United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 10, 2020 Decided April 16, 2021

No. 20-5026

GENUS MEDICAL TECHNOLOGIES LLC,
APPELLEE

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
APPELLANT

Appeal from the United States District Court
for the District of Columbia
(No. 1:19-cv-00544)

Daniel Winik, Attorney, U.S. Department of Justice, argued the cause for appellant. With him on the briefs were *Jeffrey Bossert Clark*, Acting Assistant Attorney General, *Scott R. McIntosh*, Attorney, *Robert P. Charrow*, General Counsel, U.S. Department of Health and Human Services, *AnnaMarie Kempic*, Deputy Chief Counsel for Litigation.

Noam B. Fischman was on the brief for *amicus curiae* Bracco Diagnostics Inc. in support of appellant.

James A. Boiani was on the brief for *amicus curiae* Giskit B.V. in support of appellant.

Douglas B. Farquhar argued the cause and filed the brief for appellee.

Before: HENDERSON, PILLARD and KATSAS, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* HENDERSON.

Opinion concurring in the judgment filed by *Circuit Judge* PILLARD.

KAREN LECRAFT HENDERSON, *Circuit Judge*: The Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. §§ 301 *et seq.*, sets forth separate and detailed regimes for the regulation of medical products classified, *inter alia*, as drugs or devices. The question before us is whether the U.S. Food and Drug Administration (FDA) enjoys discretion to classify as a "drug" a product that meets the statutory definition of a "device." The FDA claims that, if a medical product satisfies the statutory definitions of both a "drug" and a "device," the Act's overlapping definitions grant by implication the FDA broad discretion to regulate the product under either regime. Since 2017 the FDA has exercised its claimed discretion to classify Genus Medical Technologies' (Genus) "Vanilla SilQ" line of diagnostic contrast agents as drugs, notwithstanding the FDA's recognition that the products "appear" to satisfy the statutory definition for devices. Genus subsequently filed suit, challenging the FDA's classification decision as inconsistent with the Administrative Procedure Act (APA), 5 U.S.C. § 706(2), and the FDCA. Finding that the FDCA unambiguously forecloses the FDA's interpretation, the district court granted summary judgment in Genus's favor and vacated the FDA decision to classify Genus's products as drugs. We agree with the district court that the text, statutory structure and legislative history of the Act make plain that the Congress did

not grant the FDA such sweeping discretion. Accordingly, we affirm the district court's grant of summary judgment.

I. BACKGROUND

A. Statutory & Regulatory Framework

The FDCA grants the FDA the authority to regulate certain categories of medical products, including drugs, devices, biologics and dietary supplements. Relevant here are the statutory definitions for "drug" and "device." The Act, in relevant part, defines "drugs" to include:

> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . . .

21 U.S.C. § 321(g)(1)(B). "Devices" are defined to include:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . 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, . . . and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Id. § 321(h)(1).[1] Because the two definitions share a common "intended-use clause"—that is, both definitions include articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease—and because the drug definition features no other relevant limitations, it is apparent that any product that satisfies the "device" definition also satisfies the definition of a "drug." The converse, however, is not true. Because a device must be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," and further, because it may neither "achieve its primary intended purposes through chemical action within or on the body of man" nor be "dependent upon being metabolized for the achievement of its primary intended purposes,"[2] the set of products that satisfy the device definition is necessarily encompassed by, but narrower than, the set of products that satisfy the drug definition.

Drugs and devices are subject to distinct regulatory regimes. To begin, separate divisions of the FDA are primarily responsible for each product category. Whereas drugs are

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[1] At the time of the FDA's decision, the device definition was located at 21 U.S.C. § 321(h). The Congress later relocated the amendment to 21 U.S.C. § 321(h)(1). *See* Safeguarding Therapeutics Act, Pub. L. No. 116-304, § 2(b), 134 Stat. 4915, 4916 (2011) (codified at 21 U.S.C. § 321(h)(1)).

[2] Although FDA guidance refers to these "primary intended purpose[]" limitations as the device definition's "exclusionary clause" or exclusionary clauses, *Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff*, U.S. Dep't of Health and Human Servs., FDA, 6 & n.11 (Sept. 2017), https://www.fda.gov/media/80384/download, we refer to them as the "mode-of-action clauses" in order to distinguish them from the "instrument clause," which also has the effect of "excluding" certain products that would otherwise satisfy the device definition. *See supra* n.1.

generally regulated by the FDA's Center for Drug Evaluation and Research, devices are within the purview of the FDA's Center for Devices and Radiological Health.

The FDA holds new drugs to a high standard of pre-market review and approval. To market a new prescription drug, the sponsor (typically the manufacturer) must submit a new-drug application and demonstrate through clinical trials that the drug is safe and effective for its proposed use. 21 U.S.C. § 355(a)–(b). Sponsors may, however, be able to take advantage of an abbreviated new-drug application if their drug is sufficiently similar to drugs that the FDA has previously approved. *Id.* § 355(j).

The FDA's pre-market review of devices is more varied. Devices are assessed by the FDA and, with the assistance of expert "classification panels," classified into one of three categories based on the risks they pose. *Id.* § 360c. First are Class I devices, which are "subject only to minimal regulation by 'general controls'" because they "present no unreasonable risk of illness or injury . . . ." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476–77 (1996) (quoting 21 U.S.C. § 360c(a)(1)(A)). Class II devices include "[d]evices that are potentially more harmful" and, "although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as 'special controls.'" *Id.* at 477 (quoting 21 U.S.C. § 360c(a)(1)(B)). Finally, devices that, *inter alia*, "'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health'" are generally classified as Class III and, like drugs, subject to pre-market approval. *Id.* (alteration in original) (quoting 21 U.S.C. § 360c(a)(1)(C)); 21 U.S.C. § 360e. To introduce a new Class III device into the

market, the sponsor must provide the FDA with "detailed information regarding the safety and efficacy" of the device and the FDA must have "'reasonable assurance' that the device is both safe and effective." *Medtronic*, 518 U.S. at 477 (quoting 21 U.S.C. § 360e(d)(2)).

The regulatory differences do not end at the product approval stage. Throughout the lifecycle of a medical product, its treatment by the FDA depends upon its classification as either a drug or a device. The FDCA sets forth separate rules for, *inter alia*, annual manufacturer registration, *compare* 21 U.S.C. § 360(b)(1) (registration requirements for drug manufacturers), *with id.* § 360(b)(2) (registration requirements for device manufacturers); routine manufacturer inspections, *compare* 21 U.S.C. § 360(h)(3) (risk-based inspection schedules for drug manufacturers), *with id.* § 360(h)(2) (risk-based inspection schedules for device manufacturers); routine product reporting, *see id.* § 356i (reporting of marketing status for drugs only); and adverse-event reporting, *compare id.* § 355b (reporting of adverse drug events), *with id.* § 360i (records and reports on devices, including reporting of adverse device events).

The result is that, on average, it is more costly for a sponsor to develop and market a product as a drug than it would be to develop and market an otherwise identical product as a device. Genus maintains that its cost would be approximately $60,000 to seek device clearance for Vanilla SilQ—the product line in question here. *Genus Med. Techs., LLC v. FDA*, 427 F. Supp. 3d 74, 78 (D.D.C. 2019). If, however, the same product line were classified as drugs, Genus estimates that it would cost them more than $500,000 to obtain pre-market approval in addition to a recurring cost of more than $186,000 per year to continue marketing their products as drugs. *Id.*

Fortunately for sponsors, the FDCA contemplates at least a limited role for sponsor input in the course of the product classification process. Specifically, if the classification of a product is unclear, a product sponsor may file a request for designation (RFD) to obtain a formal, binding determination from the FDA as to the "classification of the product . . . or . . . the component of the [FDA] that will regulate the product." 21 U.S.C. § 360bbb-2(a). A sponsor submits its RFD—including a recommended classification—to the FDA's Office of Combination Products (OCP) and the OCP must respond thereto no later than 60 days after the RFD's filing. *Id.* § 360bbb-2(b). If the OCP fails to respond, the sponsor's recommended classification becomes final. *Id.* § 360bbb-2(c). A classification made through the RFD process cannot be changed "except with the written consent of the [sponsor], or for public health reasons based on scientific evidence." *Id.* § 360bbb-2(b)–(c).

