UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GENUS MEDICAL TECHNOLOGIES, LLC, **Plaintiff,** **v.** **UNITED STATES FOOD AND DRUG ADMINISTRATION,** **Defendant.**	**Civil Action No. 19-544 (JEB)**

MEMORANDUM OPINION

Those drinking the contrast agent Vanilla SilQ before undergoing an X-ray or other imaging procedure likely spend no time pondering the central issue in this case: is this barium-sulfate product a drug or is it a medical device?

Plaintiff Genus Medical Technologies, LLC manufactures Vanilla SilQ products — a line of contrast agents that are used to image structures or fluids within the body. Defendant Federal Drug Administration has authority to regulate medical products like Genus's to assure their safety and efficacy. Under the Federal Food, Drug, and Cosmetic Act (FDCA), the agency can regulate products as, *inter alia*, drugs or devices. The regulatory path the FDA chooses — that is, whether it treats a product as a drug or a device — implicates significantly different pre-market review and post-market compliance requirements under the Act and implementing regulations. Drugs are subject to a more rigorous regimen, which costs its sponsor considerably more money.

The FDA here concluded that although the Vanilla SilQ products appeared to qualify as devices under the FDCA, they were also drugs and could be regulated accordingly. Plaintiff

responded with this suit, and the parties have now cross-moved for summary judgment. Finding the agency's action to be inconsistent with the Administrative Procedure Act and the FDCA, the Court will grant Plaintiff's Motion for Summary Judgment and deny the FDA's Cross-Motion.

I. Background

To provide context for the factual background, the Court first sets out the statutory scheme.

A. Statutory Framework

The FDCA, 21 U.S.C. § 301 *et seq.*, grants the FDA, as the designee of the Secretary of Health and Human Services, the authority to regulate medical products, including "drugs" and "devices." Id. §§ 321(g)–(h), 393. The Act, in relevant part, defines "drug" to include:

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

Id. § 321(g)(1). It defines "device" in part, conversely, to mean:

> 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).

Comparing these definitions yields two conclusions that are relevant here: first, all FDA-regulated diagnostic "devices" meet the "drug" definition. That is because of the overlap in the intended-use portions of their definitions. Id. §§ 321(g)(1), (h) (drugs and devices both include articles "intended for use in the diagnosis" of disease). Second, the critical difference between

the two is that the device definition includes two exclusionary clauses. Specifically, a device, unlike a drug, neither achieves "its primary intended purposes through chemical action within or on the body of man" nor is "dependent upon being metabolized for the achievement of its primary intended purpose." § 321(h); see also ECF No. 17 (Joint Appendix (JA)) at FDA213 (FDA guidance refers to these portions as "exclusionary clauses").

1. *Regulatory Schemes*

The statutory distinctions between a drug and a device have meaningful and practical consequences. For starters, the FDA has established separate bureaucratic centers that oversee the pre-market review and post-market regulation of drugs as opposed to devices. The Center for Drug Evaluation and Research (CDER) has primary jurisdiction over drugs, while the Center for Devices and Radiological Health (CDRH) has primary jurisdiction over medical devices. See 21 C.F.R. § 3.5; Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, U.S. Food & Drug Admin. (Oct. 31, 1991), https://www.fda.gov/combination-products/classification-and-jurisdictional-information/intercenter-agreement-between-center-drug-evaluation-and-research-and-center-devices-and. Each center has its own requirements for marketing authorization.

To market new prescription drugs, for example, a sponsor — generally the manufacturer — must submit a new-drug application demonstrating that the drug is safe and effective for its proposed use. See 21 U.S.C. § 355(a)–(b). This process requires an extensive series of safety and effectiveness trials before approval. Id. § 355(b). If the prospective drug is the "same as" an existing drug already on the market, however, the sponsor can obtain approval through the less onerous abbreviated new-drug application process. Id. § 355(j). This abbreviated process requires proof that the drug in question has the same active ingredients,

effects, and labeling as a predecessor drug that the FDA has already approved. Id.; 21 C.F.R. § 314.94(a).

