s provisions to the extent they apply to a given drug or device, or effectively immunize prior conduct that violated the FDCA by approving a product’s use at a later time. The government’s opening brief in the Supreme Court also represented in a footnote that “[t]his case concerns the FDA’s authority to regulate the states’ use of drugs, lawfully in interstate commerce, for the unapproved purpose of causing death, and not the *marketing* of drugs for an unapproved use.” *Heckler* Pet’r Br. at 45–46 n.34; *accord* Reply Br. at 8, *Heckler v. Chaney*, 470 U.S. 821 (1985) (No. 83-1878) (“*Heckler* Reply Br.”) (“FDA lacks jurisdiction over the use of approved drugs by state authorities for capital punishment purposes.”). The brief asserted that an FDCA violation would occur “if a drug were marketed for the purpose of causing death without being approved for that use,” but it noted that no one was alleged to have “directly or indirectly promote[d] the use of the drugs at issue” for executions. *Heckler* Pet’r Br. at 45–46 n.34. Those statements did not reserve FDA jurisdiction over unapproved articles used in executions because the government’s briefs categorically disclaimed FDA jurisdiction over any method of execution. *See infra* notes 12–13 and accompanying text.

In the resulting litigation, the D.C. Circuit divided over whether FDA had jurisdiction over drugs intended for use in executions. *See Chaney v. Heckler*, 718 F.2d 1174 (D.C. Cir. 1983), *rev'd*, 470 U.S. 821 (1985). The majority rejected FDA's conclusions that administering capital punishment fell within the FDCA's "practice of medicine" exception or, in the alternative, that actions taken by prison officials did not qualify as misbranding under the Act. *See id.* at 1179, 1181. Then-Judge Scalia, in dissent, recognized the incongruity in treating "a law designed to protect consumers against drugs that are unsafe or ineffective for their represented use" as "mandating federal supervision of the manner of state executions." *Id.* at 1192 (Scalia, J., dissenting). He would have held that FDA lacked jurisdiction because the drugs were not "held for sale" in interstate commerce. *Id.* at 1199–1200. Because FDA did not press the point, neither opinion addressed whether "the unapproved use of drugs for lethal injection is outside the general jurisdictional provisions of the Act"—that is, whether drugs intended for use in lethal injection are subject to regulation under the FDCA. *Id.* at 1179.

In the Supreme Court, the government contended that FDA categorically lacked jurisdiction over articles used in capital punishment, and that FDA had denied the inmates' petition because it had concluded "that it lacked authority under the FDCA to regulate the states' use of lethal injections for capital punishment." *Heckler Pet'r Br.* at 13; *see id.* at 4 (similar). The government repeatedly asserted that "Congress did not intend the FDA to regulate capital punishment," *id.* at 45, and emphasized that the assessment of lethal injections would be "far removed from [FDA's] mission of protecting the consuming public from unsafe and improperly labeled drugs," *id.* at 10; *see id.* at 45 (similar).¹² The government concluded that FDA jurisdiction over the unapproved use of FDA-

¹² *See also Heckler Reply Br.* at 8 ("[T]here is not a scintilla of evidence that Congress intended for the FDCA to regulate capital punishment."); *id.* at 11 ("The FDA has no experience or particular expertise in making a comparative assessment of different methods of capital punishment, nor does it have a congressional mandate to venture into this field."); *Heckler Pet'r Br.* at 13 ("[T]here is not a hint in the legislative history that Congress had any intention to regulate the methods used by states in carrying out lawful death sentences."); *id.* at 44 ("Neither the court of appeals nor respondents have produced a shred of evidence that Congress wanted the FDA to regulate the methods of capital punishment used by the states."); *id.* at 46 ("[T]here is absolutely no evidence that Congress intended to regulate the use of drugs or devices, pursuant to a lawful court order, for the purpose of capital punishment.").

