

# Lethal Injection Opinion From DOJ Office of Legal Counsel Threatens FDA's Claims-Based Interpretation of "Intended Use"

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May 30, 2019

In an [opinion](#) dated May 3, 2019, the Office of Legal Counsel (OLC) in the U.S. Department of Justice (DOJ) concluded that an article intended to effectuate capital punishment by a state or the federal government is not subject to regulation by the Food and Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act (FDCA). In reaching that conclusion, OLC interpreted "intended use" — a foundational doctrine in food and drug law — to include a product seller's knowledge of actual use and the "circumstances surrounding distribution" of the product. The OLC opinion thus departs from FDA's 2015 proposed rule interpreting "intended use" under 21 C.F.R. §§ 201.128 and 801.4. Because OLC opinions are binding on agencies such as FDA, the opinion raises questions regarding the scope of regulated firms' liability under the misbranding and new drug/device approval provisions of the FDCA.

In 2015, FDA proposed to revise the existing regulatory definitions of "intended use" at 21 C.F.R. §§ 201.128 and 801.4 by eliminating the knowledge prong of the definitions.<sup>1</sup> Industry, particularly the Medical Information Working Group (MIWG), had urged this change through citizen petitions and litigation and supported the proposed revision.<sup>2</sup> In the proposal, FDA explained that changes to these provisions were needed "to reflect how the agency currently applies them to drugs and devices."<sup>3</sup> However, without notice that it was considering alternative approaches, FDA finalized the rule in January 2017, replacing the knowledge prong with an entirely new sentence, creating a "totality of the evidence" standard.<sup>4</sup> Industry groups filed a petition to stay and for reconsideration, challenging the validity of the final rule, stating that the new definition of intended use exceeded FDA's authority under the FDCA and that the lack of adequate notice violated the Administrative Procedure Act.<sup>5</sup> FDA relented, first delaying the effective date of the rule<sup>6</sup> and then staying it indefinitely.<sup>7</sup> When then-FDA Commissioner Scott Gottlieb announced the delay, he said, "By delaying implementation of these portions of the final rule we are not creating new policy, but instead reverting to the agency's existing and longstanding regulations and interpretations on determining intended use for medical products. These are the same regulations and interpretations that have been in effect for decades."<sup>8</sup>

The OLC opinion appears to have been issued as a result of litigation involving FDA's obligation to block the entry of misbranded and unapproved drugs used under state lethal injection protocols. In 2011,

death row inmates in Arizona, California and Tennessee challenged FDA's exercise of enforcement discretion in allowing shipments of misbranded and unapproved sodium thiopental, which was to be used in executions, to enter the United States. The U.S. District Court for the District of Columbia held that the FDCA obligated the agency to refuse admission and issued an injunction that blocked FDA from releasing future shipments of unapproved or misbranded thiopental into the United States. The injunction was upheld by the U.S. Court of Appeals for the District of Columbia Circuit in 2013 and the DOJ declined to seek further review.<sup>9</sup>

In January 2017, the State of Texas sued FDA regarding shipments of unapproved thiopental that the state had purchased from an individual doing business in India under the name Harris Pharma. Initially, the state sought an order compelling FDA to take final actions on shipments that had been detained. After FDA issued a final detention order in April 2017 (which notably cited Texas's submission that the imported thiopental "is a drug, because it is intended to affect the structure and function of the body"),<sup>10</sup> Texas filed an amended complaint seeking the release of the drug.<sup>11</sup> That litigation has been stayed since December 2017 to allow the parties to discuss a possible resolution.<sup>12</sup>

The OLC opinion states that it was requested by the Attorney General. The key points relating to intended use are as follows:

- "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." (p. 10, relying on structure/function prongs of statutory drug and device definitions and regulatory definitions of intended use)
- "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." (p. 24)
- The opinion also relies on the non-claims-focused elements of the regulatory definitions of intended use, including the "circumstances surrounding distribution" language, and the language addressing temporally shifting intended uses.<sup>13</sup>

Overall, the opinion is not consistent with the claims-based interpretation of intended use and it departs from the approach set forth in FDA's 2015 proposed rule.

The scope and implications of the opinion are not clear. On the one hand, the interpretation of intended use could affect the liability of manufacturers in cases, such as off-label promotion investigations, in which the FDCA's misbranding and new drug/device approval provisions are at issue. On the other hand, the opinion goes to some lengths to limit the scope of its analysis, stating that it does not address "whether FDA has jurisdiction over drugs intended for use in physician-assisted suicide," for example. There are strong indicia that the opinion will be limited in its practical effect to the specific question of FDA's authority to regulate articles used in administering the death penalty, but nothing in the law or in FDA or DOJ policy would preclude the federal government (or the qui tam bar) from relying on the opinion to support an expansive reading of the intended use doctrine.

