UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

EAGLE PHARMACEUTICALS, INC.,

Plaintiff,

v.

ALEX M. AZAR II in his official capacity as Secretary of Health and Human Services *et al.*,

Defendants.

Civil Action No. 16-790 (TJK)

MEMORANDUM OPINION

Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle") brings this case to challenge a decision by the Food and Drug Administration ("FDA") pursuant to its regulations implementing the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983), a part of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* The Orphan Drug Act provides pharmaceutical companies like Eagle with benefits that subsidize and incentivize the development of "orphan drugs"—that is, drugs that treat rare diseases. One of those benefits, typically referred to as "orphan-drug exclusivity," is a seven-year period during which the FDA may not approve any other manufacturer's application to market the same drug to treat the same rare disease. Eagle claims that it has a statutory right to orphan-drug exclusivity for its drug Bendeka, which the FDA designated as an orphan drug and approved to treat two rare forms of cancer. The FDA (sued here alongside the Department of Health and Human Services, and the heads of both the FDA and the Department in their official capacities) disagrees, arguing that it properly denied orphan-drug exclusivity to Bendeka because it is the same as another drug, Treanda, that previously enjoyed orphan-drug exclusivity.

The parties have filed cross-motions for summary judgment, each claiming that it is entitled to judgment as a matter of law based on the administrative record. As explained below, Eagle's motion will be granted and the FDA's will be denied. The Court will enter an order requiring the FDA to recognize orphan-drug exclusivity for Bendeka.

I. Background

A. The Orphan Drug Act and the FDA's Implementing Regulations

In general, before a company may market a drug in interstate commerce, it must first receive FDA approval of an application for the drug based on its safety and effectiveness. *See* 21 U.S.C. § 355. By the early 1980s, concerns had arisen that the high costs of research, development, and winning FDA approval had deterred the development of drugs to treat rare diseases, often referred to as "orphan drugs." *See Spectrum Pharm., Inc. v. Burwell*, 824 F.3d 1062, 1064 (D.C. Cir. 2016); *Genentech, Inc. v. Bowen*, 676 F. Supp. 301, 302-03 (D.D.C. 1987). Accordingly, in 1983, Congress enacted the Orphan Drug Act to encourage pharmaceutical companies to develop such drugs. *See Spectrum*, 824 F.3d at 1064; *Genentech*, 676 F. Supp. at 302-03. Under the Act, while a drug is under development, the FDA may designate it as an orphan drug, one "for a rare disease or condition." 21 U.S.C. § 360bb(a)(1). Designation brings several benefits, including a streamlined approval process and tax advantages. *See Baker Norton Pharm., Inc. v. FDA*, 132 F. Supp. 2d 30, 31 (D.D.C. 2001); *Genentech*, 676 F. Supp. at 303. If the FDA subsequently approves an application to market the designated drug, the drug sponsor receives an additional benefit: the FDA "may not approve" any other application for "such drug" to treat the same rare disease until seven years have passed. 21 U.S.C. § 360cc(a) (2012). Because FDA approval is mandatory, this scheme effectively grants the first manufacturer to receive approval the exclusive ability to market the drug during the seven years.

The Orphan Drug Act does not explain when two "drugs" are the same or different, even though that distinction controls the scope of the statute's exclusivity provision. If the sponsor of a particular "drug" has won exclusivity under the statute, no other manufacturer may receive approval to market the same "such drug" to treat the same rare disease. *See id.* By contrast, the statute does not restrict approval of applications for different drugs. *See id.* Thus, even if the FDA recognizes exclusivity for a particular orphan drug, that would not bar the FDA from approving a different drug to treat the same rare disease during the exclusivity period. As noted above, the statute itself does not explain when two drugs are the same or different. *See Baker Norton*, 132 F. Supp. 2d at 34-36; *Genentech*, 676 F. Supp. at 311-13. FDA regulations do address that issue, providing that a new drug is generally the same as a previously approved drug if both share the same active ingredient—except if the new drug is "clinically superior" to the previously approved drug, in which case the new drug is considered different. *See* 21 C.F.R. § 316.3(b)(14). "Clinically superior" means that the drug is more effective, is safer, or "otherwise makes a major contribution to patient care." *Id.* § 316.3(b)(3). Thus, if the new drug is clinically superior, then the FDA can approve it even though the older drug (which, once again, has the same active ingredient) continues to enjoy its seven-year period of orphan-drug exclusivity.

