UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GOVERNMENT ACCOUNTABILITY PROJECT,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
U.S. FOOD AND DRUG ADMINISTRATION,	)	**Civ. No. 1:12-CV-01954 (KBJ)**
	)	
Defendant,	)	
	)	
and	)	
	)	
ANIMAL HEALTH INSTITUTE,	)	
	)	
Intervenor-Defendant.	)	

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT AND IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

Plaintiff Government Accountability Project respectfully submits this Memorandum in Opposition to Defendants' Motions for Summary Judgment and in Support of its Cross-Motion for Summary Judgment.

INTRODUCTION

Plaintiff Government Accountability Project brought this action under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, to compel Defendant Food and Drug Administration (FDA) to produce information concerning the 2009 total sales, aggregated by antimicrobial class and broken down by route of administration, of antimicrobial drugs labeled for use in food producing animals. Plaintiff filed the request at issue on February 10, 2011. In its initial decision, dated June 7, 2011, Defendant denied Plaintiff's request, citing FOIA Exemption 4 as the basis for

withholding responsive information. On July 11, 2011, Plaintiff submitted a letter appealing Defendant's initial decision. By letter dated September 19, 2012, Defendant denied Plaintiff's appeal, again citing Exemption 4 as the basis for withholding responsive information.

Since Plaintiff filed this action, Defendant has searched and identified one document containing aggregated information concerning the 2009 total sales of antimicrobial animal drugs. *See* FDA Ex. A ¶ 11. In this document, identified by Defendant as "Document 2," the aggregate total sales for each antimicrobial class are listed as broken down by route of administration. *See* FDA Ex. A(3); FDA Ex. A ¶ 11. Another document produced by Defendant, which Defendant identifies as "Document 1," lists certain basic information about each antimicrobial animal drug sold or distributed in 2009. *See* FDA Ex. A(2); FDA Ex. A ¶ 10. Plaintiff does not challenge the scope or adequacy of Defendant's search. Nor does Plaintiff object to any of the redactions in Document 1.

The only issue requiring resolution by the Court is whether the redacted information in Document 2 is exempt from mandatory disclosure under FOIA. Defendant argues that the redacted information in Document 2 is exempt from mandatory disclosure under Exemptions 3 and 4. *See* FDA Ex. A ¶¶ 17, 26 - 40. As explained below, the information is not subject to withholding under Exemption 3. Nor has Defendant met its burden of demonstrating that the information is subject to withholding under Exemption 4. For these reasons, the Court should deny Defendants'

motions for summary judgment, grant Plaintiff's motion for summary judgment, and order the FDA to produce the redacted information in Document 2.

BACKGROUND

Antimicrobial drugs are used in humans and animals. *See* Blackwell Decl. (P. Ex. 1) ¶ 9. In food producing animals, antibiotics are used for a variety of purposes, including treatment and prevention of disease, growth promotion and weight gain. *Id*. Use in animals, like use in humans, "promotes the development of antimicrobial resistance." *Id*. This is so due to natural selection among bacteria in populations exposed to antimicrobial drugs. *Id*.; *see also* Testimony of Lance B. Price, Ph.D. before the House Committee on Energy and Commerce, Subcomm. on Health, dated April 9, 2013 (P. Ex. 2) at 3 - 4. Certain uses of antimicrobial drugs in food producing animals are believed to contribute more than others to the development of antimicrobial resistance. *Id.* For example, uses of antimicrobials in large groups of animals at low doses for prolonged periods of time is "especially effective at increasing selective pressure for antimicrobial-resistant bacteria." *Id.* Drugs utilized in this manner are typically administered in animal feed and drinking water. *Id.* Data concerning these uses is therefore of great importance to scientists seeking to study the public health impact of sub-therapeutic or non-therapeutic use of antimicrobial drugs in animals. *Id.*

Under the Animal Drug User Fee Act ("ADUFA"), sponsors of antimicrobial drugs used in animals are required to annually report certain data to the government concerning distribution of their drugs, including the total amount of active ingredients sold, and amounts sold in specific dosage forms. *See* 21 U.S.C. § 360b(l)(3). This data is

believed to be the most comprehensive collection of data concerning the use of antimicrobial drugs in food producing animals. *See* P. Ex. 2 ¶ 19. Despite its apparent public health significance, however, only a small fraction of this data is reported in aggregated form by the FDA each year in its ADUFA Summary Reports. *See* P. Ex. 1 ¶ 10 - 11; 2009 ADUFA Summary Report (P. Ex. 3); 2012 ADUFA Summary Report (P. Ex. 4). Unfortunately, these reports mask information concerning *how* these antimicrobial drugs are used, because they do not break down sales according to dosage form, strength, and route of administration, or otherwise indicate the uses for which they are sold. P. Ex. 1 ¶ 10; P. Ex. 2 at 3 - 4; P. Ex. 3; P. Ex. 4. As a result, these summaries are of limited value to scientists seeking to study the impact of particular types of use in animals on the development of antimicrobial resistance. P. Ex. 1 ¶ 11.

