

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

GOVERNMENT ACCOUNTABILITY PROJECT,)	
)	
Plaintiff,)	
)	
v.)	No. 12-cv-1954 (KBJ)
)	
FOOD & DRUG ADMINISTRATION,)	
)	
Defendant.)	
)	

MEMORANDUM OPINION

Plaintiff Government Accountability Project (“GAP”) is a non-profit organization whose mission includes “enhanc[ing] overall food integrity by facilitating truth-telling and transparency.” (Compl., ECF No. 1, ¶ 3.) To that end, GAP has requested documents from the Food and Drug Administration (“FDA” or “Defendant”) under the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552 *et seq.*, concerning total sales of antimicrobial drugs labeled for use in food-producing animals during the year 2009. (*See* Pl.’s Statement of Material Facts (“Pl.’s SMF”), ECF No. 41-1, ¶¶ 1–2.) In response, the FDA eventually turned over two responsive documents, with certain redactions. (*See id.* ¶¶ 5–6.) The only remaining dispute is whether the information redacted from the second document was properly withheld pursuant to one of FOIA’s exemptions. (*See* Pl.’s Mem. in Opp. to Defs.’ Mots. for Summ. J. & in Supp. of Cross-Mot. for Summ. J. (“Pl.’s Mem.”), ECF No. 41, 2–40, at 3.)¹

¹ Citations to the documents the parties have filed refer to the page numbers that the Court’s electronic filing system assigns.

Before this Court at present are the parties' cross-motions for summary judgment, as well as a motion for summary judgment from Intervenor-Defendant Animal Health Institute ("AHI"). (*See* Def.'s Renewed Mot. for Summ. J. ("Def.'s Mot."), ECF No. 32, 1–3; Intervenor-Def. Animal Health Institute's Mot. for Summ. J. ("AHI's Mot."), ECF No. 40, 1–2; Pl.'s Cross-Mot. for Summ. J. ("Pl.'s Mot."), ECF No. 41, 1.) GAP asserts that the redactions are improper (*see generally* Pl.'s Mem.), but the FDA maintains that the redacted information properly falls under FOIA Exemptions 3 and 4. (*See generally* Def.'s Mem. in Supp. of Def.'s Mot. ("Def.'s Mem."), ECF No. 32, 9–45.) AHI agrees with the FDA, and offers its own arguments that Exemption 4 applies. (*See generally* Intervenor-Def. Animal Health Institute's Mem. in Supp. of Mot. for Summ. J. ("AHI's Mem."), ECF No. 40, 14–46.)

As explained below, this Court concludes that FOIA Exemption 3, which protects information "specifically exempted from disclosure by statute[,]" 5 U.S.C. § 552(b)(3), does not cover the redacted information because Section 105 of the Animal Drug and User Fee Amendments of 2008—the statute that the FDA invokes—is not an exemption statute. *See* 21 U.S.C. § 360b(l)(3). Exemption 4, which protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential[,]" 5 U.S.C. § 552(b)(4), may well cover the information at issue, but there is a dispute of material fact regarding whether the release of the information would cause substantial competitive harm, as that exemption requires. Therefore, at this stage, summary judgment is not warranted in favor of any party, and all three motions must be **DENIED**. A separate order consistent with this Memorandum Opinion will follow.

I. BACKGROUND

A. Basic Facts

Antimicrobial drugs are used in food-producing animals for a variety of purposes, including to treat and prevent disease and to promote growth and weight gain. (*See* Decl. of Michael J. Blackwell (“Blackwell Decl.”), Ex. 1 to Pl.’s Mot., ECF No. 41-2, ¶ 9.) Some members of the public are concerned that the overuse of such drugs may harm public health by creating antimicrobial-resistant bacteria that might subsequently infect humans. (*See id.*) But data on the use of antimicrobial drugs in food-producing animals is hard to come by, making it difficult to study the link between such drugs and antimicrobial resistance. (*See id.* ¶ 10.)

The Animal Drug and User Fee Amendments of 2008 (“ADUFA”), 110 Pub. L. 316, 122 Stat. 3509, codified at 21 U.S.C. § 360b(l)(3), requires that sponsors of antimicrobial drugs used in animals submit an annual report to the Secretary of Health and Human Services containing “the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals.” 21 U.S.C. § 360b(l)(3)(A). This report must include, among other things, the amount of each antimicrobial active ingredient sold or distributed, and this information must reflect certain specified variables: (1) “container size, strength, and dosage form”; (2) “quantities distributed domestically and . . . exported”; and (3) “dosage form, including, for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.” *Id.* § 360b(l)(3)(B). A portion of this data is made available to the public in the form of annual summary reports, subject to certain statutory restrictions. *See id.*

§ 360b(l)(3)(E); (2009 Summary Report, Ex. 5 to Decl. of Gorka Garcia-Malene (“Garcia-Malene Decl.”), ECF No. 32-1, 33–60; Def.’s Mem. at 11 n.1).

As part of its mission to promote food quality through transparency, GAP filed a FOIA request in February of 2011, seeking certain data that were not included in the summary reports. This initial FOIA request sought

(1) printed copies of all educational and outreach materials that FDA has prepared in order to inform and assist antimicrobial drug sponsors in fulfilling their duty to report the amount of antimicrobial active ingredient in their drugs that have been sold or distributed for use in food-producing animals pursuant to [Section] 105 of the Animal Drug User Fee Amendments of 2008; (2) FDA’s data for use of antimicrobial drugs in food-producing animals in 2009 as broken down by container size, strength, and dosage form; and (3) FDA’s data for use of antimicrobial drugs in food-producing animals in 2009 as broken down by class of animal.

(Pl.’s SMF ¶ 2.) The FDA produced documents in response to the first part of GAP’s request in May of 2011; one month later, in June, the agency notified GAP that it was withholding documents with respect to the remaining parts of the request on the basis of Exemption 4. (*See* Garcia-Malene Decl. ¶¶ 6–7; Pls.’ Mem. at 2.) GAP appealed that determination in July of 2011, and the FDA denied the appeal one year later. (*See* Compl. ¶ 23.) GAP then filed the instant complaint, in December of 2012, seeking to challenge the FDA’s withholding determination. (*See id.* ¶¶ 33–36.)

Meanwhile, GAP modified portions of its FOIA request. (*See* Compl. ¶ 21; Garcia-Malene Decl. ¶ 8.) Most notably, GAP altered the second and third parts of the request to indicate that it desired “*aggregated* data concerning the amount of antimicrobial active ingredient sold for each *class* of antimicrobial drugs, rather than data concerning sales or distribution by each individual sponsor[.]” (Compl. ¶ 21 (emphasis added); *see also* Pl.’s SMF ¶ 4.) The FDA conducted a search based on this

new request and located two responsive documents, known for the purposes of this case as “Document 1” and “Document 2.” (Pl.’s SMF ¶ 5.) The agency produced both documents with redactions (*id.* ¶ 6), and at this point, GAP is not challenging the scope or adequacy of the FDA’s search, nor the redactions that the agency made to Document 1 (*see* Pl.’s Mem. at 3). Rather, the only remaining dispute between the parties is the legitimacy of the redactions in Document 2. (*See id.*)

Document 2 lists the volume (in kilograms) of the active ingredients for all antimicrobial drugs sold and distributed in 2009, broken down based on three characteristics: the market within which the drug is distributed (e.g., domestic or export); the route of the drug’s administration (e.g., injection or topical); and the drug’s antimicrobial class (e.g., aminoglycosides or tetracyclines). (*See* Ex. to Notice of Filing (“Doc. 2”), ECF No. 21-1; AHI’s Mem. at 24.) The document also indicates, for each particular antimicrobial class within a route and a market, whether the drugs in that class had one, two, or three or more sponsors in 2009. (*See* Doc. 2 at 1.) Finally, the document records the total volume of active ingredients for antimicrobial drugs sold or distributed by the type of market, and the route of administration within that market. (*See id.*) For example, according to the document, 22,957 kilograms of macrolides designed for injection were sold or distributed domestically in 2009, coming from three or more distinct sponsors. (*See id.*) And, overall, there were 388,518 total kilograms of antimicrobial drugs designed for injection sold or distributed domestically in 2009. (*See id.*)

Significantly for present purposes, the FDA has invoked FOIA Exemptions 3 and 4 to redact many of the data points in Document 2. To be specific, the FDA asserts that

it has redacted: (1) “all individualized sales and distribution data (i.e., data from a single, distinct sponsor)”; (2) “all sales and distribution data comprised of aggregated data of two distinct sponsors”; and (3) “sales and distribution data comprised of aggregated data of three or more distinct sponsors” if, through simple arithmetic using public data the agency has already released, such data could reveal aggregated sales and distribution data of one or two distinct sponsors. (Def.’s Mem. at 13.) According to the FDA, these redactions reflect the agency’s concern about potential revelations to industry competitors regarding the sales/distribution volume of a particular class/route/market combination that is attributable to a particular sponsor. (*See id.* at 22–27; 39–41.)