The FDA applies the same-drug concept not only when determining whether it can approve subsequent drugs for marketing during an orphan drug's seven-year exclusivity window, but also in deciding whether to afford a subsequent drug its own exclusivity period after the seven years have expired. That is, the FDA will not grant the Act's benefits to a drug if it has previously approved that same drug for a particular rare disease. This restriction emerges in part from concerns regarding potential "evergreening" of orphan-drug exclusivity, also called "serial

exclusivity" (an analogous term the parties have generally used in this litigation). "Serial exclusivity" means the possibility of repeating the seven-year exclusivity period that follows the statutory designation-and-approval process for a given drug and disease. *See* Orphan Drug Regulations, 78 Fed. Reg. 35,117, 35,127 (June 12, 2013) (final rule). The FDA has concluded that limiting orphan-drug exclusivity to the first manufacturer who obtains approval "best effectuates Congress' aim in enacting the Orphan Drug Act." *Id.* The FDA has thus taken steps to avoid successive grants of orphan-drug exclusivity for the "same drug" to treat the same disease. *See* 21 C.F.R. §§ 316.20(b)(5), 316.25(a)(3), 316.34(c).

The FDA does so at two stages of the process: first when determining whether to designate a drug as an orphan drug, and again when determining whether to recognize orphan-drug exclusivity once the drug has obtained marketing approval. At each stage, the FDA uses its "clinical superiority" framework to determine if the new drug is the same "such drug" as the previously approved drug. However, it applies a different evidentiary standard at each stage. At the designation stage, the drug sponsor must submit "a medically plausible hypothesis for the possible clinical superiority of the subsequent drug." 21 C.F.R. § 316.25(a)(3). At the marketing-approval stage, the FDA requires applicants to go beyond a mere hypothesis and provide evidence of actual clinical superiority in order to obtain orphan-drug exclusivity. *See id.* § 316.34(c).

In 2012, pharmaceutical company Depomed, Inc. filed a lawsuit challenging the FDA's requirement that manufacturers show clinical superiority at the marketing-approval stage. *Depomed, Inc. v. U.S. Dep't of Health & Human Servs.*, 66 F. Supp. 3d 217, 226 (D.D.C. 2014). Under the version of the statute in effect at the time—which is the same version at issue in this case—the FDA "may not approve another application" for a drug to treat a rare disease if the

FDA "approves an application" for "a drug designated" under the Orphan Drug Act. 21 U.S.C. § 360cc(a) (2012). This language, Depomed argued, meant that orphan-drug exclusivity followed automatically from designation and marketing approval, leaving no room for the FDA to impose any other conditions on Depomed prior to recognizing its right to orphan-drug exclusivity. *See Depomed*, 66 F. Supp. 3d at 226; *see also* 78 Fed. Reg. at 35,127 (discussing similar arguments by commenters during FDA rulemaking process). The FDA claimed that its regulations that require a showing of clinical superiority at the approval stage were valid under the doctrine of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *Depomed*, 66 F. Supp. 3d at 228-29. The court disagreed with the FDA. It held that the statute was unambiguous and required the FDA to recognize orphan-drug exclusivity once a drug is designated and approved. *Id.* at 230. To the extent that the FDA was concerned about the possibility of serial exclusivity, the court reasoned, it must address those concerns at the designation stage. *Id.* at 235-36.

The FDA ultimately withdrew its appeal of the *Depomed* decision. *See Depomed Inc. v. U.S. Dep't of Health & Human Servs.*, No. 14-5271, 2014 WL 5838247 (D.C. Cir. Nov. 7, 2014) (dismissing appeal on government's motion). Instead, while complying with the judgment in that case, the FDA announced that it would continue to apply its regulations as written, effectively taking the position that *Depomed* was wrongly decided. *See* Policy on Orphan-Drug Exclusivity; Clarification, 79 Fed. Reg. 76,888 (Dec. 23, 2014).

In 2017, during the pendency of this litigation, Congress amended the Orphan Drug Act so as to effectively supersede *Depomed*'s holding going forward. *See* FDA Reauthorization Act of 2017, Pub. L. No. 115-52, sec. 607(a), § 527(c)-(d), 131 Stat. 1005, 1049-50 (amending 21

U.S.C. § 360cc). However, the amendments do not apply retroactively to any decision made before their enactment. *See id.* sec. 607(b), 131 Stat. at 1050.

B. The FDA's Decision on Orphan-Drug Exclusivity for Bendeka

In 2008, the FDA granted marketing approval for Treanda, a chemotherapy drug manufactured by a subsidiary of Teva Pharmaceutical Industries, Ltd., to treat two types of cancer. AR 10.[1] Treanda's active ingredient is a chemical known as bendamustine. AR 1. The FDA subsequently recognized orphan-drug exclusivity for Treanda for those two types of cancer. AR 10. Treanda's exclusivity for both diseases ended in 2015. *See* AR 10-11.

In 2014, Eagle requested that the FDA designate Bendeka, a drug with the same active ingredient (bendamustine) as Treanda but a different formulation, as an orphan drug to treat both types of cancer. AR 10, 63-105. As required by FDA regulations, Eagle argued that Bendeka would be clinically superior to Treanda. AR 10, 76-81, 97-103. In July 2014, the FDA designated Bendeka as an orphan drug to treat the two types of cancer, concluding that Eagle had shown a plausible hypothesis of clinical superiority. AR 10, 307-32.