approved drugs in executions “would lead to the absurd result of requiring the FDA to regulate such traditional means of capital punishment as the gas chamber, electric chair, and gallows.” *Heckler* Reply Br. at 8.¹³

Although *Heckler* did not resolve the question of the agency’s jurisdiction, *see* 470 U.S. at 837–38, for more than three decades thereafter, FDA continued to avoid regulating drugs intended for use in capital punishment. In 2011, FDA explained that “[r]eviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA’s explicit public health role,” and that as a matter of “longstanding policy,” FDA would “continue to defer to law enforcement on all matters involving lethal injection.” E-mail for Nathan Koppel, from Shelly Burgess, FDA Public Affairs Specialist (Jan. 4, 2011), Doc. 13-3, *Beaty v. FDA*, No. 11-cv-289 (D.D.C. Apr. 20, 2011).

In 2012, a group of death-row inmates sued FDA, alleging that it had violated the FDCA by allowing shipments of a misbranded and unapproved new drug from an unregistered foreign establishment to enter the United States. The U.S. District Court for the District of Columbia held that, unlike in the domestic context where FDA has unreviewable discretion when enforcing violations, the statutory scheme for imports under 21 U.S.C. § 381(a) is different, and the court enjoined FDA from permitting entry of foreign-manufactured sodium thiopental, on the grounds that it was unapproved and misbranded. *Beaty*, 853 F. Supp. 2d at 37–41. The D.C. Circuit affirmed the injunction. *Beaty* and *Cook*, however, turned solely on whether FDA could exercise enforcement discretion over the imported sodium thiopental. Although the district court assumed that “thiopental is both ‘misbranded’ and an unapproved ‘new drug’ under the FDCA,” *id.* at 34 n.2, neither the district court, nor the D.C. Circuit, addressed the broader question of FDA’s jurisdiction.

Following the *Beaty* injunction, in 2015, FDA blocked Texas’s attempt to import sodium thiopental for use in capital punishment. FDA’s Southwest Import District Office detained and then refused the shipment on the

¹³ *See also Heckler* Pet’r Br. at 13–14 (if FDA had jurisdiction over FDA-approved lethal-injection drugs, then the FDCA would also “encompass many of the paraphernalia traditionally used for executions, such as the gallows and the electric chair,” and would presumably oblige FDA “to regulate the use of these devices as well”); *id.* at 44 (“the state and federal governments regularly used” the electric chair and gallows in 1938, and “there is no indication that any member of Congress even considered the possibility that enactment of the FDCA might affect these practices”).

grounds that the drug was misbranded and unapproved. See Letter from Todd W. Cato, Director, Southwest Import District Office at 1–2 (Apr. 20, 2017). FDA’s 2017 notice of final action appears to be the first instance in which FDA expressly asserted jurisdiction over a substance intended for use in capital punishment. Even then, Texas conceded that sodium thiopental “is a drug within the meaning of the [FDCA],” *id.* at 5, and FDA’s decision was based upon the premise that “FDA is bound by the terms of the order issued by the District Court” in *Beaty*, *id.* at 2; see also *id.* at 6–7, 23, 24.

An agency may, of course, change its interpretation of an ambiguous statute when the new interpretation falls within the permissible scope of the agency’s discretion and the agency shows “that there are good reasons for the new policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); see *Brown & Williamson*, 529 U.S. at 156–57. But for nearly 80 years after the FDCA’s enactment, FDA had never asserted jurisdiction over articles intended for use in capital punishment, notwithstanding thousands of cases that would have implicated FDA’s enforcement discretion under such a theory. During that period, States carried out approximately 3,700 executions, and the federal government carried out approximately 192 civilian or military executions, employing a range of methods (hanging, the electric chair, firing squads, gas chambers, and lethal injections).¹⁴ FDA did not regulate the method of execution in any of those instances or assert the authority to do so.

3.