As a practical matter, the FDA’s redaction analysis appears to have worked as follows. As noted above, the FDA first redacted all data from a single specific sponsor. There was only one sponsor in 2009 for domestic sulfas designed for injection, for example (*see* Doc. 2 at 1), and in the agency’s view, if that data point was released, anyone who knew the identity of the sole sponsor would necessarily also know that sponsor’s sales or distribution total for domestic, injection-administered sulfa drugs in 2009. (*See* Def.’s Mem. at 22–23.) The FDA also redacted all data that were aggregated from just two distinct sponsors. For example, two sponsors provided all of the aminoglycosides designed for injection that were sold or distributed in 2009. (*See* Doc. 2 at 1.) The FDA asserts that, if that data point was released, each sponsor would know the volume that was attributable to its rival simply by subtracting its own volume from the aggregated figure. (*See* Def.’s Mem. at 24, 40.) Finally, the FDA redacted any data that were aggregated from three or more distinct sponsors where other publicly

available data would reveal the sales and distribution data of two or fewer distinct sponsors. For example, while two routes of administration for domestic lincosamides (intramammary and feed) had just one sponsor and were redacted on that basis (*see* Doc. 2 at 1), two other routes for domestic lincosamides (injection and water) had three or more sponsors (*see id.*), which meant that, on the face of the document, the data related to the injection and water routes should have been publicly released. However, according to the FDA, other publicly available information (specifically, the 2009 Revised Summary Report) includes a grand total for domestic sales and distribution of lincosamides. (*See* 2009 Summary Report at 33–60.) Thus, the agency reasoned, if the lincosamide injection and water totals in Document 2 are released, a competitor could take the grand total from the Summary Report, subtract from it the injection and water totals as revealed in Document 2, and discover the total for lincosamides designed for intramammary and feed, which stem from a single sponsor. (*See* Garcia-Malene Decl. ¶ 34(a).)

B. Procedural History

The FDA and GAP filed cross-motions for summary judgment on the issue of whether Exemptions 3 and 4 justified Document 2’s redactions in 2013, and the Court held a hearing on those motions on June 5, 2014. This case was then stayed at the request of both parties while the FDA determined whether or not the figures in Document 2 were accurate. (*See* Consent Mot. to Stay Litigation, ECF No. 19; Minute Order of August 5, 2014.) The FDA disclosed an updated and revised version of

Document 2 (*see* Joint Status Report, ECF No. 22, at 1), the stay was lifted, and the parties re-filed cross-motions for summary judgment in early 2015.²

In its motion for summary judgment, the FDA argues that Section 105 of ADUFA is a withholding statute within the meaning of Exemption 3, and that its language prohibits the disclosure of the information that the FDA has withheld. (*See* Def.'s Mem. at 16–27.) With respect to Exemption 4, the FDA contends that the redacted information is confidential commercial data, the disclosure of which would cause substantial competitive injury. (*See id.* at 27–43.) For its part, GAP argues that Section 105 of ADUFA is not a withholding statute under Exemption 3 (*see* Pl.'s Mem. at 11–20), and that even if it were a withholding statute, the FDA has applied it too broadly here (*see id.* at 20–25). GAP also urges the Court to conclude that Exemption 4 does not cover the redacted information because Defendants have not shown that the information would cause substantial competitive harm. (*See id.* at 24–40.)

On January 5, 2015, the Animal Health Institute, a trade association of companies that develop and manufacture animal medications, moved to intervene in this action in order to protect its members from the “substantial competitive harm” that would allegedly accompany “public disclosure of the annual sales volume of [their] medications[.]” (Mem. in Supp. of AHI’s Mot. to Intervene, ECF No. 23-1, at 2.) The Court granted AHI’s motion (*see* Mem. Op. & Order, ECF No. 37), and AHI subsequently filed its own motion for summary judgment, supporting the FDA’s redactions on the basis of Exemption 4 (*see* AHI’s Mot.; AHI’s Mem. at 29–45.)

² Both parties agree that only this revised version of Document 2 is at issue in this case. (*See* Joint Status Report, ECF No. 22, at 1.)

All three parties' cross-motions have now been fully briefed and are ripe for this Court's review.

II. LEGAL STANDARDS

FOIA “generally requires the disclosure, upon request, of records held by a federal government agency[.]” *Sciacca v. Fed. Bureau of Investigation*, 23 F. Supp. 3d 17, 25 (D.D.C. 2014) (alteration in original) (internal quotation marks omitted) (quoting *Judicial Watch, Inc. v. U.S. Dep’t of the Treasury*, 796 F.Supp.2d 13, 18 (D.D.C. 2011)); *see* 5 U.S.C. § 552(a)(3)(A). However, FOIA also includes nine exemptions that permit agencies to withhold information from disclosure. *See Judicial Watch*, 796 F. Supp. 3d at 23. These exemptions are to be construed narrowly, *see Dep’t of the Air Force v. Rose*, 425 U.S. 352, 361 (1976), and the government bears the burden of demonstrating that any withheld information falls within the claimed exemptions, *see Maydak v. Dep’t of Justice*, 218 F.3d 760, 764 (D.C. Cir. 2000).

A. FOIA Exemption 3

Under Exemption 3, an agency may withhold information “specifically exempted from disclosure by statute[.]” provided that the statute either (1) “requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue,” or (2) “establishes particular criteria for withholding or refers to particular types of matters to be withheld[.]” 5 U.S.C. § 552(b)(3).³ These conditions are disjunctive; a

³ The text of Exemption 3 also requires that a purported withholding statute “specifically cite[.]” to the FOIA provision that authorizes the withholding. *See* 5 U.S.C. § 552(b)(3). But this requirement applies only with respect to withholding statutes that are “enacted *after* the date of enactment of the OPEN FOIA Act of 2009,” which was October 28, 2009. *Id.* § 552(b)(3)(B) (emphasis added); *see* OPEN FOIA Act of 2009, Pub. L. No. 111-83, § 564, 123 Stat. 2142, 2184 (2009). Therefore, it is not relevant here. *See* Animal Drug User Fee Program—Revision and Extension, Pub. L. No. 110-316, 122 Stat. 3509 (establishing that Section 105 of ADUFA was enacted on August 14, 2008).

statute need satisfy only one of them to qualify under Exemption 3. *See Pub. Citizen, Inc. v. Rubber Mfrs. Ass'n*, 533 F.3d 810, 813 (D.C. Cir. 2008). However, “[b]efore a court inquires into whether any of the [two statutory] conditions [for withholding information] are met . . . it must first determine whether the statute is a withholding statute at all by deciding whether it satisfies ‘the threshold requirement that it *specifically exempt* matters from disclosure.’” *Id.* at 813–14 (emphasis in original) (quoting *Reporters Comm. for Freedom of the Press v. U.S. Dep’t of Justice*, 816 F.2d 730, 734 (D.C. Cir. 1987)).

To determine whether a statute qualifies as a withholding statute as required, courts look to “the language of the statute on its face[.]” *Zanoni v. U.S. Dep’t of Agric.*, 605 F. Supp. 2d 230, 236 (D.D.C. 2009), and they do not defer to an agency’s interpretation of the statute, *see Reporters Comm.*, 816 F.2d at 735, *rev’d on other grounds*, 489 U.S. 749 (1989); *cf. Rubber Mfrs. Ass’n*, 533 F.3d at 814 (noting that all parties, including the Department of Transportation, had agreed that “[j]udicial deference is neither sought nor owed to the agency’s interpretation” of a statute’s nature under Exemption 3 (alteration in original) (citation omitted)). Only if a statute meets the threshold requirement must a court consider whether either of the two conditions articulated in 5 U.S.C. § 552(b)(3)(A) is satisfied. *See Rubbers Mfrs. Ass’n*, 533 F.3d at 815; *Zanoni*, 605 F. Supp. 2d at 236.