In 2015, Eagle sought FDA approval for Bendeka to treat the two types of cancer pursuant to 21 U.S.C. § 355(b), relying in part on the FDA's previous approval of Treanda. *See* AR 10-11. The FDA approved Eagle's application to market Bendeka in December 2015. *See* AR 11, 394-420. Even before that time, Eagle had argued that Bendeka should be entitled to orphan-drug exclusivity upon approval. AR 1779-89. In January 2016, Eagle's representatives met with the FDA to make Eagle's case for orphan-drug exclusivity for Bendeka, and Eagle

[1] All citations to the administrative record are in the form "AR __." The Court has followed the page numbering introduced with the prefix "FDA"; for example, "AR 10" refers to the page stamped "FDA 10" in the record. The Court has relied on the relevant excerpts that the parties identified in their joint appendix. The "Confidential Joint Appendix," ECF Nos. 35 & 35-1, contains the relevant excerpts of the sealed portion of the record. The "Nonconfidential Joint Appendix," ECF No. 34, contains the publicly available excerpts.

made an additional written submission in February. AR 12, 426-504. Eagle argued that the FDA was obligated to afford exclusivity to Bendeka under the reasoning of the *Depomed* decision, because it had already designated Bendeka as an orphan drug and approved it. AR 12-13, 426 n.2, 461, 486-87. Eagle also argued that it had, in any event, satisfied the FDA's regulations by showing that Bendeka was clinically superior to Treanda. AR 12, 467-82, 487. Eagle touted several benefits of Bendeka over Treanda, including that Bendeka delivers the same amount of bendamustine in a smaller amount of fluid, with lower amounts of sodium, and over a shorter period of time; that Bendeka does not (unlike some formulations of Treanda) require reconstitution before being administered or contain certain harmful chemicals; and that Bendeka is more stable and has a longer shelf life. *See* AR 13-30, 473-82, 487, 493-504; ECF No. 40 at 13-14. These features, Eagle argued, made Bendeka safer than Treanda and provided a material contribution to patient care. AR 13, 470, 487. Eagle also claimed that affording orphan-drug exclusivity to Bendeka would be consistent with prior decisions by the FDA. AR 31, 471-72.

On March 24, 2016, the FDA denied Eagle's request for exclusivity under the Orphan Drug Act. AR 1. It concluded that Eagle had not substantiated its claims of clinical superiority with adequate evidence, and rejected Eagle's analogies to prior decisions recognizing exclusivity for other drugs. AR 13-32. While conceding that Bendeka would "provide some convenience to certain patients" that Treanda did not, the FDA found no evidence that "Bendeka significantly improves outcomes and quality of life in patients." AR 32.

The agency also explained that it disagreed with the *Depomed* decision and had decided, as a matter of policy, not to follow it. AR 9, 32-40. The FDA rejected what it considered to be *Depomed*'s "hyper-literal" reading of the statute. AR 33. The Orphan Drug Act's purpose, the FDA reasoned, was to "provide treatment for *presently untreated patients*," whereas "successive,

seven-year exclusivity periods" would "deprive patients of competitive formulations of drugs for rare diseases." *Id.* The *Depomed* decision also, in the FDA's view, failed to take into account the "structure" of the statute: the FDA could not reasonably require a dispositive showing of clinical superiority at the designation phase, because the orphan drug may be in only the early stage of development. AR 34. It was more reasonable, the FDA asserted, to require only a plausible hypothesis of superiority at the designation stage, and a more concrete showing at the approval stage. *Id.* The FDA also reasoned that the *Depomed* decision, if followed, would lead to "absurd" results, including never-ending periods of exclusivity and high prices for patients in dire need of care. AR 35-37. The FDA concluded that the statute was in fact silent on "whether there could be multiple exclusivity periods when there is a previously approved same drug," such that the FDA could fill this gap in the statute. AR 37-39.

C. Procedural History

On April 27, 2016, Eagle filed this lawsuit challenging the FDA's decision on orphan-drug exclusivity for Bendeka under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.* ECF No. 1. Eagle subsequently filed a motion for summary judgment, ECF No. 19 ("Pl.'s Br"), and the FDA cross-moved for summary judgment, ECF No. 27 ("Defs.' Br."). *See also* ECF No. 29 ("Pl.'s Reply"); ECF No. 33 ("Defs.' Reply"); ECF No. 63 ("Oral Arg. Tr.").[2] Eagle raises three objections to the FDA's decision. First, Eagle claims that *Depomed* was rightly decided and that the FDA has exceeded its statutory authority by requiring manufacturers to show that a designated orphan drug is "clinically superior" to a previously approved drug as a precondition to orphan-drug exclusivity. Pl.'s Br. at 17-29. Second, Eagle argues that, even if the FDA's regulations are valid, the FDA's decisionmaking process violates due process. *Id.* at

[2] The parties' motion papers were filed under seal. Redacted versions are available to the public on the docket. ECF Nos. 40-43.