Even if there were genuine ambiguity about whether FDA has jurisdiction over articles intended for use in capital punishment, serious constitutional concerns would arise if FDA could regulate and take enforcement action against (including seizing and destroying) such articles. See *Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018) (“When a serious doubt is raised about the constitutionality of an Act of Congress, it is a cardinal principle that this Court will first ascertain whether a construction of the

¹⁴ See *Glossip*, 135 S. Ct. at 2732; Bureau of Justice Statistics, U.S. Dep’t of Justice, *Publications & Products: Executions*, <https://www.bjs.gov/index.cfm?ty=pbtp&tid=182&iid=1> (last visited Apr. 29, 2019); M. Watt Espy & John Ortiz Smykla, *Executions in the United States, 1608-2002: The ESPY File*, Inter-university Consortium for Political and Social Research (July 20, 2016), <https://www.icpsr.umich.edu/icpsrweb/NACJD/studies/8451>.

statute is fairly possible by which the question may be avoided.” (internal quotation marks omitted)). As the Supreme Court recently explained, “because it is settled that capital punishment is constitutional, [i]t necessarily follows that there must be a [constitutional] means of carrying it out.” *Glossip*, 135 S. Ct. at 2732–33 (internal quotation marks omitted); see *Bucklew*, 139 S. Ct. at 1122–23 (similar). It would present a serious intrusion on state sovereignty if Congress sought, under the guise of drug-safety regulation, to bar States from effectuating otherwise-lawful death sentences.

The Supreme Court requires an unambiguous statement of congressional intent before it will construe a federal statute as effecting a significant intrusion into an area of traditional state responsibility. Courts must “be certain of Congress’ intent before finding that federal law overrides the usual constitutional balance of federal and state powers.” *Bond v. United States*, 572 U.S. 844, 858 (2014) (internal quotation marks omitted). When States choose to impose and effectuate death sentences, they are engaged in “the punishment of local criminal activity,” which is the “clearest example of traditional state authority.” *Id.*¹⁵

So long as a State employs a method of execution that comports with the Fourteenth Amendment’s incorporation of the Eighth Amendment’s Cruel and Unusual Punishments Clause, “the Constitution affords a ‘measure of deference to a State’s choice of execution procedures.’” *Bucklew*, 139 S. Ct. at 1125 (quoting *Baze*, 553 U.S. at 51 n.2). Thus, *In re Kemmler*, 136 U.S. 436 (1890), held that the New York statute requiring execution by electrocution was “within the legitimate sphere of the legislative power of the State.” *Id.* at 449. And the plurality opinion in *Baze v. Rees*, 553 U.S. 35 (2008), explained that “[o]ur society has . . .

¹⁵ See also *Danforth v. Minnesota*, 552 U.S. 264, 280 (2008) (referring to “[t]he fundamental interest in federalism that allows individual States to define crimes, punishments, rules of evidence, and rules of criminal and civil procedure in a variety of different ways—so long as they do not violate the Federal Constitution”); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (“A basic principle of federalism is that . . . each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction.”); *Ewing v. California*, 538 U.S. 11, 24 (2003) (plurality opinion) (“Though three strikes laws may be relatively new, our tradition of deferring to state legislatures in making and implementing such important policy decisions is longstanding.”); *Patterson v. New York*, 432 U.S. 197, 201 (1977) (“[W]e should not lightly construe the Constitution so as to intrude upon the administration of justice by the individual States.”).

steadily moved to more humane methods of carrying out capital punishment” because state legislatures have taken “the steps they deem appropriate, in light of new developments, to ensure humane capital punishment.” *Id.* at 62 (opinion of Roberts, C.J.); *accord Glossip*, 135 S. Ct. at 2731–32 (similar). The Court has never endorsed an Eighth Amendment standard that would “transform [federal] courts into boards of inquiry charged with determining ‘best practices’ for executions,” because that “would substantially intrude on the role of state legislatures in implementing their execution procedures.” *Baze*, 553 U.S. at 51 (opinion of Roberts, C.J.).