B. FOIA Exemption 4

FOIA Exemption 4 protects from disclosure “trade secrets and commercial or financial information obtained from a person and privileged or confidential[.]” 5 U.S.C. § 552(b)(4). No party in the instant case argues that this case involves trade secrets, and GAP does not contest that the information in Document 2 is commercial

and obtained from a person—the sole dispute is whether the information is “privileged or confidential.” (See Pl.’s Mem. at 25–26; Def.’s Mem. at 27 & n.18.) Courts employ different tests to determine whether information is confidential, depending in part on whether the initial disclosure of the information was voluntary or compulsory. Where a party is required to submit the information to the government, such information is confidential under Exemption 4 “if disclosure of the information is likely . . . (1) to impair the Government’s ability to obtain necessary information in the future[,] or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.” *Nat’l Parks & Conservation Ass’n v. Morton* (*Nat’l Parks I*), 498 F.2d 765, 770 (D.C. Cir. 1974) (footnote omitted). “[F]or the government to preclude disclosure based on a competitive injury claim, it must prove that the submitters ‘(1) actually face competition, and (2) substantial competitive injury would likely result from disclosure.’” *Niagara Mohawk Power Corp. v. U.S. Dep’t of Energy*, 169 F.3d 16, 18 (D.C. Cir. 1999) (quoting *Nat’l Parks & Conservation Ass’n v. Kleppe* (*Nat’l Parks II*), 547 F.2d 673, 679 (D.C. Cir. 1976). And this competitive injury must “flow[] from the affirmative use of proprietary information by competitors.” *Pub. Citizen v. U.S. Dep’t of Health & Human Servs.*, 975 F. Supp. 2d 81, 114 (D.D.C. 2013) (emphasis omitted) (internal quotation marks omitted) (quoting *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 704 F.2d 1280, 1291 n.30 (D.C. Cir. 1983)).

Notably, “an agency opposing disclosure based on Exemption 4 is not required to provide detailed economic analysis of the competitive environment[.]” *Gilda Indus., Inc. v. U.S. Customs & Border Prot. Bureau*, 457 F. Supp. 2d 6, 10 (D.D.C. 2006) (citation omitted). However, the agency “must provide affidavits that contain more

than mere conclusory statements of competitive harm.” *Id.* (citation omitted).

Moreover, when invoking Exemption 4, the agency is not required “to prove disclosure certainly would cause it substantial competitive harm, but only that disclosure would ‘likely’ do so.” *McDonnell Douglas Corp. v. U.S. Dep’t of Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004) (citation omitted).

C. Summary Judgment In FOIA Cases

Courts routinely resolve FOIA disputes in the summary judgment context. *See AquAlliance v. U.S. Bureau of Reclamation*, 139 F. Supp. 3d 203, 207 (D.D.C. 2015); *Wheeler v. Dep’t of Justice*, 403 F. Supp. 2d 1, 5 (D.D.C. 2005) (explaining that summary judgment is the “routine vehicle” for resolution of a FOIA dispute).

According to Federal Rule of Civil Procedure 56, summary judgment must be granted when the “movant shows that there is no genuine dispute as to any material fact and [that] the movant is entitled to judgment as a matter of law[.]” Fed. R. Civ. P. 56(a), and a material fact is a fact “that might affect the outcome of the suit,” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The defending agency “bears the burden of proving that it has complied with its obligations under the FOIA[.]” *AquAlliance*, 139 F. Supp. 3d at 207 (citing, *inter alia*, 5 U.S.C. § 552(a)(4)(b)). This means that, to be entitled to summary judgment, the agency must demonstrate that “each document that falls within the class requested either has been produced . . . or is wholly exempt from [FOIA’s] inspection requirements,” *Gilda Indus.*, 457 F. Supp. 2d at 9 (alterations in original) (quoting *Students Against Genocide v. Dep’t of State*, 257 F.3d 828, 833 (D.C. Cir. 2001)) (internal quotation marks omitted). The agency can carry this burden by submitting affidavits or declarations, so long as the sworn statements “describe the justifications

for nondisclosure with reasonably specific detail, demonstrate that the information withheld logically falls within the claimed exemption, and are not controverted by either contrary evidence in the record nor by evidence of agency bad faith.” *Sciacca*, 23 F. Supp. 3d at 27 (quoting *Military Audit Project v. Casey*, 656 F.2d 724, 738 (D.C. Cir. 1981)) (internal quotation marks omitted).

However, summary judgment cannot be granted if dueling affidavits create a genuine dispute over issues of material fact. *See Wash. Post Co. v. U.S. Dep't of Health & Human Servs.*, 865 F.2d 320, 326 (D.C. Cir. 1989); *Sears, Roebuck & Co. v. Gen. Servs. Admin.*, 553 F.2d 1378, 1382 (D.C. Cir. 1977); *Pub. Citizen Health Research Grp. v. Food & Drug Admin.*, 953 F. Supp. 400, 403 (D.D.C. 1996).

III. ANALYSIS

As explained, the FDA has produced two partially redacted documents in response to GAP’s amended FOIA request, only one of which is currently in dispute. (*See* Pl.’s Mem. at 3; Def.’s Mem. at 13.) Document 2 is a responsive record that contains data on the volume of antimicrobial drugs sold or distributed for use in food-producing animals in 2009, and although the agency has produced much of this document, it has withheld certain data on the grounds that the redacted information is exempt from disclosure under FOIA Exemption 3 or FOIA Exemption 4 (or both). For the reasons explained below, this Court agrees with GAP that the information the agency has redacted cannot be withheld pursuant to Exemption 3; however, the Court has also concluded that a dispute of material fact that is essential to determining whether or not Exemption 4 permits the challenged withholdings exists. Accordingly, all three pending summary judgment motions must be denied.

A. The FDA Cannot Invoke FOIA Exemption 3 To Withhold The Redacted Information In Document 2

This case is, in part, a tale of two statutes: FOIA and ADUFA. As explained above, FOIA’s Exemption 3 allows an agency to withhold information that is “specifically exempted from disclosure by [another] statute” under certain conditions, 5 U.S.C. § 552(b)(3), and here, the FDA insists that the redacted portions of Document 2 are specifically exempt from disclosure under Section 105 of ADUFA, 21 U.S.C. § 360b(l)(3). (*See* Def.’s Mem. at 16–27; Garcia-Malene Decl. ¶¶ 27–34.) Thus, the key questions are whether Section 105 of ADUFA qualifies as a withholding statute for the purpose of Exemption 3, *see Pub. Citizen, Inc.*, 533 F.3d at 813–14, and if so, whether the information that the FDA has withheld in this case is exempted from disclosure under that statute.

As usual, the Court begins its analysis by examining the pertinent statutory text. Section 105 of ADUFA requires sponsors of new animal drugs that contain an antimicrobial active ingredient to submit annual reports to the FDA “on the amount of each antimicrobial ingredient in the drug that is sold or distributed for use in food-producing animals[.]” 21 U.S.C. § 360b(l)(3)(A). The key provision for the purpose of the agency’s Exemption 3 argument is § 360b(l)(3)(E), which reads:

(E) The Secretary shall make summaries of the information reported under this paragraph publicly available, except that—

(i) the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; and

(ii) the data shall be reported in a manner consistent with protecting both national security and confidential business information.

Id. § 360b(l)(3)(E). The FDA contends that this provision prohibits disclosure of information in *all* contexts, including in response to a FOIA request, and thus Section 105 qualifies as a withholding statute under Exemption 3. (*See* Def.’s Mem. at 17–19.) Moreover, it argues that subsections (E)(i) and (E)(ii) specifically preclude the disclosure of the information that the agency has redacted from Document 2, because the withheld information would allow industry participants to calculate the sales/distribution data of individual drug sponsors for the year 2009, either directly or by comparing the withheld information to other publicly available information. (*See id.* at 23 (arguing that these statutory provisions “prohibit[] from disclosure” the information that the FDA redacted); *see also id.* at 22–27.)