B. Factual and Procedural History

Genus has manufactured its Vanilla SilQ product line since 2015. Compl. ¶ 25. Vanilla SilQ belongs to a category of products known as contrast agents. Contrast agents are used in medical imaging to improve the visualization of tissues, organs and physiological processes. According to Genus, Vanilla SilQ is an oral solution used in combination with X-ray examinations or other radiologic procedures to enhance the visualization of the gastrointestinal tract for diagnostic purposes. The product's key ingredient is an inert metal salt known as barium sulfate. When swallowed, the barium sulfate coats the inside of the individual's gastrointestinal tract and facilitates the absorption of X-rays. Subsequently, the X-ray examination will appear lighter for areas coated with barium sulfate and darker for the surrounding tissues that are not coated. Although some contrast agents cannot be classified as

devices because they achieve their primary intended purpose through metabolization or chemical action within or on the body of man, the FDA agrees that Genus's Vanilla SilQ product line "appear[s] to meet the definition of 'device'" insofar as it does not achieve its primary intended purposes through either of the excluded modes.[3] Appellant's Br. 12–13.

Genus avers "that before and after it started producing Vanilla SilQ, it sought FDA clearance to distribute its products" as either devices or grandfathered drugs (which, unlike new drugs, do not require pre-market approval). *Genus*, 427 F. Supp. 3d at 79. In June 2016, however, the FDA conducted a three-day inspection of Genus's distribution facility. *Id.* The result of the inspection was a warning letter, issued on May 2, 2017, notifying Genus that its products constituted "drugs" within the meaning of the FDCA. *Id.* Genus, responding to the FDA in a letter dated May 19, 2017, asserted that its products are devices and that the FDA could not regulate them as drugs because they do not "achieve [their]

[3] We note that it is not immediately obvious to us how a contrast agent satisfies the device definition's requirement that the regulated product be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory . . . ." 21 U.S.C. § 321(h)(1). Nor is it altogether settled that Vanilla SilQ satisfies the device definition's mode-of-action clauses. *Compare, e.g.*, Amicus Bracco Br. 5–6 (arguing that Vanilla SilQ may not be regulated as a device because it achieves its primary intended purpose through chemical action), *with* Appellee's Br. 52 (arguing that Vanilla SilQ does not achieve its primary intended purpose through chemical action). Because neither question is part of the administrative decision now under review—the FDA found only that Genus's products "appear to meet" the device definition, *see* Joint Appendix (J.A.) 122, 152, and both parties continue to agree that they do—we reserve the question whether Vanilla SilQ satisfies the device definition's instrument and mode-of-action clauses.

primary intended purposes through chemical action within or on the body" or through "metaboliz[ation]." J.A. 157–61 (quoting 21 U.S.C. § 321(h)(1)). On September 6, 2018, the FDA responded that, "[a]lthough [the Vanilla SilQ products] appear to meet the definition of 'device' . . . they also meet the definition of 'drug' [under the FDCA] because they are articles intended for use in the diagnosis of disease." *Id.* at 152. The FDA stated that "[w]hile [it] generally regulates products that meet the definition of a device under the device authorities, there are certain exceptions" and "[b]ecause not all contrast agents meet the definition of a device, but all of them do meet the definition of a drug, [it] has for many years regulated these products as drugs in order to regulate them consistently under the same authority . . . ." *Id.*

Having failed to convince the FDA through its correspondence, Genus next submitted an RFD, in which it formally requested that the OCP classify its Vanilla SilQ products as devices under the FDCA. *Genus*, 427 F. Supp. 3d at 79–80. The OCP responded with an official Designation Letter in which it echoed the FDA's previous reasoning that, although the Vanilla SilQ products appeared to meet the definitions for both a device and a drug, it was nonetheless appropriate to regulate uniformly all contrast agents as drugs. *Id.* at 80.

On February 28, 2019 Genus filed suit in district court. In addition to certain claims not relevant here, Genus claimed that the FDA's decision to regulate Vanilla SilQ as a drug rather than as a device was arbitrary and capricious and in excess of statutory authority under the FDCA and the APA. In a decision filed December 6, 2019, the district court granted summary judgment to Genus, concluding that the plain language of the FDCA unambiguously requires that "a product that meets the device definition must be regulated as such" and that the court

must therefore "end[] its analysis at *Chevron* step one." *Genus*, 427 F. Supp. 3d at 84. The district court vacated the FDA's classification of Vanilla SilQ as a drug and remanded the matter to the FDA for further proceedings. *Id.* at 87.

II. ANALYSIS

Our review of a summary judgment grant is *de novo*, affirming only if "there is no genuine issue as to any material fact [and] the moving party is entitled to judgment as a matter of law." *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1278–79 (D.C. Cir. 2004) (alteration in original) (quoting *Trans Union LLC v. Fed. Trade Comm'n*, 295 F.3d 42, 48 (D.C. Cir. 2002)). In a case like this one, in which the district court reviewed an agency action under the APA, "[w]e review the administrative record and give no particular deference to the District Court's views." *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 329–30 (D.C. Cir. 2020) (quoting *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 662 (D.C. Cir. 2019)). We review the FDA decision to classify Genus's products, then, under the familiar standards of the Administrative Procedure Act, which require that we uphold the FDA decision unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations . . . ." 5 U.S.C. § 706(2). We defer to the FDA's interpretation of the FDCA "so long as the Congress has not unambiguously forbidden it and it is otherwise permissible." *Cal. Metro Mobile Commc'ns, Inc. v. FCC*, 365 F.3d 38, 43 (D.C. Cir. 2004) (citing *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984)); *see also Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1315 (D.C. Cir. 2010) (applying *Chevron* framework to FDA interpretations of FDCA contained in letter rulings); *Mylan Labs.*, 389 F.3d at 1279–80 (same). Our task requires that "[w]e examine the

statute's text, structure, purpose, and legislative history to determine if the Congress has expressed its intent unambiguously." *Eagle Pharms.*, 952 F.3d at 330 (alteration omitted) (quoting *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 605 (D.C. Cir. 2016) (per curiam)).

A. FDCA's Text

The question before us is a purely legal one: whether the FDCA grants the FDA discretion to classify as a "drug" a product that satisfies the statutory definitions of both a "drug" and a "device." In answering the question, "[w]e begin 'where all such inquiries must begin: with the language of the statute itself.'" *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 412 (2012) (quoting *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989)). We are mindful, however, that if the text alone is insufficient to end the inquiry, we may turn to other "customary statutory interpretation tools," including "'structure, purpose, and legislative history.'" *Cal. Metro Mobile*, 365 F.3d at 44–45 (quoting *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 297 (D.C. Cir. 2003)); *see also Chevron*, 467 U.S. at 843 n.9 ("If a court, *employing traditional tools of statutory construction*, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.") (emphasis added). We conclude that the FDCA's text unambiguously forecloses the FDA's interpretation.

The parties' dispute is purely legal. Genus contends that when a product satisfies both the drug and device definitions of the FDCA, the product is a device. Conversely, the FDA argues that it can choose whether to treat products that satisfy both definitions as drugs or devices. Because the FDA's legal theory did not require it to do so, it made no factual findings about whether the Vanilla SilQ products satisfied the particular

requirements of the FDCA's device definition. Instead, it found only that the products fell within the drug definition and remarked that they "appear" to also satisfy the device definition.