In light of the significance of the data possessed by Defendant concerning the use of antimicrobial drugs in animals, and it's extremely limited public disclosure of that data, Plaintiff filed the FOIA request at issue in this case seeking to compel Defendant to release aggregated data concerning sales of drugs by antimicrobial class broken down by dosage strength, dosage form and target animals. In turn, Plaintiff intends to disclose the information obtained to scientists and groups seeking to use the data to better understand the public health impact of antimicrobial use in food producing animals. Unfortunately, Defendant identified only one responsive document containing aggregated data concerning sales of these drugs by animal class. This document, referred to in Defendant's Motion and herein as Document 2, contains information concerning the total sales in 2009 of antimicrobial drugs sold for use in

animals, broken down by route of administration. *See* Document 2 (FDA Ex. 3(A)). While this 2009 data would be of minimal use to competing drug sponsors seeking to learn current information about their competitors, it can be used by scientists to study the public health impact of antimicrobial use in animals, and to evaluate recent regulatory efforts by the Food and Drug Administration to guard the effectiveness of antimicrobial drugs against erosion due to sub-therapeutic and non-therapeutic uses in animals. *See* P. Ex. 2 at 3 - 4.

As described above, Document 2 lists the aggregate 2009 total sales of antimicrobial active ingredients for each antimicrobial class, broken down by route of administration. *See* FDA Ex. 3(A). In some cases, these totals reflect the 2009 total sales by a single sponsor of active ingredients in a particular antimicrobial class sold in drugs having a particular route of administration. FDA Ex. A ¶s 11, 28. While some of the totals listed in Document 2 have been disclosed by Defendant, most remain redacted. FDA Ex. 3(A). Defendant argues that these redacted totals are exempt from mandatory disclosure under FOIA Exemptions 3 and 4.

FOIA Exemption 3 exempts information from disclosure under FOIA where disclosure is explicitly prohibited by another statute, or where another statute explicitly exempts the information from mandatory disclosure under FOIA. *See* 5 U.S.C. § 552(b)(3). In support of its argument that the redacted information is exempt from disclosure under Exemption 3, Defendant FDA argues that Section 105 of the Animal Drug User Fee Act, 21 U.S.C. § 360b, is an Exemption 3 withholding statute. *See* FDA Memo at 8 - 19. That section contains two provisions imposing mandatory disclosure

requirements. The first of these applies to sponsors of animal antibiotic drugs who sell or otherwise distribute those drugs domestically or abroad. Each year, these sponsors are required to report, to the Secretary of Health and Human Services, the total amount of each antimicrobial active ingredient sold in animal drugs during the previous year. 21 U.S.C. § 360b(l)(3)(A). In these reports, sponsors are required to provide a breakdown of the total amount by container size, strength, dosage form, quantity distributed domestically, and quantity exported. 21 U.S.C. § 360b(l)(3)(B).

The second mandatory disclosure provision in Section 105 requires the Secretary to publish annual summary reports of the data submitted by sponsors. 21 U.S.C. § 360b(l)(3)(E). The Secretary has delegated this responsibility to the FDA, which publishes ADUFA Summary Reports each year containing certain information aggregated from the sponsors' submissions. *See, e.g.*, P. Ex. 3; P. Ex. 4. The provision in Section 105 requiring the Secretary to publish annual Summary Reports imposes two limitations on the content of those reports. *See* 21 U.S.C. § 360b(l)(3)(E)(i-ii).[1] One of these limitations requires the Secretary to report the summary data by antimicrobial class, and withhold totals for any class having fewer than three distinct sponsors. 21 U.S.C. § 360b(l)(3)(E)(i). Defendant argues that this mandatory disclosure provision is

[1] The statute provides:

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

21 U.S.C. § 360b(l)(3)(E)(i-ii).

an Exemption 3 withholding statute. *See* Defendant's Motion at 8. As explained below, it is not. Moreover, even it if it were an Exemption 3 withholding statute, it would not apply to much of the redacted information in Document 2.