GAP reads 21 U.S.C. § 360b(l)(3)(E) more narrowly. It construes that section as restricting only the content of the Secretary’s mandatory annual summary reports, and not as a limitation on the disclosure of the referenced information in *other* contexts, such as in response to FOIA requests. (*See* Pl.’s Mem. at 11–16.) Thus, in GAPs view, Section 105 of ADUFA does not explicitly exempt the information from public disclosure, as is required if this statutory provision is to qualify as an Exemption 3 withholding statute. (*See id.* at 12–13.) GAP also argues that, even if Section 105 is a withholding statute, its disclosure prohibitions are not broad enough to cover all of the information that the FDA has redacted from Document 2. (*See id.* at 20–25.)

This Court agrees with GAP that Section 105 of ADUFA is not a withholding statute under Exemption 3, for the following reasons.

1. Section 105 Of ADUFA Is Not A Withholding Statute For The Purpose Of FOIA Exemption 3 Because It Does Not Specifically Exempt Matters From Disclosure

To determine whether a statute “specifically exempt[s] matters from disclosure” and thus qualifies as a withholding statute that is within the purview of Exemption 3, 5 U.S.C. § 552(b)(3), courts begin by scrutinizing “the language of the statute on its face[.]” *Zanoni*, 605 F. Supp. 2d at 236 (citation omitted), and in this regard, the Court observes that § 360b(l)(3)(E) does contain language that limits the ability of the Secretary of HHS to disclose certain information. (*See* Def.’s Mem. at 17.) But this restriction is part of a broader provision that relates to the collection and reporting of certain drug-related data provided by drug sponsors (subsection *l*), and when one homes in on the telescoping structure of the statute, it becomes clear that Congress has not specifically directed the withholding of the information under all circumstances.

Specifically, and stepping back to examine the necessary context, subdivision 3(A) of subsection *l* requires “the sponsor of [an animal] drug [to] submit an annual report to the Secretary on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals[.]” 21 U.S.C. § 360b(l)(3)(A). Subdivisions 3(B) and 3(C) expound further on the content of the mandated reports that sponsors must provide to the Secretary, *see id.* §§ 360b(l)(3)(B), (C), and subdivision 3(D) authorizes the Secretary to “share information reported [to the agency] under this paragraph with the Antimicrobial Resistance Task Force[.]” *id.* § 360b(l)(3)(D). Subdivision 3(E)—the provision at issue here—then proceeds to require the Secretary to make summaries of the antimicrobial data that she collects “under this paragraph” and to make those summaries “publicly available,” with two exceptions: that “the summary data shall be reported by antimicrobial class, and no class with fewer

than 3 distinct sponsors . . . shall be independently reported[.]” *id.* § 360b(l)(3)(E)(i), and that “the data shall be reported in a manner consistent with protecting both national security and confidential business information[.]” *id.* § 360b(l)(3)(E)(ii). Thus, when viewed in context, the limiting provisions on which the FDA relies are most naturally read to relate specifically *to the required annual summary reports*, and they do not constitute blanket restrictions on the disclosure of information in all circumstances, as the agency maintains. *Cf. Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 133 S. Ct. 2517, 2529 (2013) (“Just as Congress’ choice of words is presumed to be deliberate, so too are its structural choices.” (citation omitted)).⁴

The repetition of key language further confirms that subdivisions (E)(i) and (E)(ii) are not general withholding mandates. It is a well-established principle of statutory interpretation that repeated phrases are presumed to have the same meaning, especially when they appear in close proximity. *See Brown v. Gardner*, 513 U.S. 115, 118 (1994); *Jarecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961). With that in mind, the Court notes that § 360b(l)(3)(E) begins with the requirement that the Secretary “make *summaries* of the information reported under this paragraph publicly available,” and subdivision (E)(i) picks up this thread when it establishes a limitation that, as expressed in the statute, pertains to “the *summary* data[.]” 21 U.S.C. § 360(l)(3)(E) (emphasis added). The natural, contextual reading of this subsection is that the “summary data” subdivision (E)(i) refers to and restricts are the same as the

⁴ The fact that Congress introduces the restrictions with the phrase “except that”—i.e., the statute requires the Secretary to make certain summaries publicly available, except that those summaries must abide by the restrictions of subdivisions (E)(i) and (E)(ii), 21 U.S.C. § 360b(l)(3)(E)—underscores this point, insofar as that phrase clearly frames the listed conditions as limitations only on the public summaries that the Secretary must produce.

“summaries” § 360(b)(1)(3)(E) requires, and reading subdivisions (E)(i) and (E)(ii) to apply to *all* possible disclosures, as the FDA does, extracts these provisions from the “summary” context and gives them a life of their own, without any indication that Congress actually meant for these restrictions to have such unbounded significance.

The fact that Congress certainly knows how to create a clear withholding mandate when it wants to also bolsters the conclusion that Section 105 of ADUFA is not intended to be construed as such. In other contexts, Congress has crafted statutory terms that unambiguously prohibit disclosure in all circumstances. *See, e.g.*, 52 U.S.C. § 30109(a)(12)(A) (“Any notification or investigation made under this section *shall not be made public* by the Commission or by any person without the written consent of the person receiving such notification or the person with respect to whom such investigation is made.” (emphasis added)); *see also* 7 U.S.C. § 8791(b)(2)(A) (“[A]ny officer or employee of the Department of Agriculture . . . *shall not disclose* . . . information provided by an agricultural producer . . . in order to participate in programs of the Department.” (emphasis added)); 50 U.S.C. § 4614(c)(1) (“[I]nformation obtained for the purpose of consideration of, or concerning, license applications under this Act *shall be withheld from public disclosure* unless the release of such information is determined by the Secretary [of Commerce] to be in the national interest.” (emphasis added)). And Congress has also seen fit to reference FOIA explicitly when it seeks to mandate that the specific information be exempt from disclosure. *See, e.g.*, 39 U.S.C. § 3016(d) (“Any documentary material provided pursuant to any subpoena issued under this section shall be exempt from disclosure under section 552 of title 5, United States Code.”).

Section 105 of ADUFA does not likewise prohibit all public disclosure in unambiguous terms, nor does it mention FOIA; so it is reasonable to infer that Congress did not intend this section to serve as an all-purpose anti-disclosure statute within the meaning of FOIA Exemption 3. *Cf. Rubber Mfrs. Ass'n*, 533 F.3d at 817 (“Congress knows well how to say that disclosures may be made only under specified provisions or circumstances, but it did not do so here.” (footnote and emphasis omitted)). When one also considers the fact that reading Section 105 of ADUFA narrowly is in keeping with FOIA’s “strong presumption in favor of disclosure,” *Rubber Mfrs. Ass'n*, 533 F.3d at 813 (internal quotation marks omitted) (quoting *U.S. Dep’t of State v. Ray*, 502 U.S. 164, 173 (1991)), the FDA has a difficult row to hoe in order to argue successfully that this Court should find that it can withhold the redacted information under FOIA Exemption 3 on the basis of Section 105 of ADUFA.

2. The FDA’s Exemption 3 Arguments Are Unpersuasive

The FDA attempts to advance several arguments in support of its invocation of Exemption 3 based on Section 105 of ADUFA, none of which succeeds. For example, regarding the text of subdivision (E)(i), the FDA contends that the language “no class with fewer than 3 distinct sponsors of approved applications shall be *independently reported*,” § 360b(l)(3)(E)(i) (emphasis added), reaches beyond the Secretary’s annual summary reports and acts as a restriction on disclosing this information generally. (*See* Def.’s Mem. at 18 n.9.) But this interpretation removes the all-important context of subdivision (E)(i), and does so in a manner that is not supported by the text. That is, although “independently reported” might conceivably mean “independent from the Secretary’s summary reports” when considered in a vacuum, the most natural reading of this phrase as it appears in the statute is that it relates to, and restricts, the content and

format of the summary reports themselves—i.e., within the Secretary’s summary report, the agency cannot provide an *independent* representation of the data on any antimicrobial class with fewer than three sponsors (in contrast to a data point that has been aggregated with other classes, where such data would not be independently presented). And the repetition of the term “reported” in the subsection clearly supports this narrow construction. *See* 21 U.S.C. § 360b(l)(3)(E)(i) (“[T]he summary data shall be *reported* by antimicrobial class, and no class with fewer than 3 distinct sponsors of approved applications shall be independently *reported*.” (emphasis added)). The first use of the word “reported” unquestionably refers to the formatting of the Secretary’s annual summaries, and it makes eminent sense to infer that Congress intended to reference the same when it used the word “reported” again later in the same sentence. *See Brown*, 513 U.S. at 118. Thus, the Court is not persuaded that the phrase “independently reported” transforms subsection (E)(i) into a universal restriction on disclosure, as the FDA maintains.