30-37. Finally, Eagle claims that the FDA's application of its clinical-superiority framework to Bendeka was arbitrary and capricious. *Id.* at 37-44. The Court held a hearing on the summary-judgment motions on May 4, 2018. Oral Arg. Tr.

II. Legal Standard

Under Federal Rule of Civil Procedure 56, a court must grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). "The 'entire case' on review is a question of law." *Id.* "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Alston v. Lew*, 950 F. Supp. 2d 140, 143 (D.D.C. 2013).

Courts often analyze agency interpretations of statutes "under the familiar two-step framework of *Chevron*." *City of Clarksville v. FERC*, 888 F.3d 477, 482 (D.C. Cir. 2018) (citing *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)). "If the Court determines that 'Congress has directly spoken to the precise question at issue,' and 'the intent of Congress is clear, that is the end of the matter.'" *Id.* (quoting *Chevron*, 467 U.S. at 842). "If, however, 'the statute is silent or ambiguous with respect to the specific issue,' then the Court must determine 'whether the agency's answer is based on a permissible construction of the statute.'" *Id.* (quoting *Chevron*, 467 U.S. at 843). "[A]gencies only 'possess whatever degree of discretion [an] ambiguity allows.'" *Loan Syndications & Trading Ass'n v. SEC*, 882 F.3d 220, 224 (D.C. Cir. 2018) (second alteration in original) (quoting *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013)).

"[U]nder *Chevron*, [courts] owe an agency's interpretation of the law no deference unless, after 'employing traditional tools of statutory construction,' [they] find [themselves] unable to discern Congress's meaning." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018) (quoting *Chevron*, 467 U.S. at 843 n.9). That is, courts "examine the [statute's] text, structure, purpose, and legislative history to determine if the Congress has expressed its intent unambiguously." *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 605 (D.C. Cir. 2016) (per curiam), *cert. denied*, 137 S. Ct. 2296 (2017).

While "[t]he starting point for [courts'] interpretation of a statute is always its language," *Lindeen v. SEC*, 825 F.3d 646, 653 (D.C. Cir. 2016) (first alteration in original) (quoting *Cmty. for Creative Non-Violence v. Reid*, 490 U.S. 730, 739 (1989)), the court may not stop after reading one textual provision in isolation. "[I]n interpreting a statute, a court 'must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy.'" *Czyzewski v. Jevic Holding Corp.*, 137 S. Ct. 973, 985 (2017) (quoting *Kelly v. Robinson*, 479 U.S. 36, 43 (1986)). Thus, the statute's "structure, legislative history, or purpose" may conclusively resolve an ambiguity that the text alone cannot. *Council for Urological Interests v. Burwell*, 790 F.3d 212, 221 (D.C. Cir. 2015) (quoting *Catawba Cty. v. EPA*, 571 F.3d 20, 35 (D.C. Cir. 2009)). Conversely, it is possible for an ambiguity in a particular textual provision to become apparent only when it is read in light of the statute's overall structure and purpose. *See Sierra Club v. EPA*, 551 F.3d 1019, 1027 (D.C. Cir. 2008); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067-68 (D.C. Cir. 1998). Courts may also, on rare occasions, "examine the statute's legislative history in order to shed new light on congressional intent, notwithstanding statutory language that appears superficially clear." *Nat. Res. Def. Council ("NRDC") v. EPA*, 489 F.3d 1250, 1259 (D.C. Cir. 2007) (quoting *Consumer*

Elecs. Ass'n v. FCC, 347 F.3d 291, 298 (D.C. Cir. 2003)) (internal quotation marks omitted). But legislative history alone cannot give rise to ambiguity, because courts "do not resort to legislative history to cloud a statutory text that is clear." *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 212 (D.C. Cir. 2013) (quoting *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994)).

III. Analysis

The FDA designated Bendeka as an orphan drug pursuant to 21 U.S.C. § 360bb and then approved it for marketing under 21 U.S.C. § 355.[3] Eagle's primary argument is that on these facts the Orphan Drug Act, as interpreted by the *Depomed* court, requires the FDA to recognize orphan-drug exclusivity for Bendeka regardless of whether it is clinically superior to Treanda. The FDA argues that *Depomed* was wrongly decided, and that its regulations requiring a showing of clinical superiority are valid under the *Chevron* doctrine. Because Eagle failed to make such a showing, the FDA claims, it properly declined to recognize orphan-drug exclusivity for Bendeka. The Court agrees with Eagle that the statute unambiguously requires the FDA to afford Bendeka the benefit of orphan-drug exclusivity, and therefore will order the FDA to do so. The Court thus does not reach Eagle's remaining arguments.