By contrast, devices are reviewed and classified into three categories based on the risk they pose to the public. Class I devices are low risk — *i.e.*, they "present no unreasonable risk of illness or injury" — and "are subject only to minimal regulations by 'general controls.'" Medtronic, Inc. v. Lohr, 518 U.S. 470, 476–77 (1996) (quoting 21 U.S.C. § 360c(a)(1)(A)). Class II devices "are potentially more harmful": "[A]lthough 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)). Lastly, high-risk devices are designated as Class III. See 21 U.S.C. § 360c(a)(1)(C). To introduce a new Class III device into the market, "the manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective." Medtronic, 518 U.S. at 477 (quoting 21 U.S.C. § 360e(d)(2)). To provide a "reasonable assurance," the manufacturer undergoes a pre-market approval process, which requires "detailed information regarding the safety and efficacy" of its device. Id.

Additionally, significant cost differences exist in both the development and the continued sale of drugs and devices. Plaintiff avers that the cost of seeking clearance to market its products as devices is estimated to be $60,000, whereas seeking approval to market them as drugs could be over half a million dollars in addition to a continuing annual cost north of $186,000. See ECF No. 9 (Plaintiff's MSJ), Exh. 8 (Declaration of John E. Powers), ¶¶ 31–33.

2. *Requests for Designation*

When the classification of a product — *viz.*, as a drug or a device — is unclear or in dispute, a sponsor can 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). The relevant "components" here include the CDRH — which, again, regulates devices — and the CDER — which regulates drugs. Sponsors submit RFDs to the Office of Combination Products, which is part of the FDA's Office of the Commissioner. The Act requires OCP to respond to RFDs no later than 60 days after they are filed. Id. § 360bbb-2(b). If it fails to do so, the classification or assignment recommended by the sponsor becomes operative. Id. § 360bbb-2(c). A classification or assignment made through the RFD process can be changed only with the sponsor's written consent or for "public health reasons based on scientific evidence." Id. § 360bbb-2(b).

B. Factual History

Since 2015, Genus has manufactured "Vanilla SilQ" — a line of barium-sulfate oral-solution contrast agents. See ECF No. 1 (Complaint), ¶ 25; JA at FDA8. These products are "ingested for diagnostic purposes." JA at FDA14. The physical and chemical properties of barium sulfate — particularly its opacity — enable health-care providers to better visualize the gastrointestinal tract when performing X-rays or computer tomography (commonly referred to as a CT scan). Id. at FDA8. Significantly, because it is an inert metal salt, barium sulfate does not chemically interact with human cells or tissue to serve its purpose. Id. Ingesting it does not affect the chemical bonds or molecular structure of the gastrointestinal system or form new substances. Id. at FDA8, FDA14. Further, when used as a contrast agent, it is "neither absorbed nor metabolized" by the body. Id. at FDA15.

Genus maintains that before and after it started producing Vanilla SilQ, it sought FDA clearance to distribute its products as devices. Id. at FDA55. Alternatively, Plaintiff purported

to establish that — for reasons that are inapplicable here — its products were exempted from drug regulation. Id. at FDA58, FDA135 (citing 21 U.S.C. § 321(p)(1)).

In June 2016, the FDA conducted a three-day inspection of Plaintiff's distribution facility. Id. at FDA134. On May 2, 2017, it issued a Warning Letter, notifying Genus that its products were "drugs" within the meaning of the Act. Id. at FDA135 (citing 21 U.S.C. § 321(g)(1)). It further explained that because the products "are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling," they were also "new drugs" under the statute. Id. (citing 21 U.S.C. § 321(p)(1)). Such a classification posed a significant problem for Genus. That is because new drugs may not be introduced into interstate commerce without the FDA's approval, see 21 U.S.C. §§ 331(d), 355(a)), which would require substantially more expense for Genus. See JA at FDA135. The agency also warned Plaintiff that its products were misbranded — a separate violation of the statute. Id. at FDA135–36 (citing 21 U.S.C. §§ 331(a), 352).