The FDA also argues that “the presence of a disclosure requirement in Section 105 of ADUFA does not mean that the prohibitions on disclosure are restricted to disclosures made in the Summary Reports.” (Def.’s Mem. at 19; *see id.* at 19–20.) This is true enough, as far as it goes; there is no *a priori* reason that a statute cannot both mandate disclosure in one context and restrict disclosure in another. But the FDA’s task here is to make a persuasive argument that, whatever the scope of the disclosure requirement in Section 105 of ADUFA, Congress intended the restrictions in subdivisions (E)(i) and (E)(ii) to extend beyond the mandated summary reports. And this Court believes that the best reading of the statute’s text is that the restrictions in

Section 105 are limitations on the Secretary's mandatory disclosures rather than all disclosures, for the reasons already stated.

Undaunted, the FDA points to the case of *John Doe #1 v. Veneman*, 380 F.3d 807 (5th Cir. 2004); ironically, in this Court's view, that case supports the Court's conclusion, not the FDA's. (*See* Def.'s Mem. at 19–20.) In *Veneman*, the Fifth Circuit considered whether or not a provision of the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), 7 U.S.C. §§ 136–136y, qualified as a withholding statute under Exemption 3. Similar to ADUFA, FIFRA requires users of certain types of pesticides to submit information on the scope of the use of these chemicals to both the EPA and the USDA, and required those agencies to “publish annual comprehensive reports” based on that information. 7 U.S.C. § 136i-1(f). FIFRA also instructs that

[r]ecords maintained under [the statute] shall be made available to any Federal or State agency that deals with pesticide use or any health or environmental issue related to the use of pesticides, on the request of such agency. Each such Federal agency shall conduct surveys and record the data from individual applicators to facilitate statistical analysis for environmental and agronomic purposes, but *in no case may a government agency release data . . . that would directly or indirectly reveal the identity of individual producers.*

Id. § 136i-1(b) (emphasis added). The Fifth Circuit had no difficulty concluding that this statute fell within Exemption 3's purview. *See Veneman*, 380 F.3d at 816–17. But in this Court's judgment, the clarity of FIFRA only highlights the weaknesses of the FDA's interpretation of ADUFA. As quoted above, FIFRA plainly states that “*in no case may a government agency release*” certain specified data, 7 U.S.C. § 136i-1(b) (emphasis added); by contrast, ADUFA's restrictions are at all times couched solely in terms of the information that is to be “reported” to the public by the Secretary, *see* 21 U.S.C. § 360b(l)(3)(E). Moreover, whereas FIFRA's disclosure requirement and non-

disclosure provision are housed in separate sections, *compare* 7 U.S.C. § 136i-1(b), *with id.* § 136i-1(f), ADUFA’s purported non-disclosure provisions are nested *within* its disclosure requirement, *see* 21 U.S.C. § 360b(l)(3)(E); *id.* at §§ 360b(l)(3)(E)(i)–(E)(2), which creates a clear nexus between what must be “reported” and what must be withheld as the Secretary undertakes that reporting obligation. Thus, far from making the FDA’s case, *Veneman* only serves to underscore the gap between a true Exemption 3 withholding statute and the provisions at issue in this case.⁵

The D.C. Circuit has addressed the Exemption 3 status of a statute with an affirmative disclosure requirement in a manner that is instructive here. *See Pub. Citizen, Inc. v. Rubber Mfrs. Ass’n*, 533 F.3d 810 (D.C. Cir. 2008). The *Public Citizen* case involved the National Traffic and Motor Vehicle Safety Act of 1966 (the “Safety Act”), 42 U.S.C. §§ 30101–30183, and a subsequent amendment to that statute known as the Transportation Recall Enhancement, Accountability, and Documentation Act (“the TREAD Act”), Pub. L. No. 106-414, 114 Stat. 1800 (2000). Section 30167(b) of the Safety Act requires the Secretary of Transportation “to disclose information obtained under this chapter related to a defect or noncompliance that the Secretary decides will assist [manufacturers] in carrying out” specified provisions of that Act. 49

⁵ The FDA also relies on *Consumer Product Safety Commission v. GTE Sylvania, Inc.* (CPSC), 447 U.S. 102 (1980), a case in which the Supreme Court held that a provision of the Consumer Product Safety Act (“CPSA”) fell within the scope of Exemption 3. (*See* Def.’s Mem. at 21 (citing CPSC, 447 U.S. at 107–08, 122).) A unanimous Court affirmed the Third Circuit’s conclusion that the disclosure restriction applied not only to the Commission’s “affirmative disclosure[s]” but also to FOIA requests, *see id.* at 109 n.4; *id.* at 107 (quoting *GTE Sylvania, Inc. v. Consumer Prod. Safety Comm’n*, 598 F.2d 790, 811 (3d Cir. 1979)); however, just as with FIFRA, the language and structure of the CPSA was markedly different than that of ADUFA. The CPSA (at that time) required the agency to take certain steps “prior to its public disclosure” of any information obtained under the Act, 15 U.S.C. § 2055(b)(1) (1980), and neither the text nor structure of the Act limited that mandate to circumstances in which the agency made affirmative disclosures (such as press releases or news conferences). Thus, CPSC is distinguishable from this case insofar as ADUFA contains textual and structural indicators of congressional intent to cabin the statute’s disclosure restrictions to the Secretary’s mandatory reports.

U.S.C. § 30167(b). The TREAD Act requires car manufacturers to report to NHTSA certain data that may assist in the early identification of motor vehicle safety defects, *see id.* § 30166(m)(3)(B); 49 C.F.R. §§ 579.5, 579.21–.26, but the Act also provides that “[n]one of the information collected . . . shall be disclosed pursuant to section 30167(b) unless the Secretary” makes a particular determination about its usefulness, *id.* § 30166(m)(4)(C) (emphasis added). Thus, the TREAD Act disclosure restriction expressly references the Safety Act’s affirmative reporting requirement, and as a result, the D.C. Circuit concluded that the restriction impacted only disclosures made “pursuant to section 30167(b)[.]” *Rubber Mfrs. Ass’n*, 533 F.3d at 820. Accordingly, the Circuit held that the TREAD Act merely “exempts [early warning reporting data] from disclosure under § 30167(b)” and thus does not “specifically exempt certain matters from disclosure” in a manner that makes it a withholding statute for Exemption 3 purposes. *Id.* at 815 (internal quotation marks and citation omitted).

Although the explicit cross-reference between the disclosure restriction and the affirmative reporting requirement makes the TREAD Act somewhat clearer than ADUFA, the logic of *Rubber Manufacturers Ass’n* compels the conclusion that ADUFA is, likewise, not a withholding statute. This is because, as explained above, the text and structure of ADUFA plainly indicate that the restrictions of 21 U.S.C. §§ 360b(l)(3)(E)(i) and (E)(ii) are limited to the disclosures required by § 360b(l)(3)(E); consequently, the statute at issue here must not be read to “specifically exempt certain matters from disclosure,” as Exemption 3 requires.

Finally, this Court rejects the FDA’s suggestion that the legislative history of Section 105 of ADUFA demands a different result. (*See* Def.’s Mem. at 21–22.) The

agency points to a statement in the House Report that says: “It is the intention of this Committee that the information reported under this section be available only to representatives of Federal agencies.” Animal Drug User Fee Program-Revision and Extension, H.R. Rep. 110-804, at 15 (2008), *reprinted in* 2008 U.S.C.C.A.N. at 1295. However, although federal courts sometimes look to legislative history in the Exemption 3 context (at least to “support [their] textual conclusions”), *Rubber Mfrs. Ass’n*, 533 F.3d at 818 n.4, it is not entirely clear that legislative history should be consulted where, as here, that statute’s language is “plain on its face,” *id.* at 818; *see also id.* (noting that, in such circumstances, “courts do not ordinarily resort to legislative history” and explaining that the D.C. Circuit “has long disfavored the use of legislative history to determine whether a statute qualifies as a withholding statute under Exemption 3” (internal quotation marks and citation omitted)); *Nat’l Ass’n of Home Builders v. Norton*, 309 F.3d 26, 38 (D.C. Cir. 2002) (“We must find a congressional purpose [to] exempt matters from disclosure in the actual words of the statute . . . not in the legislative history of the claimed withholding statute[.]” (quoting *Reporters Comm.*, 816 F.2d at 735) (internal quotation marks omitted)).