A. Text

The Court starts, as it must, with the text of the statute as it stood at the time of the FDA's decision, before it was amended in 2017:

> Except as provided in subsection (b) of this section, if the Secretary . . . approves an application filed pursuant to section 355 of this title . . . for a drug designated under section 360bb of this title for a rare disease or condition, the Secretary may not approve another application . . . for such drug for such disease or condition for a person who is not the holder of such approved application or

[3] The Court notes that neither party has disputed that the "drug" the FDA approved pursuant to § 355 was the same "drug" that the FDA had designated pursuant to § 360bb.

> of such license until the expiration of seven years from the date of the approval of the approved application . . . .

21 U.S.C. § 360cc(a) (2012). "The statutory provision[] before [the court] deliver[s] unmistakable commands." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1358 (2018). Under the pre-2017 statute, if the FDA approves a drug previously designated under the Orphan Drug Act, then it "may not approve" another application "for such drug for such disease or condition" for a period of seven years. Nothing in the text of the statute suggests that this prohibition depends in any way on whether another drug has previously enjoyed the same benefit. The Court thus agrees with the conclusion in *Depomed* that this language leaves no room for the FDA's imposition of its clinical-superiority requirement after an orphan drug has been designated and approved. *See* 66 F. Supp. 3d at 230.

The FDA advances a two-step argument in favor of its interpretation. It argues, first, that the Orphan Drug Act is ambiguous on the issue of "serial exclusivity"—that is, whether the same "such drug" may twice enjoy orphan-drug exclusivity to treat the same disease. Defs.' Br. at 15. The FDA argues that its regulations fill this gap by effectively banning serial exclusivity. *Id.* at 19. The FDA's resolution of the first ambiguity raises a second one: when is a new "drug" the same as the old "drug" that previously enjoyed orphan-drug exclusivity? *Id.* at 15. To resolve that second ambiguity, the FDA argues, it has reasonably applied its clinical-superiority framework. *See id.* at 18-19.

The FDA's argument does not make it past the first step. The pre-2017 statute is not ambiguous on the subject of "serial exclusivity." If a drug has been designated as an orphan drug and approved for marketing to treat a rare disease, then under the plain language of the statute its manufacturer enjoys the benefit of orphan-drug exclusivity. The statute makes no distinction between the first manufacturer to meet those conditions and the second. If a second

manufacturer meets the statutory requirement of designation and approval, then it enjoys a duopoly alongside the first, because the Orphan Drug Act does not require the FDA to rescind the approval it previously granted to the first manufacturer.

The FDA argues that the pre-2017 statute's "silence" on the subject of serial exclusivity justifies the FDA's regulations prohibiting that practice. *See* Defs.' Br. at 15-16; Defs.' Reply at 4. But the only "silence" that matters under *Chevron* is one that remains after the Court has applied the "traditional tools of statutory construction." *Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1088 (D.C. Cir. 1996) (quoting *Chevron*, 467 U.S. at 843 n.9). "The most traditional tool, of course, is to read the text; if it clearly requires a particular outcome, then the mere fact that it does so implicitly rather than expressly does not mean that it is 'silent' in the *Chevron* sense." *Id.* Here, the statute sets out requirements for orphan-drug exclusivity. Bendeka meets those requirements, and the statute does not authorize the FDA to invent new ones. Therefore, the statutory text is not silent, but in fact answers the question of whether, following the prior grant of exclusivity for Treanda, Bendeka is also entitled to orphan-drug exclusivity. The answer is "yes."[4]

Scrambling to find a foothold in the statutory text, the FDA also asserts that the term "expiration" is ambiguous.[5] The FDA argues that "expiration" *could* mean that the first term of

[4] The fact that the statute clearly answers the question before the Court differentiates this case from another, cited by the FDA, in which the statute was "silent regarding the issue of how many exclusivity periods may arise" *and* offered several textual clues that pointed in different directions. *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 68-72 (D.D.C. 2006), *aff'd*, 226 F. App'x 4 (D.C. Cir. 2007).

[5] At oral argument, Eagle disputed whether the FDA's argument concerning the word "expiration" was properly before the Court, asserting that the FDA had not advanced this argument in the administrative record, or even until its reply brief. Oral Arg. Tr. at 34:22-35:13. The Court finds it unnecessary to resolve that question. As explained below, the word

exclusivity is subject to repetition, "but it can *also* mean that *no further bar* against the approval of subsequent 'such drug[s]' is to be imposed." Defs.' Reply at 4. But a term is ambiguous when it "admit[s] of two or more reasonable ordinary usages." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 989 (2005). "Expiration" does not have any ordinary usage that bears on the subject of serial exclusivity one way or the other. It means the "ending of a fixed period of time; esp., a formal termination on a closing date." *Expiration*, Black's Law Dictionary (10th ed. 2014). The mere fact that one period of time will end says nothing about what comes afterward—the term may be subject to renewal or repetition, or it may not. Thus, as used in the statute here, the term "expiration" is not ambiguous as to the question of what comes next; it is irrelevant. While the word "expiration" certainly would not stand in the way if other statutory text authorized the FDA to prohibit serial exclusivity, it cannot serve as a basis for the FDA to avoid the statute's clear command: once the FDA has approved an application for a designated orphan drug to treat a rare disease, it "may not approve" another application for that drug to treat that disease.