The Warning Letter prompted further correspondence between the parties. See, e.g., id. at FDA37 (Genus's May 19, 2017, Response to Warning Letter); id. at FDA32 (FDA's Sept. 6, 2018, Response to Warning Letter Response). In their letters, the parties chiefly disputed the classification of Vanilla SilQ products. Genus, on the one hand, maintained that its products are devices. Id. at FDA38–39. If so, several of the violations of the FDCA outlined in the Warning Letter, as well as the Act's drug-regulatory scheme, would be inapplicable. The FDA, on the other hand, stated that the products met the drug definition and could be regulated accordingly. Id. at FDA32–35.

With the parties at an impasse, Genus submitted an RFD, requesting that OCP classify its Vanilla SilQ products as devices. Id. at FDA17. In its response, OCP noted that Plaintiff's

products "meet the definition of drug" and "also appear to meet the definition of 'device.'" JA at FDA1–3 (Jan. 10, 2019, Designation Letter). For reasons that will be set out in more detail, OCP nevertheless concluded that Vanilla SilQ products are drugs to be regulated by CDER. Id. at FDA1. In short, the agency reasoned that it must regulate contrast agents — which all meet the definition of drugs, but not necessarily devices — uniformly. Id. at FDA3.

On February 28, 2019, Genus filed suit in this Court. It challenges the FDA's decision to regulate Vanilla SilQ products as drugs rather than as medical devices on a number of different grounds, including that it was arbitrary and capricious, as well as in excess of statutory authority, thus violating the FDCA via the APA. See Compl., ¶¶ 46–55. Plaintiff has now moved for summary judgment, seeking, *inter alia*, a declaration requiring the FDA to regulate its products as devices. See Pl. Mot. at 2. Defendant, for its part, has countered with its own Motion for Summary Judgment, seeking affirmation of its classification decision.

II. Legal Standard

Although styled Motions for Summary Judgment, the pleadings in this case more accurately seek the Court's review of an administrative decision. The summary-judgment standard set forth in Federal Rule of Civil Procedure 56(c), therefore, "does not apply because of the limited role of a court in reviewing the administrative record." Sierra Club v. Mainella, 459 F. Supp. 2d 76, 89 (D.D.C. 2006). "[T]he function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." Id. at 90 (quoting Occidental Eng'g Co. v. INS, 753 F.2d 766, 769–70 (9th Cir. 1985)). "Summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review." Loma Linda Univ. Med. Ctr. v. Sebelius, 684 F. Supp. 2d 42, 52 (D.D.C. 2010).

The APA "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009). It requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). Agency action is arbitrary and capricious if, for example, the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

III. Analysis

In bringing its suit here, Plaintiff preliminarily maintains that the FDA's response to its RFD was deficient because it failed to actually classify the products — that is, as drugs or devices. As a result, Genus believes that the agency must now accept its recommendation and classify Vanilla SilQ products as devices. Alternatively, and more substantively, it argues that even if the agency's response was not deficient, the decision to regulate the products as drugs rather than devices violates the APA as arbitrary and capricious agency action taken in contravention of the FDCA. The Court considers each of these positions in turn.

A. Designation Letter

Genus first contends that Defendant skirted its statutory responsibility by providing a deficient RFD response. See Pl. Mot. at 21–22. OCP observed that Vanilla SilQ barium-sulfate products "meet the definition of drug," while "also appear[ing] to meet the definition of 'device.'" JA at FDA2–3. It nonetheless concluded that it was appropriate for the CDER to

review and regulate these products as drugs. Id. at FDA1. Plaintiff points out that the agency's letter failed to use "the word 'classify' or 'classification' [as] applied to Vanilla SilQ." Pl. Mot. at 21. By neglecting to do so, the argument goes, OCP violated its statutory obligation to "provide a 'written statement that identifies such classification.'" Id. at 22–23 (emphasis added) (quoting 21 U.S.C. § 360bbb-2(b). And the consequence of not providing a timely determination is that the sponsor's recommendation — here, that Vanilla SilQ products should be regulated as devices — becomes operative. See 21 U.S.C. § 360bbb-2(c).