Beginning with the statute's text, the FDA argues that, because it is possible for a product to simultaneously satisfy the linguistic demands of both the drug and device definitions, the Congress must have granted the FDA discretion in such instance to choose a classification. Simply put, any product meeting the device definition may be classified as a device, any product meeting the drug definition may be classified as a drug and, according to the FDA's reading, any product meeting *both* definitions may be classified as *either*. To the extent the FDCA is silent on how to treat products that meet both definitions, the FDA argues that we should read it as a sign of statutory ambiguity and defer to the FDA's purportedly reasonable interpretation.

Whereas the FDA draws our attention to the definitional overlap, Genus urges us to focus on the elements of the device definition that set it apart, including, most prominently, its mode-of-action clauses. Genus argues that, because the drug and device definitions are broadly similar except for the device definition's mode-of-action clauses—excluding products that achieve their primary intended purposes through "chemical action within or on the body of man" or "metaboliz[ation]," 21 U.S.C. § 321(h)(1)—products that do not achieve their primary intended purposes through either excluded mode (and that otherwise satisfy both definitions) must be regulated as devices and devices alone. According to Genus, any other interpretation would "effectively read[] the Mode of Action Clause[s] out of the statute." Appellee's Br. 23.

Genus also urges us to rely on two traditional canons of statutory construction. First, the "old and familiar rule" that "the specific governs the general." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645–46 (2012) (quoting *United States v. Chase*, 135 U.S. 255, 260 (1890); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)). And second (and relatedly), the basic interpretive canon that a "statute should be construed [to give effect] to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)). Applying these canons, Genus argues that the FDA's interpretation would render the device definition's mode-of-action clauses inoperative and allow the device definition to be "swallowed by the more general drug definition." Appellee's Br. 30–31 (quoting *Genus*, 427 F. Supp. 3d at 83).

Although we are unpersuaded that the FDA's interpretation would render the mode-of-action clauses completely inoperative—under the FDA's theory, the mode-of-action clauses would still be necessary for differentiating products that *may* be regulated as devices from those that may not—we nonetheless agree with Genus that this is a case where the specific must govern the general. The FDA does not dispute that the FDCA's definition of a "device" is drawn more narrowly than its definition of a "drug." Indeed, as we discussed above, *supra* Section I.A, the set of products that satisfy the device definition is necessarily encompassed by, but narrower than, the set of products that satisfy the drug definition.[4] Moreover, the general-specific canon is

[4] The concurring opinion contends that recognizing complete overlap in the definitions would render the instrument clause surplusage. Concurring Op. 7–8. But the instrument clause, like the mode-of-action clauses, necessarily restricts which medical products are devices. It does clear work in determining which medical

particularly appropriate where, as here, the provisions at issue are "interrelated and closely positioned" as "parts of the same statutory scheme." *RadLAX Gateway Hotel*, 566 U.S. at 645 (alteration adopted) (quoting *HCSC-Laundry v. United States*, 450 U.S. 1, 6 (1981) (per curiam)). Thus, the device definition's instrument and mode-of-action clauses make it a classic candidate for application of the canon that the specific governs the general, and to the extent the drug and device definitions conflict, it is the narrower definition—the device definition—to which we must give effect. *See D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932) ("Specific terms prevail over the general in the same or another statute which otherwise might be controlling.").

The only question, then, is whether the two definitions are truly in conflict. The FDA claims they are not. More specifically, according to the FDA, the general-specific canon is inapplicable here because it is "most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission" or where "a general authorization and a more limited, specific authorization exist side-by-side." *RadLAX Gateway Hotel*, 566 U.S. at 645. The FDA argues that there is no such contradiction here because the provisions in question are definitions as opposed to authorizations or prohibitions and both definitions can be given simultaneous effect. There is "no reason," according to the FDA's opening brief, that "the statute *must* be read so that a given product qualifies as either a 'drug' or a 'device,' but not both." Appellant's Br. 24 (emphasis in original).

On this point the FDA is mistaken. In theory, it may be possible for a product to satisfy both definitions at once. What

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products, from among those that satisfy the broader drug definition, also satisfy the narrower device definition.

the FDA omits, however, is that the FDCA's statutory definitions are meaningful only insofar as they carry concrete regulatory consequences. As discussed, the FDCA elaborates distinct regulatory regimes for drugs and devices. And each scheme is mandatory: The FDCA prohibits the sale of "*any* new drug" not approved under the regime for drug approvals. 21 U.S.C. § 355(a) (emphasis added). Similarly, *all* new Class III devices are "required" to satisfy the pre-market review regime for devices, *id.* § 360e(a), and Class I and Class II devices must meet other distinct requirements, *see id.* § 360c. Nor can the Secretary circumvent these requirements. *Id.* § 355(c)(1) (Secretary "shall" either approve new-drug application pursuant to drug regime or deny application); § 360c(b)(1) (Secretary "shall" classify "all" new devices intended for human use into three device classes). In short, it is not textually possible to say that an item *is* a drug (or device) but need not be regulated as such. And no one suggests that the FDCA requires products meeting both definitions to be regulated *both* as drugs and devices, which would create a breathtaking example of statutory redundancy. The statute, then, is clear: a product may be regulated as a drug *or* a device, but not both, and while a single product may simultaneously satisfy the linguistic elements of two definitions, it is not possible for the FDA to give simultaneous *effect* to both. Thus, this is precisely the sort of setting in which we must give effect to the specific over the general. To do otherwise would be in violation of the "settled" principle that "[h]owever inclusive may be the general language of a statute, it will not be held to apply to a matter specifically dealt with in another part of the same enactment." *Fourco Glass Co. v. Transmirra Prods. Corp.*, 353 U.S. 222, 228 (1957) (quoting *Clifford F. MacEvoy Co. v. U.S. ex rel. Calvin Tomkins Co.*, 322 U.S. 102, 107 (1944)).

Before proceeding to the parties' structural claims, we briefly dispatch with the FDA's argument that we should be guided by a 1990 amendment to the FDCA's drug definition. Specifically, the FDA argues that interpreting the drug and device definitions as mutually exclusive would be to "effectively read[] back into the statute" an old version of the drug definition the Congress affirmatively abandoned when it adopted the Safe Medical Devices Act of 1990 (SMDA), Pub. L. No. 101-629, 104 Stat. 4511. Appellant's Br. 21–22. Before 1990, the FDCA definition of a drug specifically excluded "devices or their components, parts, or accessories." FDCA, Pub. L. No. 75-717, § 201(g), 52 Stat. 1040, 1041 (1938) (codified as amended at 21 U.S.C. § 321(g)(1)). The 1990 SMDA struck this exclusionary language, thereby making it possible for a single product to satisfy—simultaneously—the terms of both definitions. SMDA § 16(b)(1), 104 Stat. at 4526. The FDA argues that, by eliminating the drug definition's exclusionary language, the Congress granted it authority to regulate certain products as either drugs *or* devices.

This argument presumes that the Congress dramatically expanded the FDA's authority by deleting a phrase from a statutory definition. As the Supreme Court has counseled, "[f]undamental changes in the scope of a statute are not typically accomplished with so subtle a move." *Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter*, 575 U.S. 650, 661 (2015). Instead, we conclude that "the removal of the . . . provision was more plausibly driven by" a narrower concern. *Id.* The change occurred in a section of the statute authorizing the FDA to "regulate products that constitute a combination of a drug, device, or biological product," depending on "the primary mode of action of the combination product." SMDA § 16(a), 104 Stat. at 4526 (codified as amended at 21 U.S.C. § 353(g)) (authorizing the regulation of "combination products"). These new provisions thus created a

distinct regulatory regime that gave the Secretary flexibility to determine the standards for pre-market review of these combination products. *See, e.g.*, 21 U.S.C. § 353(g)(2)(A)(ii)(I) (entitling sponsors of combination products to meet with the Secretary to "address the standards and requirements for market approval or clearance of the combination product"); *id.* § 353(g)(7) ("Nothing in this subsection shall prevent the Secretary from using any agency resources of the [FDA] necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article."). The definitional change helped to implement the scheme by removing the previously categorical prohibition on ever treating a drug as a device and vice versa. *See Miller v. Mylan Inc.*, 741 F.3d 674, 677 (6th Cir. 2014) ("The deletion reflected the replacement of the binary scheme with a tripartite scheme[that included combination products]."). But the amended definition provides no affirmative support for the proposition that the FDA may treat drugs as devices—and vice versa—even absent any combination. As explained above, the FDCA's basic textual architecture forecloses such reading of the statute.