In addition to Exemption 3, Defendant argues that the redacted information contained in Document 2 is exempt under FOIA Exemption 4 because its disclosure would reveal, either directly or indirectly, "confidential commercial information." *See* FDA Memo at 19 - 35. In support of this claim, Defendant provides numerous declarations submitted by various drug sponsors and FDA personnel. *See* FDA Exs. C - L. In these declarations, the sponsors allege that the market for these antimicrobial drugs is highly competitive, and describe various types of competitive harm that they allege would result from disclosure of the information in Document 2. As explained below, these affidavits fail to establish that any competitive harm is likely to result from disclosure of the redacted information in Document 2. Because of seismic shifts in the market for these drugs, any risk that might have resulted from contemporaneous release of the 2009 sales information in Document 2 has dissipated. To the extent any of the sorts of harm described by the sponsors are likely to occur, the likelihood stems from far more useful information that is already publicly available.

LEGAL STANDARDS

FOIA gives individuals broad access to information held by federal agencies. Under FOIA, anyone may obtain information from executive branch agencies by sending a written request to the agency. 5 U.S.C. § 552(a)(3). The agency is then required to release the information to the requester unless the information sought is

subject to one of the nine exemptions enumerated in 5 U.S.C. § 552(b). Two of those exemptions, Exemption 3 and Exemption 4, have been claimed by Defendant to apply to the information in Document 2. *See* Defendant's Motion at 7. Exemption 3 exempts from mandatory disclosure information "specifically exempted from disclosure by statute." 5 U.S.C. § 552(b)(3). Exemption 4 exempts information reflecting "commercial or financial information obtained from a person" that is "confidential." 5 U.S.C. § 552(b)(4). Both exemptions must be narrowly construed in a manner favoring disclosure. *Dept. of the Air Force v. Rose*, 425 U.S. 352, 361 (1976). At all times, the burden is squarely on the government to prove that the information in question is covered by the exemptions claimed. *See Maydak v. Dept. of Justice*, 218 F.3d 760, 764 (D.C. Cir. 2000). Unsupported and conclusory allegations concerning an exemption's applicability are insufficient. *See Morley v. CIA*, 508 F.3d 1108, 1115 (D.C. Cir. 2007). While the government may generally meet its burden through the submission of affidavits, summary judgment is inappropriate where supporting affidavits are conclusory and do not provide sufficient detail to establish a factual basis for withholding. *See Niagara Mohawk Power Corp. v. Dept. of Energy*, 169 F.3d 16, 18 (D.C. Cir. 1999) (denying summary judgment where supporting affidavits were conclusory, despite requester's failure to present contrary evidence).

FOIA Exemption 3 exempts from mandatory disclosure under FOIA information that is "specifically exempted from disclosure by statute . . . if that statute" either "(i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or (ii) establishes particular criteria for withholding or refers to

particular types of matters to be withheld . . . ." 5 U.S.C. § 552(b)(3)(A). As a threshold requirement, to qualify as an Exemption 3 withholding statute, the statute must explicitly prohibit public disclosure or otherwise "specifically exempt matters from disclosure" to the public. *Reporters Comm. for Freedom of the Press v. Dept. of Justice*, 816 F.2d 730, 734 (D.C. Cir. 1987).

Where, as here, the information is obtained from persons or entities whom are legally compelled to submit the information to the agency, commercial information is considered "confidential" under Exemption 4 only if its disclosure is "likely" 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*, 498 F.2d 765, 770 (D.C. Cir. 1974) (*Nat'l Parks I*). To meet its burden, the agency must demonstrate that the entity from whom the information was obtained "actually face[s] competition," and that "substantial competitive injury would likely result from disclosure." *Nat'l Parks & Conservation Ass'n v. Kleppe*, 547 F.2d 673, 679 (D.C. Cir. 1976) (*Nat'l Parks II*).

ARGUMENT

Defendant FDA Unlawfully Redacted Responsive Information from Document 2

FDA has claimed that the redacted information in Document 2 is subject to withholding under FOIA Exemptions 3 and 4. *See* FDA Memo at 8 - 35. As explained below, it is not. In support of its claim that the information would likely cause substantial competitive harm, Defendant submits declarations from most of the drug

sponsors whose information was used by FDA to produce the withheld information in Document 2. *See* FDA Exs. C - L. As explained below, the allegations in these declarations are largely conclusory and highly speculative. Moreover, the types of harm alleged would not likely flow from disclosure of the information in Document 2. Rather, they would likely flow from much more detailed information that is already readily available to competitors.

A. FOIA Exemption 3 Does Not Apply to the Information in Document 2.

Defendant's withholding of information concerning sales data in Document 2 under FOIA Exemption 3 was unlawful. ADUFA Section 105 does not qualify as an Exemption 3 withholding statute. Moreover, even if it did, its scope would not be as broad as Defendant has claimed.