Moreover, and in any event, just as in *Rubber Manufacturers Ass’n*, “there is no text to which such support [i.e., the legislative history] may be attached in this case[.]” 533 F.3d at 818 n.4, because the enacted text of ADUFA does not contain any express restriction on who may ultimately access the information collected under the statute. And the FDA’s suggestion that Congress implicitly intended for Section 105 of ADUFA to be read in conjunction with Exemption 3 to prohibit disclosure of the referenced information to members of the public in the FOIA context, as a means of shielding

antimicrobial drug sponsors from “the harmful effects of public disclosure of their individualized information” (Def.’s Mem. at 21), appears to be overblown, all things considered. Congress has provided protection for national security and confidential business information—the same categories safeguarded by § 360b(l)(3)(E)(ii)—via FOIA Exemptions 1 and 4. *See* 5 U.S.C. § 552(b)(1); *id.* § 552(b)(4). Thus, the agency’s insistence that Exemption 3 must be invoked to do the work of protecting confidential antimicrobial data (otherwise, the sponsors are doomed) is unpersuasive.

In the final analysis, then, this Court disagrees with the agency’s assertions regarding the nature of Section 105 of ADUFA, and it concludes that that statute is not a withholding statute for Exemption 3 purposes. Consequently, the Court “do[es] not need to consider whether the statute meets the additional conditions of 5 U.S.C. § 552(b)(3)(A) or (B),” *Rubber Mfrs. Ass’n*, 533 F.3d at 815, nor must it address whether the FDA has read § 360b(l)(E) too broadly in withholding on Exemption 3 grounds the particular information it redacted from Document 2. (*See* Pl.’s Mem. at 20–25.)

B. No Party Is Entitled To Summary Judgment At This Time

Although the FDA cannot base the redactions at issue in this case on FOIA Exemption 3 for the reasons explained above, the agency also seeks to justify its withholdings on the basis of FOIA Exemption 4, which allows agencies to withhold “trade secrets and commercial or financial information obtained from a person and privileged or confidential.” 5 U.S.C. § 552(b)(4). Everyone agrees that this case does not involve trade secrets, and that the information redacted from Document 2 is commercial and obtained from a person. Thus, the sole dispute regarding the agency’s invocation of Exemption 4 is whether the withheld information is “privileged or

confidential.” (See Pl.’s Mem. at 25–27; Def.’s Mem. at 27 & n.18; AHI’s Mem. at 27.) In this regard, the parties also agree that the governing standard for confidentiality in this circumstance is whether disclosure is “likely to cause . . . substantial harm to the competitive position of the person from whom the information was obtained,” *Nat’l Parks I*, 498 F.3d at 770; (see Pl.’s Mem. at 26; Def.’s Mem. at 29; AHI’s Mem. at 27–29), and that to clear this hurdle, the government must prove that the people who submitted the information to the government “(1) actually face competition, and [that] (2) substantial competitive injury would likely result from disclosure,” *Niagara Mohawk*, 169 F.3d at 18 (quoting *Nat’l Parks II*, 547 F.2d. at 679) (internal quotation marks omitted); (see Pl.’s Mem. at 27; Def.’s Mem. at 29; AHI’s Mem. at 28).

But, unfortunately, the parties’ agreement ends there. The FDA and Defendant-Intervenor AHI assert that there are myriad ways that the sponsors of antimicrobial animal drugs face competition and would be harmed by the disclosure of the information that the agency has redacted from Document 2, and they have provided a bevy of affidavits to this effect from industry members and experts. (See Def.’s Mem. at 29–44; AHI’s Mem. at 29–45.) GAP retorts that these arguments are all speculative, and it provides its own experts’ affidavits to support this contention. (See Pl.’s Mem. at 27–40.) This Court has carefully considered each side’s arguments and evidence, and it concludes that, although Defendants have carried their burden of showing that antimicrobial animal drug sponsors face actual competition, there is a genuine dispute of material fact regarding whether or not the drug sponsors whose information is reflected in Document 2 would be likely to face substantial competitive injury as a

result of the government's disclosure of the redacted data. Therefore, summary judgment cannot be granted in favor of any party.

1. Defendants Have Demonstrated That There Is Actual Competition In The Antimicrobial Animal Drug Market

With respect to the requirement of actual competition, the FDA and AHI have provided various affidavits attesting to the fact that the antimicrobial animal drug market “is very competitive and highly price sensitive” (Def.’s Mem. at 30), and that competition exists “both among the different classes of antimicrobial drugs and among drugs with different routes of administration” (Def.’s Reply in Supp. of Def.’s Mot., ECF No. 44, at 19). For example, Dr. Thomas Elam, the president of FarmEcon LLC, which is an agricultural and food industry consulting firm, avers that “[t]he market for animal drugs containing an antimicrobial active ingredient for use in food-producing animals is highly competitive[,]” and lists 27 different competing companies. (Decl. of Thomas Elam (“Elam Decl.”), Ex. C to Def.’s Mot., ECF No. 35-1, 1–20, ¶ 15.) Dr. Elam also states that “[t]hese drug products compete head-to-head across routes of administration . . . and across drug classes[,]” explaining that different drugs across different classes and routes of administration can be in competition because they are used to treat the same conditions (e.g., pig diarrhea). (*Id.* ¶ 16; *see also* AHI’s Mem. at 31 (“In other words, although certain animal health companies may only sell products using certain classes of antimicrobial active ingredients, two companies with products in entirely different classes can still compete against one another, as their two different products (using different active ingredients) may be indicated to treat the same ailment.”).)

Dr. Elam further explains that the customer base for these products is highly concentrated, leading to intense price competition. (*See id.* ¶ 19 (“[A]ntimicrobial drug manufacturers compete fiercely for the business of a few large distributors and customers.”).) And many of the other affidavits Defendants have submitted corroborate Dr. Elam’s general conclusions. (*See, e.g.*, Decl. of Neal Bataller, Ex. B to Def.’s Mot., ECF No. 32-2, ¶¶ 10 (“Because different animal products may be used to treat the same disease or condition, competition exists among the different classes of antimicrobial drugs and among different routes of administration,”); *id.* ¶¶ 11–16; Decl. of Jeet Uppal, Ex. D to Def.’s Mot., ECF No. 35-1, 21–31, ¶ 18 (“Animal drug manufacturers compete against companies producing drugs in the same route of administration and class of antimicrobial drugs as well as companies producing drugs in other classes and routes of administration. Companies compete across routes of administration and classes in part because drugs in different classes can be indicated for the same disease in the same animal.”); Decl. of Scott Bormann, Ex. F to Def.’s Mot., ECF No. 35-1, 46–57, ¶ 12 (“The market for animal drugs containing an antimicrobial active ingredient for use in food-producing animals is highly competitive. . . . The products listed in Document 1 and revised Document 2 compete head-to-head across routes of administration and antimicrobial classes. Thus Merck [Animal Health] competes directly with both manufacturers of products in the same class as Merck and in other classes.”); Decl. of Cathy Martin, Ex. G to Def.’s Mot., ECF No. 35-1, 58–65, ¶ 11 (“Elanco competes with many animal health companies, and there is heavy competition across classes of antimicrobial drugs. . . . The [animal health business] competitors have annual revenues of one (1) to almost five (5) billion dollars, and the competition is

vigorous . . . Many hundreds of millions of dollars are spent annually on research and development . . . to win market share.”.)⁶

GAP offers no evidence to rebut the Defendants’ contention that the antimicrobial animal drug market is competitive; and, indeed, GAP’s expert witness, Dr. Michael J. Blackwell, admits in his declaration that “there is considerable overlap in the purposes for which these drugs are used in practice, even among drugs in different classes and routes of administration[]” (Decl. of Michael J. Blackwell, Ex. 1 to Pl.’s Mot., ECF No. 41-2, ¶ 22), which is a statement that strongly implies that actual competition between various drug sponsors exists. GAP’s only response to the evidence of competition that the FDA and AHI have offered is to argue that the dozens of statements these parties have presented are “conclusory” (Pl.’s Mem. at 28) and do not contain “specific examples of drugs that face actual competition” (Pl.’s Reply in Supp. of Pl.’s Mot., ECF No. 49, at 12).