The FDCA does not reflect any clear statement of congressional intent to regulate the States’ administration of capital punishment. Had Congress sought to enable FDA to prohibit articles that States have chosen to use for executions, it would have said so explicitly. But Congress did no such thing. The FDCA’s definitions of “drug” and “device” are broad, but breadth alone fails to manifest the intent needed to alter federal-state relations so dramatically with respect to capital punishment. *See, e.g., Bond*, 572 U.S. at 860 (“insist[ing] on a clear indication that Congress meant to reach purely local crimes [in a statute implementing a chemical-weapons treaty] before interpreting the statute’s expansive language in a way that intrudes on [States’] police power”). This principle of federalism provides further support for the conclusion that the FDCA should not be read to regulate—and therefore, effectively prohibit—the States’ administration of capital punishment.

D.

We emphasize the narrowness of our conclusion that articles intended for use in capital punishment may not be regulated under the FDCA. We are not concluding that the FDCA covers only “drugs” or “devices” that have a medical or therapeutic purpose. For example, FDA has consistently regulated other products that affect the structure or function of the human body for an aesthetic, rather than medical or therapeutic, purpose (e.g., implants to augment breasts, dermal fillers to correct wrinkles, and silicone injections to augment buttocks and breasts). Likewise, FDA has long regulated drugs with non-therapeutic or recreational uses, including narcotics, street drugs, and their alternatives. *See, e.g., FDA, Guidance for Industry: Street Drug Alternatives* (Mar. 2000), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/>

ucm070343.pdf. Unlike with tobacco products or articles intended for use in capital punishment, however, federal statutes evince no “collective premise” that drugs intended to be used in achieving a recreational high “will continue to be sold in the United States.” *Brown & Williamson*, 529 U.S. at 139. To the contrary, the manufacture and distribution of recreational drugs is already highly restricted by other federal statutes, such as the Controlled Substances Act. *See* 21 U.S.C. § 812.

Nor do we address whether FDA has jurisdiction over drugs intended for use in physician-assisted suicide. In marked contrast with capital punishment and tobacco products, at the time of the FDCA’s enactment, there was not—so far as we are aware—any history of federal or state laws authorizing human euthanasia. As with recreational drugs, there is no congressional determination that human-euthanasia drugs remain lawfully on the market, nor has FDA historically disclaimed jurisdiction over them. *Cf. Brown & Williamson*, 529 U.S. at 137–53. Accordingly, human-euthanasia drugs lack the historical backdrop that weighs heavily against FDA jurisdiction over capital punishment.

We further note that a contrary conclusion regarding articles intended for use in capital punishment could sweep well beyond execution-related articles. If FDA had jurisdiction over such articles simply because they are “intended to affect the structure or any function of the body,” 21 U.S.C. § 321(g)(1)(C), (h)(3), such reasoning would likely mean that FDA also had jurisdiction in a host of other areas that have long been considered well beyond its purview. Any type of firearm, when used for hunting or by the military or law enforcement, is intended to affect the structure or function of the body by killing or disabling a person or animal. But FDA has never sought to regulate firearms when they are intended to be used for hunting, police operations, or military purposes, and such an implausible interpretation of the FDCA would raise serious constitutional questions of its own.

Finally, there is nothing unusual about our conclusion that articles intended for use in capital punishment fall outside FDA’s jurisdiction, even though the same articles could be subject to regulation when intended for other uses. For example, as noted above, FDA has classified articles such as hot tubs, saunas, and treadmills as devices for some purposes, but not for others. *See supra* pp. 3–4. Therefore, finding that substances fall outside FDA’s jurisdiction when they are intended for use in capital punishment does not bear upon FDA’s potential jurisdiction over other intended uses of the same substances.

IV.

We conclude that articles intended for use in capital punishment by a State or the federal government cannot be regulated as “drugs” or “devices” under the FDCA. FDA accordingly lacks jurisdiction to regulate such articles for that intended use.

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