Genus's semantics argument stretches too far. Contrary to its suggestion, the Act does not have a "magic words" requirement — that is, the agency need not use any specific terms in designating a product. Instead, the FDCA simply requires that the FDA, within 60 days of receiving an RFD, "determine the classification of the product . . . or . . . the component of the [FDA] that will regulate the product," and then "provide to the person a written statement that identifies such classification or such component, and the reasons for such determination." Id. § 360bbb-2(b) (emphases added). The FDA's designation letter here does just that. The agency reasoned that Vanilla SilQ products are drugs, and its letter spells out that the CDER is the proper component to regulate them. See JA at FDA1–5. As such, the Court can make quick work of Genus's first contention and find that the FDA's letter easily passes muster under § 360bbb-2(b).

B. APA/FDCA Violations

The harder question relates to Plaintiff's claim that the FDA's designation of its products as drugs rather than devices contravened the FDCA. On this score, Genus focuses on the exclusionary clauses in the device definition. See Pl. Mot. at 24; ECF No. 12 (Plaintiff's Opposition and Reply) at 2. Specifically, it notes that a device, unlike a drug, "does not achieve

its primary intended purposes through chemical action within or on the body of man or other animals" or through "being metabolized for the achievement of its primary intended purposes." Pl. Mot. at 24 (quoting 21 U.S.C. § 321(h)). In Plaintiff's telling, the record makes clear that its products do not operate this way, so the plain text directs the FDA to regulate Vanilla SilQ as a device rather than a drug. Id. at 26 (citing JA at FDA3, FDA6–21). Interpreting the language any differently would, according to Plaintiff, read out the exclusionary clauses entirely and nullify Congress's intent to create two separate regulatory tracks for devices and drugs. Id. at 22–28.

In response, the agency argues that the fact that Plaintiff's products "appear to meet the definition of 'device'" does not end the matter. See ECF No. 10 (Def. Cross-MSJ) at 2 (quoting JA at FDA3). Because "the definitions of drug and device are overlapping, rather than mutually exclusive," JA at FDA3 — *i.e.*, because both are defined as "articles intended for use in the diagnosis of disease," 21 U.S.C. §§ 321(g)(1), (h) — Defendant contends that it has discretion to decide how to regulate a diagnostic product that falls within both categories. See Def. Cross-MSJ at 19–20; ECF No. 14 (Def. Reply) at 5–6.

With that backdrop, the Court tees up the issue: did Congress grant the agency the discretion to regulate any medical diagnostic device as a drug?

1. *Legal Framework*

To tackle this question, the Court turns to Chevron's familiar framework. See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984); see also, e.g., Shays v. FEC, 414 F.3d 76, 96 (D.C. Cir. 2005) (outlining Chevron framework); Republican Nat'l Comm. v. FEC, 76 F.3d 400, 404 (D.C. Cir. 1996). Under Chevron, the first step is to "examine the statute *de novo*, 'employing traditional tools of statutory construction.'" National Ass'n of Clean Air