This Court disagrees. It is hard to imagine what more information the FDA and AHI could have provided to demonstrate that antimicrobial animal drug sponsors face actual competition: their many affidavits are comprehensive, and contain far more than the mere *ipse dixit* that the market is competitive. The affiants name specific competitors, explain the structure of the market, and/or provide specific examples of instances in which products across drug classes and routes of administration compete because they address identical conditions. (*See e.g.*, Elam Decl. ¶ 15; Bataller Decl.

⁶ (*See also* Decl. of Warren M. Harper, Ex. E to Def.’s Mot., ECF No. 35-1, 32–44, ¶¶ 15–16; Decl. of Michael Mlodzik, Ex. H to Def.’s Mot., ECF No. 35-1, 66–74, ¶¶ 16–17; Suppl. Decl. of Kelly W. Beers, Ex. I to Def.’s Mot., ECF No. 35-1, 75–79, ¶ 4; Decl. of Robert Solynas, Ex. J to Def.’s Mot., ECF No. 35-1, 80–85, ¶ 10; Decl. of S. Lee Whaley, Ex. K to Def.’s Mot., ECF No. 35-1, 86–89, ¶ 6; Decl. of Douglas Rupp, Ex. L to Def.’s Mot., ECF No. 35-1, 90–93, ¶¶ 9–10.)

¶ 14; Bormann Decl. ¶ 12; Martin Decl. ¶ 11; Mlodzik Decl. ¶ 17; Rupp. Decl. ¶ 9.)

Thus, Defendants have thoroughly “list[ed] the number of competitors in the . . . industry and describe[d] the nature of the competition.” *People for Ethical Treatment of Animals v. U.S. Dep’t of Agric.*, No. 03-195, 2005 WL 1241141, at *6 (D.D.C. May 24, 2005). What is more, GAP “has not offered [its own] evidence to contradict [Defendants’] testimony.” *Id.*⁷

Consequently, this Court concludes that Defendants have provided sufficient evidence to demonstrate actual competition. *See id.* (finding actual competition in the puppy distribution industry where an industry member’s affidavit described “the number of competitors in the . . . industry and . . . the nature of the competition,” and was “based on . . . thirteen years of experience in the . . . industry”); *see also In Def. of Animals v. U.S. Dep’t of Agric.*, 656 F. Supp. 2d 68, 80 (D.D.C. 2009) (finding actual competition in the human pharmaceutical industry because, like in the antimicrobial animal drug industry, there exists a race “to be the first to get a particular type of drug to market[.]”).

⁷ Apparently, GAP believes that the most fruitful way to rebut its opponents’ testimony is to seek to have some of it stricken on the ground that particular statements within the affidavits are “conclusory, lack foundation, lack personal knowledge, and/or state a legal conclusion[.]” (Pl.’s Mem. at 37–40.) GAP’s effort is unavailing, in part because it has moved to strike *all* of the identified statements without attempting to articulate the specific flaws with each; moreover, the myriad problems to which GAP alludes are not apparent on the face of the affidavits: most of the statements are made by independent experts or industry participants who are providing their informed opinions on the antimicrobial animal drug market and how competitors in that market might use 2009 sales volume data. (*See id.* at 38–39.) In any event, motions to strike are generally disfavored, *see Canady v. Erbe Elektromedizin GmbH*, 384 F. Supp. 2d 176, 180 (D.D.C. 2005), and GAP’s conclusory allegations are insufficient to carry its “heavy burden” of showing that each of the statements was not based on personal knowledge, did not set forth facts that would be admissible in evidence, or was made by an affiant who is not competent to testify to the matters stated therein, *id.* (citing Fed. R. Civ. P. 56(e)).

2. A Genuine Dispute Of Material Fact Exists As To Whether Disclosure Of The Withheld Information Would Cause Substantial Competitive Injury

In addition to establishing actual competition, the FDA must also show that disclosure of the withheld sales and distribution data would cause substantial competitive injury to the drug sponsors who submitted the data, if it plans to rely on Exemption 4 to justify the challenged withholdings. To this end, the FDA and AHI assert that release of the data that have been redacted from Document 2 would permit competitors to determine the volume of specific antimicrobial medications that certain sponsors sold in 2009 in a manner that would be harmful those sponsors. (*See* AHI's Mem. at 32.) And they maintain that their legion of affiants have provided testimony that establishes the potential competitive injury in at least four respects.

For one thing, according to the FDA and AHI, the data would reveal to competitors a sponsor's market share with respect to particular products, thereby exposing which products are worthwhile to target for competition. (*See* Def.'s Mem. at 31–33; AHI's Mem. at 33.) Many of Defendants' affidavits support this claim. (*See, e.g.,* Elam Decl. ¶ 21 (“Because the animal drug market is highly competitive and drug manufacturers' profitability is driven primarily by their ability to capture market share (rather than by intellectual property rights), accurate data regarding the sales of, and demand for, certain products manufactured by competitors is highly valuable and could be used by a manufacturer to capture business from a competitor, thereby reducing its sales and profitability.”); Uppal Decl. ¶ 19 (“Competitors that possess reliable estimates of the sales volume of Zoetis' drugs are likely to use that information in determining whether to enter a particular market segment. Competitors will be incentivized to bring new products to market to capture market share from Zoetis where the data reveals a

relatively high volume of sales for a Zoetis product.”); Harper Decl. ¶ 16 (“Phibro’s competitors seek to determine whether there are market segments into which they could profitably introduce new generic drugs or market segments from which they should withdraw (shifting their resources to other market segments) based on their assessment of market trends.”).)

Second, the FDA and the AHI contend that the data would reveal to competitors which markets are ripe for *re*-entry, allowing them to put back into circulation any products that have been approved but that they are not currently distributing. (*See* Def.’s Mem. at 33–34; AHI’s Mem. at 36–37.) In other words, a competitor could use the data to determine if there is high demand in a market segment for which it already has an approved product, and, if so, put that product back into circulation to capture market share. Again, the affiants affirm this possibility. (*See* Bataller Decl. ¶ 16 (“[M]any drugs . . . are the subject of approved [new animal drug applications] but . . . are not currently being marketed. . . . [M]any competitors with approved [applications] can decide to actively market again and provide additional competition.”); Elam Decl. ¶ 31 (“[C]ompetitors [who] already hold an approved application for products that are not currently marketed . . . could use the information regarding market segment profitability to decide to market those dormant products, thereby capturing market share from, and causing financial harm to, companies that already sell products in those market segments.”); *see also* Bormann Decl. ¶ 12; Martin Decl. ¶ 15; Mlodzik Decl. ¶ 20.) A particularly harmful reentry circumstance could arise if the data reveal that a sponsor has made a significant investment in discovering and funding the production line for a profitable sub-market; its competitors could be emboldened to free ride off

that investment by contacting a third-party manufacturer to initiate production on the same line, thus swooping into the newly revealed sub-market. (*See* Def.’s Mem. at 33–34; Mlodzik Decl. ¶ 23; *see also* Def.’s Mem. at 31–33 (arguing that a competitor may also decide to enter a revealed sub-market with a new product); AHI’s Mem. at 34–36; Elam Decl. ¶ 30; Uppal Decl. ¶ 19.)

Third, the FDA also argues that the release of this data could eliminate the need for competitors to perform market research for certain products, thereby conferring an unearned advantage on those sponsors who do not pay for market intelligence reports and predictive models. (*See* Def.’s Mem. at 35.) For example, Dr. Elam attests that animal drug manufacturers undertake “considerable efforts, at substantial cost . . . to obtain . . . market information by, for example, purchasing market intelligence reports prepared by third party vendors[.]” (Elam Decl. ¶ 38; *see* Uppal Decl. ¶ 26.) But these third-party reports are mere estimates, and their value pales in comparison to that of the precise and accurate information in Document 2. (*See* Elam Decl. ¶ 39; Harper Decl. ¶ 26.) Thus, industry members report that the release of that data would “allow[] [their] competitors to make more accurate projections and trending analyses . . . all at lower cost[,]” thereby conferring “a very real competitive advantage” on those industry participants who did not pay for market evaluations or whose data would not be disclosed. (Beers Decl. ¶ 6; *see* Martin Decl. ¶ 20.)