B. Purpose and Structure

The FDA also suggests that ambiguity latent in the statutory text becomes apparent when considering its "legislative history, structure, and purpose." Defs.' Br. at 24. But these arguments are unconvincing. Nothing in the Orphan Drug Act's purpose, structure, or legislative history undermines Eagle's interpretation of the statute, which is firmly grounded in the text.

The FDA argues that "the central purpose of the Orphan Drug Act is to incentivize drug development for otherwise untreated patients." *Id.* at 27. This purpose, the FDA argues, is

"expiration" cannot take the FDA where it wants to go. Therefore, the Court assumes, without deciding, that this argument is properly presented.

furthered only if the benefit of orphan-drug exclusivity is reserved for the first manufacturer to earn it:

> If exclusivity were available to *any* manufacturer who produces a drug, regardless of whether the drug was approved previously, companies would have no reason to invest in developing superior drugs. Rather, they could just sit back and make minor tweaks to existing orphan drugs, knowing that they could eventually benefit from exclusivity after the original drug's exclusivity period expired. Such a regime does not foster innovation, or serve patients. By contrast, awarding the monopoly to only the *first* orphan drug developer, as FDA does, sharpens the incentives so that only products that provide meaningful benefits to patients over a previously approved drug receive the award.

Id.

But this argument about the statute's broad purpose simply cannot override its text, which provides an unambiguous answer to the question at hand. "[N]either courts nor federal agencies can rewrite a statute's plain text to correspond to its supposed purposes." *Landstar Express Am., Inc. v. Fed. Mar. Comm'n*, 569 F.3d 493, 498 (D.C. Cir. 2009). And even on its own terms, the argument is unpersuasive insofar as it asserts that Eagle's interpretation is inconsistent with the statute's purpose. Eagle's interpretation does not *require* the FDA to hand out the benefit of orphan-drug exclusivity to undeserving drug manufactures. Despite its protestations, the FDA in fact has unchallenged statutory authority at the *designation stage* to ensure that drug manufacturers cannot "just sit back and make minor tweaks to existing orphan drugs" to earn orphan-drug exclusivity. Defs.' Br. at 27. As Eagle argues and the *Depomed* court suggested, the FDA can address this problem by declining to grant orphan-drug designation to drugs that offer only marginal improvements over existing treatments. *See* Pl.'s Br. at 25-26; *Depomed*, 66 F. Supp. 3d at 235-36. And the FDA has done so: it will not grant orphan-drug designation if it has previously approved a drug with the same active ingredient to treat the same rare disease, unless the applicant can advance a plausible hypothesis of clinical superiority over the existing

drug. 21 C.F.R. § 316.25(a)(3). That requires more than just a "minor tweak." In this case, for example, Eagle submitted a 20-page designation request to the FDA, replete with technical details and citations to medical literature, explaining why its formulation of bendamustine was superior to Treanda. AR 65-84. If it were so inclined, the FDA could impose even more rigor at the designation stage.

The FDA also argues that the "timing structure" of the Orphan Drug Act suggests that Congress intended to hand out the benefits of orphan-drug designation liberally, while more carefully restricting the benefit of orphan-drug exclusivity. It reasons that many of the post-designation benefits (such as tax breaks and research grants) are intended to assist drug development and are best distributed to many manufacturers, whereas exclusivity is better limited to one manufacturer because the benefits of exclusivity must be balanced against higher prices for consumers. *See* Defs.' Br. at 30-32; Defs.' Reply at 10-12. This, the FDA argues, counsels in favor of imposing additional requirements after designation has been granted.

It is true, of course, that a textual provision that seems clear in isolation may take on new meaning when viewed in light of the statutory structure. *See, e.g.*, *King v. Burwell*, 135 S. Ct. 2480, 2495 (2015). But "[r]eliance on context and structure in statutory interpretation is a 'subtle business, calling for great wariness lest what professes to be mere rendering becomes creation and attempted interpretation of legislation becomes legislation itself.'" *Id.* at 2495-96 (quoting *Palmer v. Massachusetts*, 308 U.S. 79, 83 (1939)). Here, the FDA's structural argument amounts to just such an exercise in policymaking rather than statutory interpretation. In fact, it does not appear to be grounded in the statute's structure at all. The primary authority cited by the FDA for it is dictum in the "background" section of the district court's opinion in *Genentech, Inc. v. Bowen*, 676 F. Supp. 301 (D.D.C. 1987): "While any number of drugs may

receive the development-phase benefits of the Act, only one manufacturer may receive exclusive marketing rights. This post-development benefit is reserved for the first manufacturer to receive full FDA approval of its drug as safe and effective for commercial sale." *Id.* at 304. This dictum—assuming it means what the FDA thinks it means[6]—simply provides this Court no basis to ignore the statute's unambiguous text.