Agencies v. EPA, 489 F.3d 1221, 1228 (D.C. Cir. 2007) (quoting Chevron, 467 U.S. at 843 n.9); see also Mount Royal Joint Venture v. Kempthorne, 477 F.3d 745, 754 (D.C. Cir. 2007) (court begins by "applying customary rules of statutory interpretation"). Courts consider "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) (quoting Catawba Cty. v. EPA, 571 F.3d 20, 35 (D.C. Cir. 2009)). "Congress may have done so . . . either by prescribing a precise course of conduct other than the one chosen by the agency, or by granting the agency a range of interpretive discretion that the agency has clearly exceeded." Id. At this stage, courts afford an agency's interpretation no special deference: "[I]f the agency has either violated Congress's precise instructions or exceeded the statute's clear boundaries then, as Chevron puts it, 'that is the end of the matter' — the agency's interpretation is unlawful." Id. at 660 (quoting Chevron, 467 U.S. at 842); see also Eagle Broad. Grp., Ltd. v. FCC, 563 F.3d 543, 552 (D.C. Cir. 2009) (if the "search for the plain meaning of the statute . . . yields a clear result, then Congress has expressed its intention as to the question, and deference is not appropriate") (quoting Bell Atlantic Tel. Cos. v. FCC, 131 F.3d 1044, 1047 (D.C. Cir. 1997)).

If, however, "the statute is silent or ambiguous with respect to the specific issue," Chevron, 467 U.S. at 843, the analysis proceeds to "determine the deference, if any, [the court] owe[s] the agency's interpretation of the statute." Kempthorne, 477 F.3d at 754. Under this step, "[i]f Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." Chevron, 467 U.S. at 843–44. When a "legislative delegation to an agency on a particular question is implicit rather than explicit," id. at 844, the

Court must uphold any "'reasonable interpretation made by the administrator' of that agency." Am. Paper Inst., Inc. v. EPA, 996 F.2d 346, 356 (D.C. Cir. 1993) (quoting Chevron, 467 U.S. at 844).

2. *Chevron Step One*

At the first step, the Court must use the "customary statutory interpretation tools of 'text, structure, purpose, and legislative history'" to determine whether Congress's intent regarding the FDCA is clear. California Metro Mobile Commc'n, Inc. v. FCC, 365 F.3d 38, 44–45 (D.C. Cir. 2004) (quoting Consumer Elecs. Ass'n v. FCC, 347 F.3d 291, 297 (D.C. Cir. 2003)).

The Court thus begins "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)). As set out above, the FDCA provides for classification of a diagnostic product as, *inter alia*, a drug or a device. The intended-use provision is common to both, while the definition of device excludes products that undergo chemical reactions within the body or are metabolized to perform their primary intended purposes. See 21 U.S.C. §§ 321(g)(1), (h).

In determining which of these definitions controls, the Court is guided by the "old and familiar rule" that "the specific governs the general." RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 645 (2012) (quoting Morales v. Trans World Airlines, Inc., 504 U.S. 374, 384 (1992)). Here, there is no dispute about which definition is more specific: Congress, as both parties agree, more narrowly defined devices. See JA at FDA212 (FDA Guidance) (characterizing device definition as "more restrictive"). There is good reason for that more specific definition to govern in this dispute. That is, a product that falls within both definitions is more appropriately classed as a device, else the device definition would be

"swallowed" by the more general drug definition. See RadLAX Gateway Hotel, 566 U.S. at 645; accord Bloate v. United States, 559 U.S. 196, 207 (2010) ("[G]eneral language of a statutory provision, although broad enough to include it will not be held to apply to a matter specifically dealt with in another part of the same enactment.") (quoting D. Ginbserg & Sons, Inc. v. Popkin, 285 U.S. 204, 208 (1932)).

Put differently, adopting an interpretation in which a diagnostic product is a drug — even if it plainly falls under the device definition — would read out the exclusionary clauses altogether. That result would be at odds with the way courts ordinarily interpret statutes — namely, they attempt to give effect to all their 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); then quoting 2A N. Singer, Statutes and Statutory Construction § 46.06, 181–86 (rev. 6th ed. 2000)).