Legislative history confirms that the amendments seek only to facilitate the FDA's regulation of the new category of "combination products."[5] *See* S. Rep. No. 101-513, at 43 (1990) ("Section 19 [of the SMDA] alters the drug and device definitions in [21 U.S.C. § 321]. Language is removed from the drug definition *that will permit an approval of a drug/device combination*.") (emphasis added); *id.* at 30 ("By deleting this language, a product whose primary mode of action

[5] We note that our analysis of the FDA's argument regarding the 1990 SMDA depends upon the FDCA's legislative history, which we further discuss in the following section, *infra* Section II.B. Because the FDA's SMDA argument is primarily textual, we address it here.

is attributable to a drug, but has a device component, may be reviewed under this Act's drug authority."). Thus, we read the SMDA to facilitate the regulation of combination products, not to grant the FDA near-limitless discretion to categorize as drugs *any* product meeting the device definition.[6]

B. FDCA's Structure, Purpose and Legislative History

We turn next to the FDCA's structure, purpose and legislative history. *See, e.g.*, *Pharm. Rsch. & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 224 (D.C. Cir. 2001); *see also Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 101 (2012) ("[Because s]tatutory language . . . 'cannot be construed in a vacuum . . . [i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'") (quoting *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 809 (1989)). All of these considerations reinforce our conclusion.

As set out above, *supra* Section I.A, the FDCA establishes two distinct regulatory tracks, one for drugs and one for devices. Although certain aspects of the regulatory regimes are common, *see, e.g.*, 21 U.S.C. § 352 (defining a single standard by which "[a] drug or device shall be deemed to be misbranded"), several vital aspects are not. Especially salient here are the FDCA's dual regimes for pre-market review and approval. Subject to limited exceptions, new drugs require pre-

[6] The concurring opinion reads the amendment as "just the kind of 'textual indication' that may override" the general-specific canon. *See* Concurring Op. 6–7 (alteration adopted) (quoting *RadLAX Gateway Hotel*, 566 U.S. at 646). But deleting the express exclusion from the drug definition only raised the general-specific question without answering it. And as discussed, we decline to embrace such a large grant of authority from a negative inference in statutory history.

market approval based upon clinical showings of safety and efficacy, *see* 21 U.S.C. § 355(a)–(b), while devices are subject to varying levels of pre-market review depending upon the risk they pose. Only Class III devices—so classified because they "present[] a potential unreasonable risk of illness or injury" or because they are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," *id.* § 360c(a)(1)(C)—generally require pre-market approval. *Id.* § 360e. Nor is the FDA's authority over the classification of devices entirely unfettered. The FDA is required to convene expert panels to provide recommendations on its device classification decisions, *id.* § 360c(b), and device sponsors are entitled to participate in the classification process. *Id.* § 360c(b)(6). It would make little sense, then, for the Congress to have constructed such elaborate regulatory regimes—carefully calibrated to products' relative risk levels—only for the FDA to possess the authority to upend the statutory scheme by reclassifying *any* device as a drug, no matter its relative risk level.

The legislative history underscores our analysis. As discussed above, *see supra* Section I.A, setting aside products that are not "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," 21 U.S.C. § 321(h)(1), what distinguishes a drug from a device under the FDCA is that a device excludes a product that achieves its primary intended purposes through either chemical action or metabolization. This, however, was not always the case. The two mode-of-action clauses were added to the FDCA's device definition by the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539, and the legislative history strongly suggests that the Congress's aim, at least in part, was to formalize a distinction—apparently already "administratively developed"

by the FDA—between drugs and devices based upon their modes of action and the relative risk levels created by those modes of action. *See* S. Rep. No. 94-33, at 6 (1975) (explaining that the "FDA has administratively developed a distinction between drug and device, which favors classifying a product as a drug if its intended action is chemical, or based on highly complex technology potential hazards of which may be reduced through new drug controls"). Granted legislative history is hardly dispositive, but we nonetheless see in it additional evidence that the Congress established separate regulatory tracks for drugs and devices and that the device definition's mode-of-action clauses were critical to effectuating this bifurcated scheme.

The FDA offers its own arguments regarding the FDCA's statutory structure but none is compelling. Specifically, the FDA directs our attention to two provisions of the FDA Reauthorization Act of 2017 (FDARA), Pub. L. No. 115-52, 131 Stat. 1005, both of which relate to the marketing of a medical imaging device intended for use with a prior-approved contrast agent but the contrast agent's new intended use is different from the prior-approved intended use. The first provision grants the FDA authority to approve certain "medical imaging device[s]" notwithstanding they "involve[] the use of a contrast agent" in a manner different from that described in the agent's approved labeling. *Id.* § 706(a), 131 Stat. at 1058–59 (codified at 21 U.S.C. § 360j(p)). The FDA latches onto language in this provision defining a "contrast agent," in relevant part, as "*a drug* that . . . is intended for use in conjunction with an applicable medical imaging device . . . ." *Id.* § 706(a), 131 Stat. at 1059 (emphasis added) (codified at 21 U.S.C. § 360j(p)(4)(B)). The second provision grants the FDA authority to approve a contrast agent's new intended use based upon the submission of a supplement to the sponsor's original new drug application. *Id.* § 706(b), 131 Stat. at 1059–60

(codified at 21 U.S.C. § 355(y)). The FDA argues that both FDARA provisions evince a congressional intent to ratify the FDA's practice of uniformly regulating all contrast agents as drugs.

Despite its superficial appeal, the FDA's argument is unavailing. First, the FDARA's definitional language—defining a contrast agent as "a drug"—was explicitly provided "[f]or purposes of *this subsection* . . . ." *Id.* § 706(a), 131 Stat. at 1059 (emphasis added) (codified at 21 U.S.C. § 360j(p)(4)). Subsection 360j(p) authorizes treating as devices the combination of imaging devices paired with contrasting agents previously approved as drugs. 21 U.S.C. § 360j(p). But some contrast agents work through chemical action within the body and thus plainly *are* drugs. *See id.* § 321(h)(1). The special rules provided in this context thus hardly suggest that the FDA may generally treat *all* contrast agents as drugs, much less constitute "express congressional approval" for such a rule. *Gen. Am. Transp. Corp. v. ICC*, 872 F.2d 1048, 1053 (D.C. Cir. 1989) (quoting *AFL-CIO v. Brock*, 835 F.2d 912, 915 (D.C. Cir. 1987)). The second provision cited by the FDA, 21 U.S.C. § 355(y), likewise governs contrast agents previously approved as drugs, which does not suggest that all contrast agents must (or even may be) so classified. Even more fundamentally, we strongly doubt that the Congress would have chosen to hide such a major grant of regulatory discretion in so narrow an amendment. Had it intended to endorse the view that the FDA may regulate *all* contrast agents as drugs rather than devices, it would have used more explicit language to do so. Here as elsewhere we "must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency" and we are skeptical that the Congress would grant the FDA such vast authority "in so cryptic a

fashion." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 160 (2000).