Finally, Defendants and affiants contend that the disclosed data would allow competitors to estimate a slew of sensitive information about their rivals more accurately, which would allow them to better poach market share and cause substantial competitive injury to sponsors who submitted data to the FDA. This sensitive

information includes a company's production and manufacturing capacity. (*See* Def.'s Mem. at 35–36; Bormann Decl. ¶ 17 (“A competitor could use the Redacted Information to determine Merck’s baseline production capacity” and “harm Merck competitively. For example, if a competitor determined that Merck was operating at its maximum capacity and could not fulfill any additional demand in the market, the competitor could use that information in determining whether to enter that market segment and compete with Merck.”); Whaley Decl. ¶ 7.) The costs other sponsors face and their price sensitivity are also sensitive matters that the affiants say the data might reveal. (*See* Def.'s Mem. 37–38; Harper Decl. ¶ 23 (“Because volume and costs are often interrelated . . . a sponsor’s ability to reduce the price for a given product depends on the volume of the product that it sells. Knowing the sales volume for Phibro’s products would provide a competitor with insight into Phibro’s price sensitivity and as to how Phibro may respond to price changes by a competitor.”).) The FDA, AHI, and the affiants maintain that the data could also disclose the current sales volume of particular products (*see* AHI’s Mem. at 41–45); the identities of sponsors’ customers (*see id.* at 41); and the revenue and profit generated by specific products (*see* AHI’s Mem. at 35; Beers Decl. ¶ 5 (“A competitor’s ability to undercut another sponsor’s prices depends on more than knowledge of publicly available prices. The amount of potential revenue gain cannot be estimated based on price alone. The competitor would also need to know estimate sales distribution to accurately estimate revenue. This is exactly the information that Huvepharma considers . . . confidential and that is redacted in Document 2.”).

For its part, GAP insists that none of the litany of harms that the FDA and AHI highlight is a realistic possibility because the data at issue are from 2009—*seven years* ago—and thus is far too stale to pose a substantial risk to drug sponsors today. (*See* Pl.’s Mem. at 29–32.) Indeed, according to at least one of GAP’s expert witnesses, there have been many changes in market conditions since 2009 (*see* Decl. of Richard A. Levins, Ex. 6 to Pl.’s Mot., ECF No. 41-7, ¶ 9), and such changes “would be difficult to incorporate into a forecasting model,” which makes it “difficult to see how 2009 sales data would be useful in validating a model in 2015 and subsequent years” (*id.* ¶ 10). And to underscore this point, GAP cites to a table from the 2012 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, which indicates significant variation in the total amounts of certain active ingredients sold or distributed between 2009 and 2012. (*See* Pl.’s Mem. at 31 (citing 2012 Summary Report, Ex. 4 to Pl.’s Mot., ECF No. 41-5 at 39 tbl.9).)

GAP further contends that it is unlikely, if not impossible, to develop any reliable contemporary market analysis from a single year of data. (*See id.* at 32; *see also* Levins Decl. ¶ 7 (“It is clear enough that a single observation, or even multiple observations from a single point in time . . . cannot be useful in any type of forecasting model. . . . As I understand that only data from 2009 are disputed in this lawsuit, and that same data for other years are not publicly available, there is no way to develop a model or trend based solely on the 2009 data.”).) And it has offered a declaration in which an expert avers that sales volume alone does not reveal production capacity or production cost (*see* Decl. of John E. Ikerd, Ex. 5 to Pl.’s Mot., ECF No. 41-6, ¶ 19 (stating that “it would be naïve to assume that a drug’s annual sales, which is largely a

function of consumer demand for the drug, is identical to the manufacturer’s production capacity”), and that those factors have likely changed significantly as drug sales have fluctuated during the past seven years (*id.* ¶ 20; *see also* Pl.’s Mem. at 33).

These competing arguments and evidence regarding the effect of the disclosure of the redacted information in Document 2 create a genuine issue of fact that is material to the question of whether disclosure would cause substantial competitive injury, and that question must be resolved before this Court can determine whether the FDA is entitled to invoke Exemption 4 to withhold the data at issue in this case. To be sure, federal courts have recognized that the competitive injury that Exemption 4 is designed to prevent can be significantly mitigated if the disclosed information is stale. *See, e.g., Lee v. FDIC*, 923 F. Supp. 451, 455 (S.D.N.Y. 1996) (finding that agency had failed to carry its burden of demonstrating substantial competitive harm in party because “the financial information in question is given for the 1994 year and any potential detriment caused by its disclosure would seem likely to have mitigated with the passage of time[]”). But assessing the likelihood of substantial competitive injury is a fact-intensive inquiry, and information that is several years old is not necessarily harmless. *See, e.g., Braintree Elec. Light Dep’t v. U.S. Dep’t of Energy*, 494 F. Supp. 287, 291 (D.D.C. 1980) (finding that data from 1973 and 1974 “retain[ed] its importance in the 1980 market” and was protected under Exemption 4); *Zenith Radio Corp. v. Matsushita Elec. Corp.*, 529 F. Supp. 866, 891–92 (E.D. Pa. 1981) (“While at first blush one might doubt that harm could be caused by the disclosure of stale information, . . . old business data may be extrapolated and interpreted to reveal a business’ current strategy, strengths, and weaknesses. It would appear that, in the hands of an able and shrewd

competitor, old data could indeed be used for competitive purposes.”). Furthermore, here, the battle lines regarding the significance of the passage of time have been sharply drawn: GAP and its experts maintain that revelation of the 2009 data will not injure drug sponsors because the market has changed significantly since then (*see* Pl.’s Mem. at 31), while Defendants and their experts contend that the 2009 data are still highly relevant because the market has not changed dramatically (*see* Def.’s Mem. at 41; AHI’s Mem. at 42–44; Elam Decl. ¶ 41; Bataller Decl. ¶ 18 (“[M]any animal drug products have not experienced much of a change in sales and distribution volume or market share over these past few years.”)), and also because competitors can couple the 2009 information with their internal predictive models to generate better estimates of contemporary data and improve the accuracy of their models (*see* Def.’s Mem. at 41–42; Uppal Decl. ¶ 16 (“With the combination of predictive analytics and an accurate baseline dataset from 2009, an industry competitor . . . could generate more accurate estimates of current sales for each class of drugs identified in Revised Document 2.”)).

In short, both sides have presented credible arguments regarding a material issue—i.e., whether disclosure of the redacted data likely will cause substantial competitive injury to the sponsors who submitted the information—and both have submitted evidence in support of their respective positions. Thus, this genuinely disputed remaining question of fact precludes the granting of summary judgment with respect to the Exemption 4 issue that is presented in this case. *See, e.g., Washington Post*, 865 F.2d at 326 (holding, in the FOIA context, that there was “a genuinely controverted factual issue in the case which is not ripe for disposition by summary judgment” because “[t]o resolve this case the judge must pick and choose between

competing experts' affidavits as to the effect of disclosure"); *Sears, Roebuck & Co.*, 553 F.2d at 1382 ("Where there is a conflict in the affidavits as to what adverse consequences will flow from the revelation of the facts contained in the documents sought to be disclosed, then it appears that there is indeed a conflict regarding very material facts which [precludes summary judgement]."); *In Def. of Animals v. U.S. Dep't of Agr.*, 501 F. Supp. 2d 1, 7 (D.D.C. 2007) (finding that "direct contradictions" among affiants "preclude[d] summary judgment" as to the applicability of Exemption 4); *Pub. Citizen Health Research Grp.*, 953 F. Supp. at 403 (holding that because the parties had submitted conflicting affidavits regarding the potential competitive harm stemming from disclosure, "summary judgment is presently an inappropriate vehicle for the resolution of this matter").

IV. CONCLUSION

The structure and text of Section 105 of ADUFA demonstrate that this statutory provision is not a withholding statute for the purpose of FOIA Exemption 3 and, therefore, the FDA cannot seek to justify the redactions from Document 2 on Exemption 3 grounds. Exemption 4 might well justify those same withholdings, but the parties here have a genuine dispute of fact regarding the material issue of whether the disclosure of the redacted information would be likely to cause substantial competitive injury to the sponsors whose data are disclosed. Thus, as set forth in the accompanying Order, no party has demonstrated that it is entitled to judgment as a matter of law.

DATE: August 26, 2016

Ketanji Brown Jackson
KETANJI BROWN JACKSON
United States District Judge