What is more, the exclusionary clauses would not be the only casualties under the agency's reading. If a product that meets both definitions is nonetheless treated as a drug, then the device-drug distinction would be rendered meaningless. Put otherwise, the FDA could classify any diagnostic device as a drug because no limiting principle would trammel its authority. That would turn the statutory scheme on its head. See K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 291 (1998) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole."). As set out above, *supra* Section I.A.1, Congress erected entirely different statutory and regulatory compliance regimes for drugs and devices, including separate systems for registration, market authorization, regulation, and reporting requirements. Compare, e.g., 21 U.S.C. §§ 355, 355b, 360(h)(3) (drugs), with id. §§ 360(h)(2), 360(k), 360c, 360e (devices). Were Defendant

able to decide whether to regulate any device as a drug, it could then subvert this dual-track scheme at will. This Court cannot countenance such an outcome. See RadLax Gateway Hotel, 566 U.S. at 645 (instructing that "effect shall be given to every clause and part of the statute") (quoting D Ginsberg & Sons, 285 U.S. at 208).

In the end, the plain text dictates the result here. Congress readily could have afforded the agency discretion to determine which of these pathways a product must take. It in fact has done so with respect to agency decisions under other parts of the FDCA. See, e.g., 21 U.S.C. §§ 360c(a)(3)(A), 360c(a)(3)(B), 360d(a)(1), 360bbb-3(i), 379(h)(a)(1)(G) (granting FDA discretion to varying degrees). But it did not do so here. See Whitman v. Am. Trucking Ass'n, 531 U.S. 457, 468 (2001) ("Congress . . . does not alter the fundamental details of a regulatory scheme in vague or ancillary provisions — it does not, one might say, hide elephants in mouseholes."). Because "courts must presume that a legislature says in a statute what it means and means in a statute what it says there," the Court holds that a product that meets the device definition must be regulated as such. See Conn. Nat'l Bank v. Germain, 503 U.S. 249, 252–53 (1992). The Court accordingly ends its analysis at Chevron step one.

3. Other Arguments

Not ready to throw in the towel, Defendant offers a number of other reasons why the Act grants it discretion to classify Vanilla SilQ products as drugs or, at the very least, is more ambiguous on this front than appears at first blush. None is persuasive.

a. Drafting History

The agency first points to evidence that Congress removed language from an earlier version of the FDCA that specifically excluded devices from the definition of drugs. See Pl. Mot. at 2, 10, 23. Because the statute now apparently contains definitional overlap, Defendant

argues that Congress implicitly vested the FDA with discretion "to determine the appropriate regulatory regime . . . when a product satisfies both definitions." Id. at 2. The Court disagrees. Because this legislative amendment was aimed at an entirely different problem — to wit, facilitating a regulatory track for so-called "combination products" — it cannot shoulder the weight that Defendant places on it.

Some background is in order. For several years, the Act specified that a drug "does not include devices or their components, parts, or accessories." 21 U.S.C. § 321(g) (1938); see also United States v. Article of Drug, Bacto-Unidisk, 394 U.S. 784, 793 (1963) ("a 'device' expressly cannot be a 'drug' under the last phrase of the drug definition"). That changed in 1990 when Congress amended the Act and removed the exclusion of devices from the definition of drug. See Safe Medical Device Act of 1990, Pub. L. No. 101–629, 104 Stat. 4511, 4526 ("[i]n paragraph (g)(1), by striking out '; but does not include devices or their components, parts or accessories'").

Significantly, in the same amendment, Congress added another category of medical products — "combination products" — to the FDA's regulatory plate. See 104 Stat. at 4526 (codified as amended at 21 U.S.C. § 353(g)). A combination product comprises two or more "regulated components," such as a drug component and a device component, that are "produced as a single entity." 21 C.F.R. § 3.2(e)(1). Take, for example, a surgical mesh with anesthetic coating, which has a device component (the mesh) and a drug component (the anesthetic). The FDA reviews a combination product according to its "primary mode of action." 21 U.S.C. § 353(g). Put simply, it will regulate a product depending on which constituent part — *e.g.*, device or drug — is most responsible for its intended use. (Genus, it should be noted, does not contend that Vanilla SilQ are combination products. See Pl. Mot. at 16.)