The FDCA's structure, purpose and legislative history confirm our reading of the text. *See Teva Pharms.*, 595 F.3d at 1315 (analyzing statutory structure and setting aside FDA's interpretation of FDCA where text alone "hardly rules out alternative readings that, absent consideration of statutory structure, also appear plausible"). They make plain that the Congress did not grant the FDA near-limitless discretion to classify any device as a drug. Rather, the Congress has elaborated separate regulatory tracks for drugs and devices and, to the extent that the FDA possesses the discretion to choose one track or the other, such discretion must be exercised in a manner consistent with the statutory "drug" and "device" definitions.

We note that we are especially troubled by the FDA's inability to articulate a limiting principle with which to cabin its asserted discretion. The FDA offers only that, like all other agency actions, its classification decisions are subject to the APA's arbitrary and capricious standard. But the arbitrary and capricious standard is necessarily narrow, *see Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), and seldom is that more true than in the context of highly technical matters like the FDA's medical product classifications, *see, e.g.*, *Kennecott Greens Creek Min. Co. v. Mine Safety & Health Admin.*, 476 F.3d 946, 954–55 (D.C. Cir. 2007) (agency is entitled to "extreme degree of deference" when "evaluating scientific data within its technical expertise") (quoting *Hüls Am. Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir. 1996)). Thus, what the FDA attempts to claim for itself is the near-limitless authority to classify *any* device as a drug, subject only to a highly deferential standard of judicial review. We cannot reasonably infer such broad discretion

without a clearer statement. *See Whitman v. Am. Trucking Ass'ns*, *Inc.*, 531 U.S. 457, 467–68 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").[7]

The concurring opinion stresses the need for the FDA to bring its expertise to bear on close questions regarding whether the instrument clause covers particular kinds of medical products. Concurring Op. 11–14. We do not deny that when the instrument clause (and, for that matter, the mode-of-action clauses) are ambiguous in their application to some kind of medical product, reviewing courts should respectfully consider the expert views of the FDA, which may even qualify for *Chevron* deference. But here, the FDA did not invoke its expertise to contend that Vanilla SilQ does not satisfy the device definition and so should be regulated as a drug. Instead, it assumed that Vanilla SilQ meets the definition of a device but nevertheless undertook to regulate it as a drug. In rejecting that position, we do nothing to restrict the agency's discretion to determine, in close cases, whether a particular product satisfies the device definition. Indeed, we expressly reserve that question in this case. *See supra* n.3.

We emphasize the purely legal nature of the question before us. Because its interpretation of the FDCA did not require it to do so, the FDA made no factual findings with respect to Vanilla SilQ except that it is an article intended for use in the diagnosis, cure, mitigation, treatment or prevention

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[7] We also disagree that the FDA's restrained use of discretion in the past blunts this concern or otherwise provides a basis to limit any purported discretion. *See Carlson v. Postal Reg. Comm'n*, 938 F.3d 337, 349 (D.C. Cir. 2019) ("[N]o amount of historical consistency can transmute an unreasoned statutory interpretation into a reasoned one." (internal quotations omitted)).

of disease—that is, the minimum findings necessary for classification as a drug. We do not and cannot consider whether the FDA's assumption that Vanilla SilQ satisfies the device definition is a valid one because it was not the basis for the FDA's decision. *See SEC v. Chenery Corp.*, 318 U.S. 80, 93–94 (1943). Instead, we necessarily address only the FDA's conclusion that the FDCA grants it discretion to classify as a "drug" any product that meets the statutory definition of a "device." We hold that it does not. Excepting combination products, *see* 21 U.S.C. § 353(g), devices must be regulated as devices and drugs—if they do not also satisfy the device definition—must be regulated as drugs.[8] Thus, the FDA's decision must be set aside because it was based on an erroneous interpretation of law. *See* 5 U.S.C. § 706(2).

For the foregoing reasons, the judgment of the district court is affirmed.

So ordered.

[8] Our reading does not, as the concurring opinion suggests, limit the drug definition "to products with the modes of action specified in the device definition's exclusions." Concurring Op. 14. A product that satisfies the drug definition and the mode-of-action clauses in the device definition would still be a drug if it could not satisfy the instrument clause.

PILLARD, *Circuit Judge*, concurring in the judgment: Our role on review is limited to determining whether Congress has unambiguously foreclosed the FDA's statutory interpretation, and, if not, whether the agency's decision is nonarbitrary and reasonably explained. In regulating Vanilla SilQ as a drug, the FDA asserted that the FDCA's drug definition fully subsumes the device definition so grants the FDA authority to regulate any device as a drug. *See* J.A. 121-22; Appellant's Br. 6-7, 15-17. Vanilla SilQ is a contrast agent used in radiologic procedures including X-rays. The mode of action of some other contrast agents prevents their regulation as devices. Because the agency deemed it administratively convenient to regulate Vanilla SilQ together with other contrast agents, whatever their mode of action, it decided to regulate Vanilla SilQ under the drug regime. *See* J.A. 122 & n.5.

The majority acknowledges that the text of the drug and device definitions describes some overlap. *See* Maj. Op. 4, 13. But, cued by the FDA's overbroad claim of discretion, my colleagues view the textual overlap as conferring implausibly "sweeping," "near-limitless" power on the FDA to regulate any device as a drug, contrary to the congressional scheme. *Id.* at 3, 18, 22. Cognizant that Congress defined devices separately from drugs for important reasons, the majority resorts to statutory structure and history to conclude that the drug and device definitions overlap not at all, so are entirely mutually exclusive. *Id.* at 11, 14-15, 17-18, 22, 24.

I agree with my colleagues that the FDA misread the statute in concluding that the drug definition fully subsumes devices. But I join the judgment only, because the majority overshoots in the other direction by insisting the statute unambiguously eliminates all overlap of the drug and device definitions. There is overlap, but it is only partial.

Both the FDA's and my colleagues' readings overtly disregard textual specificity within the device definition that

assigns particular types of products to the regulatory pathway for devices, not drugs. Whereas the drug definition refers to "articles" intended for medical uses, 21 U.S.C. § 321(g)(1)(B), the device definition singles out as devices any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory," intended for those same uses, *id.* § 321(h)(1). That more specific list—the "instrument clause," for short—communicates Congress's intent not to grant the FDA the broad discretion it claims. The FDA is wrong to view the device definition as describing a fully nested subset of the drug definition; it clearly prevents assignment of many devices—from bathroom scales and band-aids to respirators and ultrasound machines—to the regulatory pathway for drugs.

The FDA has yet to grapple with the product characteristics Congress deemed relevant. The agency simply assumed that Vanilla SilQ meets the device definition. It treated the instrument clause as a nullity and proceeded as if the mode-of-action exclusions did not apply to Vanilla SilQ. *See* Appellant's Br. 21; J.A. 121-22, 152; *see also* Oral Arg. Tr. 5:10-6:12. It neither identified in what respect Vanilla SilQ might or might not be considered an "instrument," nor verified how it avoids the device definition's mode-of-action exclusions. The agency accordingly failed to explain its decision to regulate Vanilla SilQ as stringently as a drug in any way that accounts for the factors Congress deemed relevant to its design of distinct drug and device regimes. The explanation it did provide, turning on little more than administrative convenience, falls short, so requires remand to the FDA. That is as far as we need to go to decide this case.

I.

Our review of the FDA's classification decision pursuant to the FDCA turns on "whether Congress has unambiguously foreclosed the agency's statutory interpretation." *Vill. of Barrington v. Surface Transp. Bd.*, 636 F.3d 650, 659 (D.C. Cir. 2011) (internal quotation marks and citation omitted). "If the agency's interpretation is not unambiguously foreclosed by the statute, we defer to its interpretation so long as it is reasonable." *Sorenson Commc'ns, LLC v. FCC*, 897 F.3d 214, 224 (D.C. Cir. 2018) (internal quotation marks and citation omitted); *see also Serono Lab'ys, Inc. v. Shalala*, 158 F.3d 1313, 1319-22 (D.C. Cir. 1998) (applying that framework to the FDA's interpretation of the FDCA). We cannot defer to an agency decision that rests on an erroneous statutory interpretation.