1. Section 105 is Not an Exemption 3 Withholding Statute.

FDA argues that the mandatory reporting provision in Section 105 requiring the Secretary to publish annual summaries, 21 U.S.C. § 360b(l)(3)(E), qualifies as a FOIA Exemption 3 withholding statute. *See* FDA Memo at 9 - 10. FOIA Exemption 3 exempts from mandatory disclosure under FOIA information that is "specifically exempted from disclosure by statute . . . if that statute" either "(i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld . . . ." 5 U.S.C. § 552(b)(3)(A). FOIA mandates a "strong presumption in favor of disclosure," *U.S. Dept. of State v. Ray*, 502 U.S. 164, 173 (1991), and Exemption 3, like all FOIA exemptions, "must be narrowly construed." *Dept. of the Air Force v. Rose*, 425 U.S.

352, 361 (1976). Congress' choice of words and structure reveal that the pertinent subsection of Section 105 does not qualify as an Exemption 3 withholding statute.

Section 105 of ADUFA requires sponsors of animal drugs containing antimicrobial active ingredients to submit reports to the Secretary each year listing the total amounts of antimicrobial active ingredient sold during the previous calendar year. *See* 21 U.S.C. § 360b(l)(3). In these reports, sponsors are required to provide a breakdown of these totals by container size, strength, dosage form, domestic sales and exports. *Id.* Section 105 imposes a similar mandatory reporting requirement on the Secretary. Specifically, Section 105 requires the Secretary to "make summaries of the information reported" by animal drug sponsors "publicly available, except that-- . . . ." 21 U.S.C. § 360b(l)(3)(E). Section 105 goes on to impose two limitations on the content of the Secretary's mandatory annual reports. One limitation, at issue here, states that "the summary data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors shall be independently reported . . . ." 21 U.S.C. § 360b(l)(3)(E)(i).

As a threshold requirement, to qualify as an Exemption 3 withholding statute, the statute must explicitly prohibit public disclosure or otherwise "specifically exempt matters from disclosure" to the public. *Reporters Comm.*, 816 F.2d at 734. Congress' intent to prohibit or otherwise exempt the information from public disclosure must be apparent in the text of the statute itself. *Id.* at 735 ("a statute that is claimed to qualify as an Exemption 3 withholding statute must, on its face, exempt matters from disclosure"). This intent must be *explicit*. *Irons & Sears v. Dann*, 606 F.2d 1215, 1220 (D.C. Cir. 1979)

("Only explicit nondisclosure statutes . . . will be sufficient to qualify under the exemption.") (emphasis added). It cannot be found "in the legislative history of the claimed withholding statute, nor in an agency's interpretation of the statute." *Reporters Comm.*, 816 F.2d at 735. Congress' choice of words reveals that the mandatory reporting requirement in Section 105, and the limitations thereon, do not meet this threshold requirement.

Rather than prohibiting the public disclosure of information, or otherwise exempting information from disclosure under FOIA, Section 105 imposes a mandatory disclosure requirement on the Secretary, requiring the Secretary to publish, annually, summary reports of the data received from sponsors. *See* 21 U.S.C. § 360b(l)(3)(E). Congress' choice of words reveals that the limitations contained in subsections (i) and (ii) of 21 U.S.C. § 360b(l)(3)(E) were intended only to limit the content of the Secretary's mandatory annual summary report, and were not intended to prohibit the public disclosure of any information under FOIA or in other contexts. 21 U.S.C. § 360b(l)(3)(E) states, in pertinent part, that: "The 'Secretary shall make summaries of the information' reported by drug sponsors under ADUFA Section 105 '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* . . . ." 21 U.S.C. § 360b(l)(3)(E)(i). Interpretation of the meaning of words should be informed by their context within a statute. *Jerecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961) ("[A] word is known by the company it keeps"). The context in which the words "summary data" appear in subsection (i) indicates that those words were intended to

refer to the mandatory summary that the Secretary must release annually. Similarly, context indicates that the word "reported" immediately following "summary data shall be" is intended to describe the annual publication of this summary data. Words appearing in a statute are presumed to bear the same meaning where appearing multiple times in the same sentence. *Brown v. Sec. of Veterans Affairs*, 513 U.S. 115, 118 (1994) ("[T]here is a presumption that a given term is used to mean the same thing throughout a statute . . . a presumption surely at its most vigorous when a term is repeated within a given sentence"). It follows that the final appearance of the word "reported" in subsection (i), was likewise intended to refer to the annual publication of the summary data, and not to public disclosure in other contexts, such as in response to FOIA requests or to members of the Antibiotic Resistance Task Force. Indeed, disclosures to the Antibiotic Resistance Task Force are discussed in an entirely separate subsection of Section 105. Therefore, the limitations on reporting imposed by subsection (i) should likewise be read as applying only to the Secretary's annual mandatory summary reporting of data.