The provision excluding devices from the drug definition, therefore, was removed to enable combination drug/device products to be regulated as drugs in appropriate cases. See S. Rep. No. 101–513, at 43 (1990) ("Section 19 alters the drug and device definitions in [§ 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 is attributable to a drug, but has a device component, may be reviewed under the Act's drug authority."). Congress's intent was not — as the FDA would have the Court believe — to delegate unfettered discretion to the FDA to regulate all devices as drugs.

Congress, moreover, did not alter the essential nature of the device regulatory regime — a framework that has been in place since 1976. See Medical Device Amendment of 1976, Pub. L. No. 94–295, 90 Stat. 539 (1976) (establishing device regulatory regime). Notably, legislative history surrounding the implementation of this scheme makes clear that Congress intended the FDA "to classify all medical devices intended for human use into three regulatory categories (classes) based upon the extent of control necessary to insure the safety and efficacy of each such device." H.R. Rep. No. 94–853, at 3 (1976) (emphasis added). Indeed, the House Committee Report notes that "[t]here is an apprehension that medical devices have not been clearly delineated from drugs and that legislation directing regulation of devices by the same system currently used for drugs would be inappropriate." Id. at 11. That the 1990 amendment left the device regulatory scheme largely intact evidences Congress's intent for the FDA to regulate drugs and devices using the exclusionary clauses as a dividing line.

The agency also calls attention to the definition of contrast agents as drugs in recently enacted legislation. See 21 U.S.C. § 360j(p)(4)(B) ("the term 'contrast agents' means a drug that is approved under section 355 of this title or licensed under section 262 of [the Public Health

Service Act"); Def. Cross-Mot. at 22 n.5. But this argument, too, misses the mark. This definition of contrast agent operates solely for "the purposes of this subsection." 21 U.S.C. § 360j(p)(4) (emphasis added). And this subsection concerns the FDA's approval of medical-imaging devices that use a contrast agent in a manner different from that in the agent's labeling. Id. If the FDA were correct that Congress intended that this definition should control the entirety of contrast agents, the "for purposes of this subsection" language would be superfluous. In brief, § 360j(p)(4)(B) does not support the regulation of all contrast agents as drugs or even all contrast agents for use with medical-imaging devices as drugs. Rather, this provision underscores that some contrast agents for use with medical-imaging devices are regulated as drugs.

b. Caselaw

Defendant's position gains no traction from the principal cases on which it relies. Start with Bacto-Unidisk — a 1963 decision that involved a challenge to the agency's decision to regulate a product as a drug, rather than as a device. See 394 U.S. at 789–91. The Supreme Court ruled in favor of the agency, finding that the product fell within the definition of drug. Id. at 792–93. In doing so, it explained that "Congress fully intended that the Act's coverage be as broad as its literal language indicates," and "remedial legislation such as the [Act]" must be afforded a "liberal construction." Id. at 798. The Court also observed an "obvious area of overlap" that at the time existed between the drug and device definitions, id. at 799 — an observation Defendant emphasizes to conclude that even when a product possibly meets the device definition, the agency has discretion to regulate it as a drug. See Def. Reply at 7–8.

Not so fast. To begin, the decision was issued in an era when devices were not subject to pre-market testing. See Bacto-Unidisk, 394 U.S. at 785. The only way to ensure the safety and efficacy of the product and subject it to pre-market authorization requirements was to classify it

as a drug. Id. at 784–85, see id. at 798 (given "the Act's overriding purpose to protect the public health . . . [and] to ensure that antibiotic products marketed serve the public with 'efficacy' and safety,'" Court liberally construed term "drug"). That, of course, changed when, in 1976, Congress amended the Act to introduce a comprehensive device regulatory regime. See 90 Stat. at 539 (1976) (amending Act "to provide for the safety and effectiveness of medical devices intended for human use").