Our deference to the agency depends on its having engaged in reasoned decisionmaking, explaining how it accounted for all the factors relevant to the exercise of the authority Congress has given it. *See Judulang v. Holder*, 565 U.S. 42, 53 (2011); 5 U.S.C. § 706(2). We cannot sustain a ruling that fails to consider and explain an important aspect of the issue at hand. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *see also Pharm. Mfg. Rsch. Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020) (applying that standard to FDA action taken pursuant to the FDCA).

The bulk of my colleagues' analysis trains on the functional separation and mandatory character of the drug and device regulatory pathways. But nobody questions that, when faced with a product with the intended use common to both the drug and device definitions—*i.e.*, a product intended for use in the diagnosis, cure, mitigation, treatment, or prevention of

disease—the agency must regulate it as either a drug or a device, not both. *See* Appellant's Br. 16-17, 25-26; Maj. Op. 14-15. And all agree that the respective drug and device regimes are mandatory on the agency and the regulated parties. *See* Oral Arg. Tr. 9:18-10:9; Maj. Op. 15. The dispute here is whether the statute does all the work of sorting drugs from devices or whether it affords the agency some discretion in doing so and, if the latter, how much and with what guideposts.

The FDA claims leeway well beyond what the statute affords. My colleagues overlook definitional overlap the statute allows. I start with the overlap the majority denies, and then discuss how the FDA's discretion is bounded in ways the agency overlooks. I defend Congress's decision to allow for some overlap in the drug and device definitions in view of the complexity and heterogeneity of medical products and the challenge of assessing their efficacy and safety.

A.

The Supreme Court has long acknowledged "obvious areas of overlap in definition" of drugs and devices under the FDCA, even under an earlier version of the statute that manifested exclusivity in a way that it does not today. *United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 799 (1969). Congress codified a particular definitional overlap in 1990, when it cut from the drug definition its prior, express exclusion of "devices or their components, parts, or accessories." Safe Medical Devices Act of 1990 (SMDA), Pub. L. No. 101-629, § 16(b)(1), 104 Stat. 4511, 4526. It did so to clearly permit the FDA to regulate as drugs some products also meeting the device definition. The products foremost on the congressional agenda at that time were "combination products"—such as surgical mesh with anesthetic coating and drug-eluting cardiovascular stents that are "instruments" as

referenced in the device definition but that also function in part through chemical action or metabolization that would define them as drugs. *Capsular Decisions – Products Assigned to CDRH*, FDA (Feb. 16, 2018), https://www.fda.gov/combination-products/rfd-jurisdictional-decisions/capsular-decisions-products-assigned-cdrh. But the SMDA did not limit the amendment to those products, so we have no business doing so.

The majority insists Congress removed the drug category's exclusion of devices "only to facilitate the FDA's regulation of the new category of 'combination products.'" Maj. Op. 17. But it is the enacted text "rather than the principal concerns of our legislators by which we are governed." *Bostock v. Clayton County*, 140 S. Ct. 1731, 1749 (2020) (quoting *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998)). "The fact that Congress may not have foreseen all of the consequences of a statutory enactment is not a sufficient reason for refusing to give effect to its plain meaning." *Union Bank v. Wolas*, 502 U.S. 151, 158 (1991); *see* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 56 (2012) ("[T]he purpose must be derived from the text, not from extrinsic sources such as legislative history or an assumption about the legal drafter's desires."). Congress easily could have limited the scope of the amendment as the majority says it meant to do by writing it as an exception within the new provision for combination products, 21 U.S.C. § 353(g), relieving only combination products' device components from the drug definition's exclusion. Instead, Congress removed the device exclusion altogether.[1] It thus did not enact the mutual

[1] Even in referencing combination products, the legislative history does not describe the amendment as confined to them. *See* S. Rep. No. 101-513, at 43 (1990) (explaining that Congress removed the device exclusion from the drug definition to "permit" combination products); *id.* at 30 (explaining that the amendment

exclusivity of the statute's drug and device definitions that my colleagues detect.

The majority sees the device definition's mode-of-action exclusions as "critical to effectuating" non-overlapping statutory drug and device definitions. *See* Maj. Op. 20; *see also* Oral Arg. Tr. 29:2-17 (Genus arguing that the mode-of-action clauses are what distinguish drugs from devices). But those exclusions do not unambiguously remove definitional overlap. They prevent regulation of a product as a "device" insofar as it "achieve[s] its primary intended purposes through chemical action within or on the body of man or other animals" or is "dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(1). But by their terms those exclusions operate only in one direction: The text nowhere provides that the drug definition is confined to products reliant on the modes of action that the device definition excludes. Definitional overlap remains for products that do not achieve their primary intended purposes by chemical or metabolic action—a category that the FDA here assumed without deciding includes Vanilla SilQ.

The general-governs-the-specific canon on which the majority's reading depends is not to the contrary. *See* Maj. Op. 13-15. That canon is "a strong indication of statutory meaning" but "not an absolute rule." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 646 (2012). It cannot resolve all cases when the more specific provision is as qualitative as the device definition's instrument clause. (More on that below.) Plus, the partial overlap wrought by the 1990 Amendment is just the kind of "textual indication[]" that may

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ensured that drugs with device components "may be reviewed" as drugs).

override the canon in a case in which the agency provides sufficient explanation. *Id.*

Neither the mode-of-action exclusions nor the 1990 Amendment requires that Vanilla SilQ be regulated as a device. Nor do they together effectuate mutual exclusivity of the drug and device definitions.

B.

At the same time, acknowledgment of the statutory drug and device definitions' overlap—and the FDA's factual assumption that Vanilla SilQ falls within it—does not suffice to allow the FDA to classify the product as a drug. The agency claims that, apart from products the mode-of-action clauses identify as drugs, any product with the requisite intended use may be regulated as either a device or a drug. But the FDA is wrong that the mode-of-action exclusions are the only relevant constraint. *See* Appellant's Br. 6-7; *see also* Oral Arg. Tr. 5:10-6:12, 48:20-23. The device definition also has inclusionary language, defining a product as a device if it is an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory." 21 U.S.C. § 321(h)(1).

The FDA sees "device" as a fully nested subset of "drug" by noting that the general reference to "articles" in the drug definition, *id.* § 321(g)(1), is broad enough to subsume every "instrument, apparatus, . . . or other similar or related article" listed in the device definition's instrument clause, *id.* § 321(h)(1). *See* Appellant's Br. 6-7; Oral Arg. Tr. 8:12-20. Genus agrees, at least when it comes to the instrument clause. *See* Oral Arg. Tr. 29:2-17 (noting that both definitions use the term "articles," and that the statute distinguishes them with the device definition's mode-of-action clauses). That reading is

impermissible. "A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (citation omitted and formatting modified). The FDA violates the canon against superfluity by failing to give meaning to a big piece of the device definition.

The only argument the FDA puts forward is that its reading creates no superfluity because the two definitions remain distinct: "Products that satisfy the 'device' definition may be regulated either as drugs or as devices, whereas those that satisfy the 'drug' definition but not the 'device' definition may be regulated only as drugs." Appellant's Br. 16. But that misses the point. It does nothing to explain why Congress used twenty words in the device definition's instrument clause if it meant nothing more specific than is expressed by the word "articles" alone in the drug definition.