The structure of Section 105's mandatory summary reporting provision also indicates that the limitations on disclosure in 21 U.S.C. § 360b(l)(3)(E)(i-ii) were intended to apply only to the Secretary's annual summary reports mandated by § 360b(l)(3)(E), and were not intended to limit disclosures in other contexts. "Just as Congress' choice of words is presumed to be deliberate, so too are its structural choices." *Univ. of Texas Sw. Med. Ctr. v. Nassar*, 133 S. Ct. 2517, 2529, 186 L. Ed. 2d 503 (2013) (concluding that the fact that Congress inserted the "motivating factor" provision

as a subsection of §2000e-2, the section of Title VII prohibiting status-based discrimination, indicated that the "motivating factor" provision was intended to apply exclusively to that section, and not to the section of Title VII prohibiting retaliation for protected conduct). Here, the fact that Congress placed the limitation on reporting antimicrobial data for classes with fewer than three distinct sponsors in a subsection of § 360b(l)(3)(E), the provision of Section 105 requiring the Secretary to publish annual summaries, indicates that it was intended to apply only to publication in that context, and not to disclosures in other contexts, such as in responses to FOIA requests.

Nothing in the text of Section 105 or its legislative history indicates that Congress intended the limitations set forth in 21 U.S.C. § 360b(l)(3)(E)(i) to prohibit or exempt information from disclosure under FOIA, or that Congress otherwise sought to provide special protection for this information under FOIA than is afforded to parties in other industries. Indeed, the creation of a mandatory summary publication requirement indicates the opposite that Congress intended to create an atypically heightened level of transparency with respect to the information submitted by drug sponsors. As indicated by the statute's plain language, the limitations set forth in 21 U.S.C. § 360b(l)(3)(E) were not intended to exempt information from disclosure under FOIA, but were instead simply intended to govern the content of the Secretary's annual summary reports.[2] That Congress didn't intend for these limitations to apply in the FOIA context is not

[2] FDA unconvincingly asserts that Plaintiff's argument fails "because subsection (E) applies to how information may be publicly disclosed (not just in the Summary Reports), while another section, subsection (D), applies to non-public sharing of information with the Antibiotic Resistance Task Force." FDA Memo at 10 – 11. However, FDA's argument assumes a general restriction to public access, as provided by FOIA, that is not present in the plain language of the statute.

surprising. Congress already provided protections under FOIA Exemption 4 that were, in its judgment, sufficient to protect private industry from undue competitive harm resulting the sharing of information with government. Nothing in the statute or legislative history indicates that Congress saw a need for or otherwise intended to create additional protections for the information submitted by sponsors in this industry.

Had Congress intended to create special FOIA exemption for the information submitted by drug sponsors to extend protection from disclosure under FOIA beyond that already provided by FOIA Exemption 4, it certainly knew how. *See Franklin Nat'l Bank v. New York*, 347 U.S. 373, 378 (1954) (finding "no indication that Congress intended to make particular phase of national banking subject to local restrictions, as it had done by express language in other instances"). Congress has demonstrated its ability to explicitly prohibit disclosure of information universally. *See, e.g.*, 2 U.S.C. § 437g(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."). Similarly, Congress has demonstrated its ability to explicitly prohibit or exempt information from disclosure under FOIA. *See, e.g.*, 39 U.S.C. § 3016(d) ("Disclosure. 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."). Congress' decision not to do so in Section 105 of ADUFA indicates that it did not intend for the limitations on the content of the Secretary's

annual summary report described in 21 U.S.C. § 360b(l)(3)(E)(i) to apply universally or to create an exemption from disclosure under FOIA.

Defendant FDA argues that the legislative history of Section 105 indicates that Congress intended the limitations on the content of the Secretary's annual summary reports described in 21 U.S.C. § 360b(l)(3)(E) to exempt the information described therein from disclosure under FOIA. Defendant correctly notes that the House Report states that:

> The Secretary may share information reported under this section with the Antimicrobial Resistance Task Force …. As of the date of enactment of this Act, the Antimicrobial Resistance Task Force was composed solely of representatives of Federal Agencies …. It is the intention of this Committee that information reported under this section be available only to representatives of Federal agencies. If the membership of the Antimicrobial Resistance Task Force is ever expanded to include representatives of non-Federal agencies….