In tandem with these changes, Congress beefed up the device definition itself. At the time Bacto-Unidisk was decided, the definition contained an earlier version of the intended-use language. See 394 U.S. at 789–90 ("intended for use in the diagnosis . . . of disease in man"). Congress later defined devices as products that did not achieve their "principal intended purpose" through chemical interaction with the body or through metabolization. See 90 Stat. at 575; see also 104 Stat. at 4526 (1990) (then amending "principal" to "primary"). It is no surprise that the Supreme Court recognized that the language of the statute as it then existed was "of little assistance in determining precisely what differentiates a 'drug' from a 'device.'" Bacto-Unidisk, 394 U.S. at 799. For the reasons set out above, however, this is plainly no longer true. The Court concludes, accordingly, that the logic in Bacto-Unidisk does not decide the issue here.

Similarly, Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20 (D.D.C. 1997), does not carry the day for the agency. The district court there considered whether the FDA's disparate treatment of two "functionally indistinguishable" products — *i.e.*, one was regulated as a device while another as a drug — was arbitrary and capricious. Id. at 24, 28. It answered this question in the affirmative, finding it problematic for the agency to apply two different regulatory frameworks to essentially identical products. Id. at 24, 27–28. In its analysis, the court also stated: "[The products at issue] all likely meet both the definition of a drug and the definition of a

device under the [Act], and the FDA therefore has discretion in determining how to treat them." Id. at 28 (citing 21 U.S.C. § 353(g)).

So, Defendant argues, when a product meets the definition of both drugs and devices, the agency has discretion to decide into which category to place them. See Def. Cross-Mot. at 15, 23. The agency also believes that Bracco supports its decision to regulate all contrast agents — regardless of whether any one of them meets the device definition — as drugs for the sake of uniformity. Id. at 11–14; JA at FDA3 ("Because not all contrast agents meet the definition of a device, but all of them do meet the definition of a drug, the agency has for many years regulated these products . . . as drugs in order to regulate them consistently under the same authority."). As a result, Defendant maintains that its position with respect to Genus is neither arbitrary nor capricious. Id. at 15; see JA at FDA3 n.5.

Bracco, however, is less helpful to the FDA than it initially appears. To be sure, it holds that an agency acts unlawfully when it treats differently products that are the same in all material respects. Such holding, however, arose on a motion for preliminary injunction and was not a final merits ruling. See 963 F. Supp. at 22. The injunction simply prohibited the FDA from proceeding with approval of the plaintiff's product as a device until after it had resolved a citizen's petition addressing whether the agency could treat as a device a product the other manufacturers of which had received approval to market as a drug. Id. at 23. The court left it to the FDA to decide whether the FDCA entitled the plaintiff to proceed under § 353 as a device, which is, of course, the heart of the matter here. Id. at 27–28. In addition, although Bracco states that the FDA has the "discretion" to decide how it treats contrast agents, it points to § 353(g), which confers the authority to regulate combination products — products that are not at issue here. Id. at 28.

It is also notable that Congress further amended the FDCA after Bracco was decided in the Federal Food and Drug Administration Modernization Act of 1997 and did so in ways that reduced the administrative burden on device manufacturers. Nothing in the 1997 amendments betrays a Congressional intent to force a device manufacturer to tread a more difficult or demanding path to market than what the characteristics of its device would require, even though doing so might be administratively "efficient" for the FDA.

Plaintiff, finally, is not maintaining that similarly situated products should receive disparate treatment. Rather, it posits that not all contrast agents are the same. Because the Vanilla SilQ products, unlike other contrast agents, do not chemically interact with the body, they should be treated as devices. See Pl. Reply at 27–28. In sum, Bracco does not suggest that the FDA can ignore the plain language of the FDCA; it does not have discretion to regulate all contrast agents uniformly, irrespective of their defining features under the statute.

IV. Conclusion

For these reasons, the Court will vacate Defendant's decision to regulate Genus's Vanilla SilQ products as drugs and will remand to the agency for further administrative proceedings consistent with this Opinion. A separate Order so stating will be issued this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
United States District Judge

Date: December 6, 2019