The FDA also suggests that its "timing" argument is compelled by the statute's purpose. *See* Defs.' Br. at 31. But that too is unconvincing. Liberally granting both orphan-drug designation *and* exclusivity would plausibly advance the statute's recognized purpose of incentivizing manufacturers to develop orphan drugs. Under Eagle's interpretation, the first manufacturer to win approval receives a substantial benefit: a seven-year monopoly (although one relatively limited in scope) on marketing the drug. The second manufacturer does not receive a "monopoly," as the FDA asserts. Defs.' Br. at 27. Instead it receives a duopoly (because it shares the benefit of orphan-drug exclusivity with the first manufacturer), one that begins only *after* the first manufacturer's seven years are up. This benefit is much less substantial than the first manufacturer's, but still meaningful. *Cf. Noramco of Del., Inc. v. DEA*, 375 F.3d 1148, 1158 (D.C. Cir. 2004) (noting that a drug duopoly offered higher profit margins than free competition). And so on for subsequent manufacturers.[7] Thus interpreted, the statute

[6] As noted below, legislators made several unsuccessful proposals in the years following the Orphan Drug Act's passage to allow multiple manufacturers to enjoy orphan-drug exclusivity simultaneously during the first seven-year term of exclusivity. *See infra* note 8. It is thus quite possible that the *Genentech* court was not saying anything about serial exclusivity, but merely referring to the undisputed fact that the statute, as written, *initially* allows only one manufacturer to enjoy orphan-drug exclusivity.

[7] Because serial exclusivity does not create a monopoly, the FDA misses the mark when it argues that serial exclusivity runs afoul of a traditional rule of statutory construction requiring monopolies to be construed narrowly. *See* Defs.' Br. at 23 (citing *Louisville Bridge Co. v.*

encourages drug manufacturers to obtain orphan-drug designation (because they know that designation will lead to at least a share of orphan-drug exclusivity upon approval), and encourages manufacturers who have obtained orphan-drug designation to work quickly to seek approval (because the first manufacturer to earn approval receives the greatest benefit).

Of course, the FDA may well be right that the statute would *better* advance Congress's policy objectives if it had been written differently to further restrict who could receive the benefit of orphan-drug exclusivity. Congress ultimately agreed, and in 2017 it modified the statute to permit the FDA to require a showing of clinical superiority at the approval stage before recognizing orphan-drug exclusivity. FDA Reauthorization Act of 2017, Pub. L. No. 115-52, sec. 607(a), § 527(c)-(d), 131 Stat. 1005, 1049-50. But even if the pre-2017 statute, as written, did not represent the *best* way of advancing Congress's goals, it represented *a* way of doing so.

Ultimately, in this case, the FDA's arguments about the statute's "purpose" and "structure" are really just policy arguments in favor of revising the statute so that, in the FDA's view, it works better. "At *Chevron* step one, however, such policy arguments have no relevance." *Loving v. IRS*, 917 F. Supp. 2d 67, 79 (D.D.C. 2013), *aff'd*, 742 F.3d 1013 (D.C. Cir. 2014). Indeed, it is well established that policy arguments have no relevance in statutory interpretation, except when the outcome is "'so bizarre' that Congress could not have intended it." *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 188 (1994) (quoting *Demarest v. Manspeaker*, 489 U.S. 184, 191 (1991)); *see Depomed*, 66 F. Supp. 3d at 234. Were it otherwise, courts undertaking routine statutory interpretation would become

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United States, 242 U.S. 409, 417 (1917)). In any event, it is doubtful that this rule of construction, which common law courts used to curtail "public franchises" that often "amounted to little more than favors" from government officials, has any purchase in this context. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1385 (2018) (Gorsuch, J., dissenting).

"policymakers choosing what the law *should be*," not "expounders of what the law *is*." *Epic Sys. Corp. v. Lewis*, No. 16-285, 2018 WL 2292444, at *8 (U.S. May 21, 2018). Because the FDA has not come close to suggesting an absurd outcome in this case, its policy arguments are beside the point. Indeed, nothing about Eagle's interpretation is illogical or absurd, nor is it contrary to the structure or purpose of the statute.

C. Legislative History

The FDA also seeks to rely on legislative history. But legislative history is of no help to the FDA here, because courts "do not resort to legislative history to cloud a statutory text that is clear." *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 212 (D.C. Cir. 2013) (quoting *Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994)). "[T]he authoritative statement is the statutory text, not the legislative history or any other extrinsic material. Extrinsic materials have a role in statutory interpretation only to the extent they shed a reliable light on the enacting Legislature's understanding of otherwise ambiguous terms." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005). As explained above, there is no ambiguity in the statutory text that requires the Court to resort to legislative history.