H.R. Rep. 110-804, at 15, reprinted in 2008 U.S.C.C.A.N. at 1295. FDA Memo at 14.[3] However, the legislative history of a statute may not be used to determine whether the statute qualifies as an Exemption 3 withholding statute. Congress' intent to prohibit or exempt information from disclosure under FOIA must be explicit and apparent in the statutory text itself. *Reporters Comm. v. DOJ*, 816 F.2d at 734-35 ("a statute that is claimed to qualify as an Exemption 3 withholding statute must, on its face, exempt matters from disclosure"). Congress' intent cannot be found "in the legislative history

[3] FDA references several cases to make the point that legislative history can serve as a basis for determining that a statutory provision qualifies as an Exemption 3 withholding statute. FDA Memo at 14 n.13. However, the cases cited by FDA are distinguishable because the references to legislative history in their analyses either included specific discussions of disclosures under FOIA or the language of the statutory provisions at issue focused on restricting the release of information rather than setting limits on a mandatory reporting obligation as is the case with ADUFA.

of the claimed withholding statute, nor in an agency's interpretation of the statute." *Id.* at 735.

In any event, to the extent the House Committee on Energy and Commerce desired that information only be shared with representatives of Federal Agencies, the plain language of the statute indicates that Congress apparently ultimately chose not to impose such a limitation on the Secretary. Having recognized that the membership of the Task Force might one day include parties other than representatives of Federal Agencies, Congress nonetheless reasonably chose not to limit the Secretary's discretion to share information to that particular class of Task Force members. Rather, the relevant statutory provision simply states: "The Secretary may share information reported under this paragraph with the Antimicrobial Resistance Task Force established under Section 319E of the Public Health Service Act [42 USCS § 247d-5]." Had Congress intended Section 105 to limit the Secretary's discretion to share information with a particular sub-class of Task Force members, it would have done so. Congress' decision not to do so, particularly after expressly acknowledging the possibility that Task Force membership might someday be expanded to include non-Federal personnel, indicates that it did not intend for the statute to impose such a limitation.

Finally, Defendant argues that several cases support its argument that statutes with disclosure requirements may also be Exemption 3 withholding statutes. FDA Memo at 11 – 13. Defendant argues that *Doe v. Veneman*, 380 F.3d 807 (5th Cir. 2004) supports this proposition. There, the court held that a provision in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, qualified as an

Exemption 3 withholding statute. That statute required applicators of certain pesticides to maintain records concerning their use, and requires the Secretary of Agriculture and Administrator of EPA to "publish annual comprehensive reports concerning agricultural and nonagricultural pesticide use." 7 U.S.C. § 136i-l(f). FIFRA also contains a provision limiting the publication of certain information by government agencies. *See* 7 U.S.C. § 136i-l(b).

However, quite unlike 21 U.S.C. § 360b(l)(3)(E)(i), this provision appears prior to, and in an entirely different subsection of 7 U.S.C. § 136i-l than the provision requiring the Secretary of Agriculture and Administrator of EPA to publish annual reports. Furthermore, unlike § 360b(l)(3)(E)(i), 7 U.S.C. § 136i-l(b) incorporates language indicating an intent to broadly prohibit disclosure of certain information to the public, and not merely to limit the content of the "annual comprehensive reports" published under § 136i-l(b). *See* 7 U.S.C. § 136i-l(b) ("Each such Federal agency shall conduct surveys and record the data from individual applicators to facilitate statistical analysis for environmental purposes, but *in no case may a government agency release* data, including the location from which the data was derived, that would directly or indirectly reveal the identity of individual producers.").

Similarly, *Consumer Product Safety Commission*, cited by FDA, is inapposite. There, the court merely found that the term "public disclosure" used in the relevant statute encompassed disclosures made to the public under FOIA. *See Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 108, 100 S. Ct. 2051, 2056, 64 L. Ed. 2d 766 (1980).

The case much more on point is *Greentree v. U.S. Customs Service*, 674 F.2d 74 (D.C. Cir. 1982). In *Greentree*, the court observed that the various disclosure exemptions listed in the Privacy Act were written to apply only to disclosures made in response to requests under the Privacy Act. As a result, the Court held that the statute, which it characterized as "self-contained," did not meet Exemption 3's threshold requirement. *Greentree*, 674 F.2d at 79 ("This portion of the statute thus appears to be self-contained: the general exemptions, as well as the specific exceptions, limit only other provisions of the Privacy Act itself.").

2. Defendant's Interpretation of Section 105 is Unreasonable and Overbroad.

Even if 21 U.S.C. § 360b(l)(3)(E)(i) were an Exemption 3 statute, the Defendant's assertions about the breadth of its coverage are incorrect. Defendant claims that all of the redacted information in Document 2 is exempt under Exemption 3. *See* FDA Memo at 14 - 19. However, 21 U.S.C. § 360b(l)(3)(E)(i), on its face, would only apply to information concerning antimicrobial classes for which there are fewer than three sponsors of drugs. Defendant's sweeping interpretation of 21 U.S.C. § 360b(l)(3)(E)(i) is unreasonably overbroad and should not be given deference or weight.