Notwithstanding that the FDA treats it as a nullity here, the instrument clause has all along done substantial work in assigning products to the device rather than the drug pathway. For starters, the FDA accounts for that clause in classifying as devices all manner of medical products, such as crutches, X-ray machines, and other "things that go clank." Oral Arg. Tr. 6:3; *see, e.g.*, 21 C.F.R. § 890.3150 (classifying a crutch as a device); *id.* § 892.1680 (classifying a stationary X-ray system as a device). With the instrument clause in view, it is obvious that the statute does not afford the agency the "near-limitless discretion," Maj. Op. 18, 22, that the FDA says it does and that animates the majority's too-restrictive response, *see id.* at 16 (voicing concern that the 1990 Amendment "dramatically expanded" the FDA's authority). The instrument and mode-of-action clauses make clear the elephant that the majority sees is only a mouse. *See id.* at 23 (citing *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 467-68 (2001)).

In the decades since Congress in 1990 removed the device exclusion from the FDCA's drug definition to create some textual overlap, there is little evidence that the FDA has treated as drugs what should be regulated as devices. *See* Oral Arg. Tr. 11:21-23 (FDA referencing the lack of cases); *cf. Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 28 (D.D.C. 1997) (saying of contrast agents that "all likely meet both . . . definition[s] . . . and the FDA therefore has discretion in determining how to treat them," though it cannot "permit two sets of similar products to run down separate tracks . . . for no apparent reason"). The only other instance the parties identify of a product that meets the device definition but that the FDA nonetheless regulates as a drug is sunblock. As with contrast agents, the FDA uniformly regulates the entire group of sunscreen products as drugs even though some, "such as those commonly marketed for use with infants and small children," are also eligible to be regulated as devices insofar as they operate by providing a physical barrier (*e.g.*, zinc) against solar rays, rather than through chemical action that would subject them to the device definition's mode-of-action exclusion. Appellant's Br. 31-32; *see also* Appellee's Br. 47. The dearth of litigated cases, or even illustrative examples, of products arguably meeting the device definition but being regulated as drugs owes much to the instrument clause.

The FDA here treats the instrument clause as superfluous, but its own guidance and regulations recognize the clause's robust role informing the FDA's product classifications. The FDA's 2017 Guidance points out that, "[i]n some cases," products that are not themselves instruments, apparatuses, or so forth "are appropriately considered 'similar or related articles'" under the instrument clause "and may be classified as devices." J.A. 332. It notes how, for example, "gels or powders put on the skin" come within the instrument clause when used "as a barrier," "gases" satisfy the clause when "used

as space fillers," and certain "liquids" qualify when "used to clean either surgical instruments or contact lenses." *Id.*; *see, e.g.*, 21 C.F.R. § 886.5928 (classifying "contact lens care products" for soft contact lenses, including solutions, as devices); *see also* Topical Drug Products for Over-the-Counter Human Use; Products for the Prevention of Swimmer's Ear and for the Drying of Water-Clogged Ears; Final Rule, 60 Fed. Reg. 8916, 8917 (Feb. 15, 1995) (explaining that the products at issue were not devices because they did not satisfy the instrument clause, and that they were drugs even though they worked through physical, not chemical or metabolic, means); *Capsular Decisions – Products Assigned to CDER*, FDA (Feb. 16, 2018), https://www.fda.gov/combination-products/rfd-jurisdictional-decisions/capsular-decisions-products-assigned-cder (listing "[d]ye mouthrinse to examine oral tissue" as a drug).

The FDA is bound by "the core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014). Because it incorrectly treated the instrument clause as a nullity and assumed without deciding that the mode-of-action clauses do not apply to Vanilla SilQ, *see* Appellant's Br. 21 (citing J.A. 122), the agency concluded the statute was silent as to whether Vanilla SilQ should be regulated as a drug or device. With none of the device definition's clauses placing any restriction on its action here, the FDA says, it had free rein to choose how to regulate Vanilla SilQ, and it chose the drug pathway. *See id.* at 15-18.

The FDA is not entirely wrong that the drug and device definitions overlap—they do, in part. But it fell short in neither acknowledging the detailed instrument clause nor providing a lawful and nonarbitrary explanation of whether and how

regulating Vanilla SilQ as a drug accords with both that clause and the mode-of-action exclusions in the device definition. It is no answer that the FDA's classification decisions are subject to APA review, nor that its thousands of duly promulgated product classifications constrain its decisions as a practical matter. *See* Oral Arg. Tr. 16:12-17:7. The statutory framework governing the FDA's exercise of its discretion is what provides traction for those procedural safeguards—and the instrument clause that the agency ignored here is a crucial part of that framework.

We have said, in relation to the FDCA, that a "statutory phrase must be read in the context of the kind of drug at issue." *Serono Lab'ys*, 158 F.3d at 1319. The FDA's interpretation of the drug and device definitions and their application to Vanilla SilQ failed even "to wrestle with the relevant statutory provisions," including the instrument clause, and "we cannot do [the agency's] work for it." *Hosp. of Barstow, Inc. v. NLRB*, 820 F.3d 440, 445 (D.C. Cir. 2016) (quoting *Children's Hosp. & Rsch. Ctr. of Oakland, Inc. v. NLRB*, 793 F.3d 56, 59 (D.C. Cir. 2015)). We are therefore "left wondering how the [agency] in these circumstances interprets the statute"—that is, how it would account for the instrument clause as a limit on the definitional overlap and a constraint on its discretion. *Id.* (internal quotation marks omitted). Because of that uncertainty, I would follow "[o]ur general practice in these sorts of situations" and remand for the agency to interpret the statute in the first instance, including the instrument clause that it simply did not apply. *Id.*

C.

The nub of my disagreement with the majority concerns whether, as between dueling statutory definitions, the correct choice might legitimately turn in part on the agency's expert

determination of predicate facts and its sound discretion as to which definition best applies. It seems unremarkable to me that Congress conferred such authority on the FDA.

The majority disagrees. It concludes that, because the FDCA "elaborates distinct regulatory regimes" in which "each scheme is mandatory" for the agency and regulated parties, Maj. Op. 15, there can be no definitional overlap of the drug and device categories. Where the text does not clearly eliminate overlap, the majority says that interpretive canons make the definitions' mutual exclusivity unmistakable. But the premise that the statute makes sense only if there is no definitional overlap is wrong.

There is no escaping some classificatory judgment by the FDA. To see why, it is helpful to identify two layers of judgment that can be required to apply the right definition to a given product. My colleagues take no issue with the first, but hold that the second is inimical to the statutory structure and function. But the two are not materially different. Both call for expert determinations and judgments by the agency—choices that the statutory scheme as written does not obviate and that, no matter how much detail Congress might add, could not be wholly eliminated.

First, even accounting for textual specificity the FDA ignores, gray areas remain. With the help of the instrument and mode-of-action clauses, applied in relation to a product's intended use, most products can readily be identified as either a drug or a device. But classification is not always obvious. Nor could it be. The drug and device definitions—in relevant part, each a single sentence—apply to many thousands of widely heterogeneous products. Those products present varied and often complex questions of safety and efficacy. Determining the appropriate scrutiny—as drug or device—can

be complicated by the detailed knowledge and experience and the high stakes involved in assessing certain products' efficacy and safety for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Congress knew it could not codify all that distinguishes drugs from devices. It was content to sketch the basics and leave it to the FDA to bring to bear the distinct expertise of the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, informed by the detailed input of many expert panels and advisory committees. *See id.* at 4-5; *see also Advisory Committees*, FDA, https://www.fda.gov/advisory-committees (last visited Apr. 14, 2021).