Footnote 1 of the opinion states that, in reaching its conclusion, OLC “solicited and considered the views of FDA and of the Office of the Associate Attorney General.” The footnote does not state precisely what position FDA took. It has been reported that former FDA Commissioner Gottlieb and former Attorney General Jeff Sessions “had a heated argument” over whether execution drugs could enter the United States without FDA oversight.<sup>14</sup>

OLC opinions are binding on federal agencies, such as FDA.<sup>15</sup> The agency has stated publicly that it will “follow the conclusion of the opinion to the extent permissible” under the existing district court injunction in the *Cook* case.<sup>16</sup>

OLC opinions generally are not subject to direct judicial review. Their validity, however, may be contested in litigation in circumstances where parties can establish that agency compliance with an OLC opinion adversely affects them.<sup>17</sup> It is thus possible that prisoners could, in appropriate circumstances, seek declaratory and injunctive relief against actual or likely importation of drugs intended for use in lethal injection, and thereby challenge the validity of the OLC interpretation of the FDCA.

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<sup>1</sup> 80 Fed. Reg. 57,756, 57,764-65 (Sept. 25, 2015).

<sup>2</sup> MIWG, Citizen Petition, Docket No. FDA-2013-P-1079, at 4, 15-19 (Sept. 3, 2013), <https://www.regulations.gov/document?D=FDA-2013-P-1079-0001>.

<sup>3</sup> 80 Fed. Reg. at 57,756.

<sup>4</sup> 82 Fed. Reg. 2193, 2217 (Jan. 9, 2017).

<sup>5</sup> MIWG, PhRMA & BIO, Petition to Stay and for Reconsideration, Docket No. FDA-2015-N-2002-1977 (Feb. 8, 2017), <https://www.regulations.gov/document?D=FDA-2015-N-2002-1977>.

<sup>6</sup> See 83 Fed. Reg. 2092 (Jan. 16, 2018); 82 Fed. Reg. 14,319 (Mar. 20, 2017).

<sup>7</sup> 83 Fed. Reg. 11,639 (Mar. 16, 2018).

<sup>8</sup> Press Release, FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA Decision to Seek Additional Time to Reassess Rule that Would Have Changed Longstanding Practices for How the Agency Determined the ‘Intended Use’ of Medical Products* (Jan. 12, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fda-decision-see-additional-time-reassess-rule-would>.

<sup>9</sup> *Beatty v. FDA*, 853 F. Supp. 2d 30 (D.D.C. 2012), *aff’d in part and vacated in part sub nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013).

<sup>10</sup> FDA, Admissibility Determination re: Thiopental Sodium Imported by the Texas Department of Criminal Justice (Apr. 20, 2017), <https://www.fda.gov/media/104729/download>.

<sup>11</sup> Plaintiff Texas Department of Criminal Justice’s Second Amended Complaint for Declaratory and Injunctive Relief, *Tex. Dep’t of Criminal Justice v. FDA*, No. 3:17-cv-00001 (S.D. Tex. May 22, 2017), ECF No. 36.

<sup>12</sup> Order Staying Case, *Tex. Dep’t of Criminal Justice v. FDA*, No. 3:17-cv-00001 (S.D. Tex. Dec. 4,

2017), ECF No. 52.

<sup>13</sup> 21 C.F.R. § 201.128 (“The intent . . . may be shown by the circumstances surrounding the distribution of the article. . . . It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.”); 21 C.F.R. § 801.4 (same).

<sup>14</sup> Laurie McGinley & Mark Berman, *Justice Department says FDA ‘Lacks Jurisdiction’ Over Death-Penalty Drugs*, Wash. Post (May 14, 2019), [https://www.washingtonpost.com/national/health-science/justice-department-says-fda-lacks-jurisdiction-over-death-penalty-drugs/2019/05/14/da056e6c-764d-11e9-b7ae-390de4259661\\_story.html?utm\\_term=.d37439985b0d](https://www.washingtonpost.com/national/health-science/justice-department-says-fda-lacks-jurisdiction-over-death-penalty-drugs/2019/05/14/da056e6c-764d-11e9-b7ae-390de4259661_story.html?utm_term=.d37439985b0d).

<sup>15</sup> See Arthur H. Garrison, *The Opinions by the Attorney General and the Office of Legal Counsel: How and Why They Are Significant*, 76 Alb. L. Rev. 217, 242-43 (2012/2013) (describing legal and historical support). See also *Citizens for Responsibility & Ethics in Washington v. U.S. Dep’t of Justice*, 922 F.3d 480, 484 (D.C. Cir. 2019) (describing OLC’s views).

<sup>16</sup> Josh Gerstein, *FDA Can’t Control Death Penalty Drugs, DOJ Says*, Politico (May 14, 2019), <https://www.politico.com/story/2019/05/14/fda-death-penalty-drugs-1323248>.

<sup>17</sup> See, e.g., Complaint for Declaratory Relief, *NeoPollard Interactive LLC v. Barr*, No. 1:19-cv-00170-SM (D.N.H. Feb. 15, 2019) (contesting OLC’s conclusion that the federal Wire Act applies to State lotteries); Complaint, *N.H. Lottery Comm’n v. Barr*, No. 1:19-cv-00163-PB (D.N.H. Feb. 15, 2019) (same).

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## CONTACTS

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