FDA asserts four rationales for redacting information in Document 2 pursuant to FOIA Exemption 3:

- "First, FDA redacted the following numbers because fewer than three distinct sponsors reported selling or distributing animal drugs domestically in 2009 for the following antimicrobial classes: Aminocoumarins, Amphenicols,

Diaminopyrimidines, Fluroquinolones, Glycolipids, Pleuromutilins, Polymyxins, Polypeptides, Quinoxalines, and Streptogramins . . ."

- "Second, FDA also redacted sales and distribution data for antimicrobial classes with "fewer than 3 distinct sponsors" when those classes were broken down by a particular route of administration . . ."
- "Third, pursuant to Exemption 3, and in accordance with Congress' clear instructions, FDA redacted the following route (e.g., Feed, Injection, Water, Oral) totals (rather than antimicrobial class totals), made up of less than three distinct sponsors . . ."
- "Fourth, in accordance with Exemption 3, FDA properly redacted aggregated sales and distribution data of three or more distinct sponsors in twelve instances where the release of the numbers would effectively reveal the sales and distribution data of a single distinct sponsor or only two distinct sponsors . . ."

FDA Memo at 15 -17. While the Defendant's first rationale to restrict disclosure of information because fewer than three distinct sponsors reported selling or distributing certain classes of antimicrobial drugs, appears consistent with ADUFA, the other three rationalizations are clearly outside the scope of the statute's restrictions.

Defendant argues that the remaining information withheld in Document 2, even that concerning classes for which there were three or more active sponsors in 2009, would nonetheless be exempt from disclosure under 21 U.S.C. § 360b(l)(3)(E)(i). *See* FDA Memo at 15 – 17. This is so, Defendant argues, because disclosure of that information would enable one or more sponsors in the industry to calculate a particular

sponsor's sales volume. *Id.* The plain language of Section 105 indicates that Defendant's interpretation of 21 U.S.C. § 360b(l)(3)(E)(i) is unreasonable and contrary to Congress' intent.

Section 105 provides, in pertinent part, 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 . . . ." 21 U.S.C. § 360b(l)(3)(E)(i) (emphasis added). Defendant argues that this provision would apply not only where a particular *antimicrobial class* has fewer than 3 distinct sponsors, but also where a particular *route of administration* within an antimicrobial class has fewer than 3 distinct sponsors, regardless of the number of sponsors within the *class*. *See* FDA Memo at 15 – 17.

However, Congress did not state that no route of administration "with fewer than 3 distinct sponsors" shall be independently reported. *See* 21 U.S.C. § 360b(l)(3)(E)(i). Instead, Congress stated that no "class with fewer than 3 distinct sponsors" shall be independently reported. *Id.* Congress knew that "antimicrobial class" held a distinct meaning and was not synonymous with route of administration. *Compare* 21 U.S.C. § 360b(l)(3)(E)(i) ("data shall be reported by antimicrobial class, and no class with fewer than 3 distinct sponsors…") *with* 21 U.S.C. § 360(l)(3)(B) ("Each report … shall specify the amount of each antimicrobial active ingredient (i) by container size, strength, and dosage form; (ii) by quantities distributed domestically and quantities exported; and (iii) by dosage form, including for each dosage form, a listing of the target animals . . . ."). Congress' "choice of words is presumed to be deliberate."

Univ. of Texas Sw. Med. Ctr. v. Nassar, 133 S. Ct. 2517, 2529, 186 L. Ed. 2d 503 (2013). When interpreting the inclusion or exclusion of certain words or terminology used in a statute, courts must "give effect to Congress' choice." *Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 177, 129 S. Ct. 2343, 2350, 174 L. Ed. 2d 119 (2009). Defendant's sweeping interpretation of § 360b(l)(3)(E)(i) unreasonably ignores Congress' deliberate word choice, and this Court should not give the FDA's unsupportable statutory interpretation any deference.

Defendant's interpretation of § 360(l)(3)(E)(i) is also unreasonable because it renders § 360(l)(3)(E)(ii)[4] superfluous. Statutes should be interpreted "so as to avoid rendering superfluous" any statutory language. *Astoria Federal Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991). Defendant argues that § 360(l)(3)(E)(i), as an Exemption 3 withholding statute, requires it to withhold information that would reveal a particular sponsor's 2009 sales volume, or that would enable any other sponsor to ascertain a particular sponsor's 2009 sales data, even where the information concerns an antimicrobial class with three or more sponsors. *See* FDA Memo at 16 - 17. In support of this argument, Defendant illustrates that it has interpreted § 360(l)(3)(E)(i)'s alleged prohibition on disclosure of information concerning any antimicrobial "class with fewer than 3 distinct sponsors" to require withholding of information in any form whose disclosure would reveal an individual sponsor's sales volume, regardless of the number