As already discussed, the instrument clause contains material specificity. But, at the end of the day, its terms are unavoidably qualitative and imprecise. For example, deciding whether a product is a "contrivance" or "apparatus"—let alone "similar or related" to one—requires some judgment about the product's character. That judgment is not unguided but, per the FDCA and APA, informed by whether treating it as a drug or device best aligns with what Congress meant to achieve in articulating separate definitions keyed to distinct regulatory approaches. Also relevant is how the product compares to others already classified, not least because the agency acts arbitrarily if it regulates similar products differently. But there is no avoiding the exercise of judgment at the margins. Provided the agency makes nonarbitrary determinations based on substantial evidence, we must defer. My colleagues express no disagreement with this. *See* Maj. Op. 8 n.3 (noting that it is "not immediately obvious" how a contrast agent satisfies the device definition's instrument clause, "[n]or is it altogether settled that Vanilla SilQ satisfies the device definition's mode-of-action clauses"); *id.* at 23 (acknowledging that, when the instrument and mode-of-action clauses "are ambiguous in their

application to some kind of medical product, reviewing courts should respectfully consider the expert views of the FDA").

A second layer of classification judgment, called into play by definitional overlap, is what the majority reads the statute to unambiguously eliminate. If a product is neither clearly within or outside the instrument clause, for example, and not excluded by the mode-of-action clauses, as a definitional matter it is plausibly both a drug and device. Even though it ultimately can only be regulated as one or the other, the statute does not alone determine which one it is. Assume, for example, that nanotechnology ingested or injected for the purpose of delivering light to cancer cells is not excluded from regulation as a device because it relies not on chemical action, but on some purely physical process. On my colleagues' reading, that product could be regulated only as a device. Provided that it might plausibly be thought to fall within the instrument clause, they would hold that the device definition's mode-of-action clauses—"critical to effectuating" mutual exclusivity, *id.* at 20—necessarily sort it into the device category. On my reading, the statute authorizes the FDA to make an informed judgment whether to regulate that type of product—rare as it may be—as a drug or a device. Congress did not unambiguously leave that call to us rather than to the FDA.

The majority's reading has another type of anomalous effect. Without the overlap Congress in 1990 built into the definitions, an "article" that does not meet the device definition's more specific "instrument" clause, and that also does not rely on chemical or metabolic action to achieve its primary intended purposes, would be neither drug nor device. By insisting, through negative implication, that the drug category is confined to products with the modes of action specified in the device definition's exclusions, the majority eliminates coverage for any product not described as a device

by the instrument clause but also not deemed a drug by the mode-of-action clauses. For example, if Vanilla SilQ's presumed mode of action were confirmed as non-chemical and non-metabolic, and if it were proposed to be used not for its arguably device-like function of blocking X-rays with its molecular density (and thus, *e.g.*, an "accessory" to an X-ray machine) but instead to be consumed to treat disease in its own right (and thus an uneasy fit for "instrument"), the majority's reading would exclude it from both the drug and device categories. Interpreting the statute to exclude a category of products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease from both the drug and device definitions squarely conflicts with Congress's design in a manner that acknowledging some overlap does not.

In my view, the statutory overlap effected by the 1990 Amendment would give the FDA a choice how to classify such products—provided its justification addressed the product's material characteristics and Congress's definitions of the distinct regulatory pathways. Whether the product was nanotechnology or Vanilla SilQ, the agency would have to consider whether its device-like character and function as it is intended to be used suggest it should be grouped with devices. It would have to analyze whether its mode of action, even if not chemical or metabolic, presents questions of efficacy or risk that warrant regulating it on the same pathway with otherwise similar products that have different modes of action. And it would have to explain how its judgments on those points accorded with the text, nature, and purpose of the distinct definitions to advance the statute's objectives.

These two types of classificatory judgments—at the margins of definitions, and in the overlap between them—are not all that different. Both depend on legal and factual expertise and judgment calls informed by scientific and

regulatory experience. The majority accepts the first kind yet rejects the second. But Congress did not unmistakably eliminate the type of judgment calls that definitional overlap would require of the FDA. And nothing about that is anomalous.

Similar judgment calls are built into multiple provisions of the FDCA. For example, we have observed that, "although the consequences of classification as a 'drug claim' or a 'health claim' are quite substantial"—if the former, a product would have to be approved as a drug to be marketed in that way—"Congress has given definitions that at least partially overlap" with "little guidance as to how the FDA should sort out claims that seem to fit both definitions." *Whitaker v. Thompson*, 353 F.3d 947, 949 (D.C. Cir. 2004). Faced with that statutory overlap, we deferred to the agency's reasonable interpretation. *Id.* at 951-52.

In *Serono Laboratories, Inc. v. Shalala*, we likewise deferred to the FDA's interpretation of an FDCA provision requiring the agency to approve a generic drug with the "same" active ingredients as a listed drug, in part because the statute did not foreclose treating a generic as clinically the same even if not completely chemically identical to the pioneer version. 158 F.3d at 1318-20. In so holding, we emphasized the significant judgment that Congress entrusted to the agency in the FDCA: "The FDA's determination of what is required to establish 'sameness' for purposes of the Act rests on the agency's evaluations of scientific data within its area of expertise, and hence is entitled to a high level of deference." *Id.* at 1320 (internal quotation marks and citations omitted). In sum, the majority's statutory analysis is unpersuasive, and the concern that animates it illusory.

But because the FDA has neither recognized the statutory constraints that bear on its classification of Vanilla SilQ nor made findings on the relevant facts, I agree we must remand to the agency to do so.

II.

I credit the majority for recognizing a lack of clarity at the margins, specifically "reserv[ing] the question whether Vanilla SilQ satisfies the device definition's instrument and mode-of-action clauses" and thus not prejudging the outcome. Maj. Op. 8 n.3; *accord id.* at 23. The court's decision leaves the agency with several options on remand. For instance, the FDA might determine that Vanilla SilQ—an oral solution consumed by patients to improve imaging of their gastrointestinal tracts with X-ray machines and CT scanners—is sufficiently "related" to those devices or an "accessory" to them, 21 U.S.C. § 321(h)(1), such that it, too, is a device within the meaning of the FDCA and must be regulated as such. Or the FDA might make a contrary determination, in which case Vanilla SilQ remains amenable to classification and regulation as a drug. And if, after further study, the FDA were to determine that Vanilla SilQ in fact achieves its primary intended purpose through chemical action, as an *amicus* urges, *see* Amicus Bracco Br. 5-6, that conclusion would call for its regulation as a drug. (At this juncture, no one suggests that Vanilla SilQ achieves its primary intended purpose through metabolization, *see id.* at 7, but that possibility likewise remains open and would require regulation as a drug.)

That is all to say that the agency must make the requisite factual determinations and attend to all relevant statutory provisions to decide whether to classify Vanilla SilQ as either a drug or device in the first instance, and that it may "deal with the problem afresh" on remand. *Dep't of Homeland Sec. v.*

Regents of the Univ. of Cal., 140 S. Ct. 1891, 1908 (2020) (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 201 (1947)). Once the FDA does the work of applying the explicit constraints of the device definition's instrument and mode-of-action clauses, it might determine that Vanilla SilQ is not a device, but only a drug. In that event, there would have been no reason to address the existence or not of definitional overlap between drugs and devices.

The majority goes further than required to resolve this appeal when it interprets the device and drug definitions as mutually exclusive. I have explained why the majority errs as a matter of statutory interpretation. More fundamentally, we need not—so should not—decide that issue because it is not yet apparent whether the existence or not of definitional overlap matters in the case of Vanilla SilQ. If the FDA on remand were to confirm that it believes that Vanilla SilQ could be either a device or drug and make an assignment with the proper reasoning in support, we would then be faced with the question whether statutory overlap permits it to do so, and whether its assignment comports with the APA. For now, it suffices to identify the flaws in the FDA's decision and the inadequacy of the unelaborated administrative convenience rationale it gave for subjecting contrast agents with materially varying modes of action to the same degree of regulatory rigor.

* * *

Because the FDCA does not give the FDA the discretion that it claims to regulate any device as a drug, and the agency has failed to explain its choice in a manner that grapples with the applicable statutory terms, I concur in the court's judgment.