Moreover, examining the particular legislative history proffered by the FDA, the Court concludes that it sheds no new light on the question at hand. The FDA has identified nothing in the legislative history of the Orphan Drug Act itself that supports its interpretation of the statute. The agency instead relies on several subsequent statements by individual legislators, and one by President George H.W. Bush, evincing a belief that the statute allows only one manufacturer of a given drug to receive the benefit of orphan-drug exclusivity. *See* Defs.' Br. at 16; Defs.' Reply at 9; Oral Arg. Tr. at 27:24-28:5. Even if the text were less than entirely clear, these statements would be of limited value. "[F]loor statements by individual legislators rank among the least illuminating forms of legislative history." *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 943 (2017).

That is doubly true here, where these statements postdate the 1983 enactment of the Orphan Drug Act and relate to amendments proposed in 1986 and 1990 (the first of which never made it out of committee, and the second of which became the victim of a pocket veto) on matters only loosely related to serial exclusivity.[8] Such after-the-fact legislative "history" drawn from unenacted amendments is, at best, "an unreliable guide to legislative intent." *Verizon v. FCC*, 740 F.3d 623, 639 (D.C. Cir. 2014) (quoting *N. Broward Hosp. Dist. v. Shalala*, 172 F.3d 90, 98 (D.C. Cir. 1999)). As the D.C. Circuit has explained, "the isolated remarks of a few senators" are not enough to warrant deviating from clear statutory commands. *NRDC v. EPA*, 489 F.3d 1250, 1259 (D.C. Cir. 2007). Perhaps recognizing the weakness of this legislative history, the FDA has disclaimed any argument that Congress somehow ratified its interpretation of the statute—even though that is, in effect, the result it seeks. Defs.' Reply at 10; *cf. Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 169-70 (2001) (declining to infer "congressional acquiescence to administrative interpretations" based on unenacted amendments).

Finally, the Court notes that both parties have sought to leverage Congress's 2017 amendment of the Orphan Drug Act, which authorized the FDA to require a showing of clinical superiority before recognizing orphan-drug exclusivity. Eagle seeks to infer that "the prior text of the Orphan Drug Act did not support FDA's extra-statutory clinical superiority requirement." ECF No. 44 at 5. The FDA suggests that the new legislation could be interpreted as having

[8] The amendments proposed in 1986 and 1990 would have allowed multiple manufacturers to simultaneously enjoy the benefit of orphan-drug exclusivity during the *first* seven-year exclusivity window. *See* 132 Cong. Rec. 21,933-34 (1986) (statement of Sen. Hatch); 136 Cong. Rec. 20,376-77 (1990) (statement of Sen. Nielson); 136 Cong. Rec. 32,768 (1990) (statement of Rep. Bliley). But neither proposal directly addressed the issue of *serial* exclusivity, and in any event, neither was passed into law.

ratified its regulations. ECF No. 49 at 3. The Court draws neither inference from the 2017 amendment. Congress may have amended the statute because it believed *Depomed* was wrongly decided, but was concerned that other district courts might follow course. Or Congress may have believed that *Depomed* was rightly decided, and chosen to change the statute in line with the FDA's policy prescriptions. The Court need not engage in such speculation, because Congress expressly instructed that "[n]othing in the amendments . . . shall affect any determination under" the prior orphan-drug exclusivity provision. FDA Reauthorization Act of 2017, sec. 607(b), 131 Stat. at 1050. Therefore, by its own terms, the 2017 amendment is irrelevant to the outcome here. By the same token, of course, the Court's opinion in this case has no bearing on determinations made under the version of the statute currently in force.

D. Remaining Issues

Having established that the statute unambiguously permits "serial exclusivity" where two manufacturers have received an orphan-drug designation and marketing approval for the same drug, the Court does not reach the second ambiguity that the FDA has proffered, which concerns the meaning of "such drug." Although the FDA's briefing sometimes attempts to conflate these two issues, *see* Defs.' Br. at 21-22; Defs.' Reply at 3-6, the Court agrees with the *Depomed* court's conclusion that any ambiguity in the meaning of "such drug" is irrelevant if the statute cannot be fairly read to prohibit serial exclusivity. *Depomed*, 66 F. Supp. 3d at 232. Indeed, the FDA appeared to concede as much at oral argument. *See* Oral Arg. Tr. at 19:25-22:2. The Court also need not reach Eagle's claims that the FDA's application of its clinical-superiority requirement was procedurally and substantively improper. Rather, based on the undisputed facts in the record, Bendeka is entitled to orphan-drug exclusivity under the version of the statute in force at the time of the FDA's decision.

IV. Conclusion

For all of the above reasons, the Court will grant Eagle's motion for summary judgment (ECF No. 19) and deny the FDA's cross-motion (ECF No. 27) in a separate Order, which will instruct the FDA to recognize orphan-drug exclusivity for Bendeka pursuant to 21 U.S.C. § 360cc(a) (2012).

/s/ Timothy J. Kelly
TIMOTHY J. KELLY
United States District Judge

Date: June 8, 2018