4 Defendant has not claimed or argued that 21 U.S.C. § 360(l)(3)(E)(ii) is or would qualify as an FOIA Exemption 3 withholding statute. It would not qualify for the same reasons that § 360(l)(3)(E)(i) fails to qualify. Moreover, its coverage of "national security" and "confidential business information" would be coextensive with FOIA Exemptions 1 and 3.

of sponsor's in the antimicrobial class. *See* FDA Memo at 16 – 17. As Defendant acknowledges, however, this interpretation does nothing more than incorporate 21 U.S.C. § 360b(l)(3)(E)(ii)'s alleged prohibition on disclosure of "confidential business information." FDA Memo at 17 – 19. Defendant's interpretation of § 360b(l)(3)(E)(i) to include a prohibition on the disclosure of "confidential business information," other than concerning antimicrobial classes with three or more distinct sponsors, unreasonably renders the language in § 360b(l)(3)(E)(ii) superfluous, and is undeserving of any weight or deference. It is clear that § 360b(l)(3)(E)(i) governs the scope of the restriction, while § 360b(l)(3)(E)(ii) provides further instruction on how the reported information can be characterized. Section 360b(l)(3)(E)(ii) does not create a separate basis for withholding information that does not fall under § 360b(l)(3)(E)(i)'s description.

In sum, 360b(l)(3)(E) mandates rather than prohibits disclosure, while subsections (i) and (ii) merely limit the content of the annual summary reports that 360b(l)(3)(E) requires the FDA to publish, limiting those reports to summaries of data aggregated by antimicrobial class, and further to data concerning classes with 3 or more sponsors and data whose disclosure would not cause harm to a sponsor. There is no conflict between the statute's disclosure limitation and FOIA's mandate requiring disclosure upon request. Under these circumstances, withholding in no way serves FOIA Exemption 3's purpose. *See FAA v. Robertson*, 422 U.S. 255, 266-67 (1975) (explaining that Exemptions 3 was intended to ensure that FOIA's disclosure mandate

did not conflict with and threaten the viability of statutes prohibiting the disclosure of particular information).

For the foregoing reasons, should this Court find that 21 U.S.C. § 360b(l)(3)(E)(i) is an Exemption 3 withholding statute, it should nonetheless decline to follow Defendant's sweeping interpretation of that statute's scope. Instead, if this Court finds that § 360b(l)(3)(E)(i) is an Exemption 3 withholding statute, this Court should give effect to the plain text of the statute, and hold that § 360b(l)(3)(E)(i) only exempts from disclosure that information concerning antimicrobial classes for which there were fewer than three distinct sponsors in 2009.

B. FOIA Exemption 4 Does Not Apply to the Information in Document 2.

Defendants FDA and AHI next argue that the information withheld in Document 2 is exempt from mandatory disclosure under FOIA Exemption 4. *See* FDA Memo at 19 - 35; AHI Memo at 8 - 28. Exemption 4 exempts from mandatory disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The parties agree that the information in Document 2 does not contain trade secrets.

Rather, Defendants contend that the redacted information in Document 2 is exempt from disclosure under Exemption 4 because its release would reveal confidential commercial information. Confidential commercial information has been defined to mean information that is: (1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential. Plaintiff agrees with Defendants that the information in Document 2 is commercial. Plaintiff also agrees that the information was

obtained from a person. Therefore, the only question to be resolved is whether the information is "confidential."

The test used to determine whether information is "confidential" under Exemption 4 depends on whether disclosure of the information was voluntary or compulsory. Where, as here, disclosure of the information is mandatory, the information is "confidential" under Exemption 4 only if its public disclosure 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 I*, 498 F.2d at 770. Defendants do not argue that disclosure of the information in Document 2 would impair the FDA's ability to obtain the same information in the future. Indeed, any sponsor actively selling or otherwise distributing animal drugs containing antimicrobial active ingredients is required by statute to submit this information to the agency annually. *See* 21 U.S.C. § 360b(l)(3)(A)-(C).

Defendants claim that disclosure of the information would likely cause substantial competitive harm to the various drug sponsors who submitted the information contained in Document 2. *See* FDA Memo at 19 - 35; AHI Memo at 8 - 28. As explained below, Defendants have failed to demonstrate that disclosure of the information in Document 2 would likely cause substantial competitive harm. The relevant test is whether disclosure of the information is "likely . . . to cause substantial harm to the competitive position of the person from whom the information was obtained." *National Parks and Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.

Cir. 1974), *aff'd in part and rev'd in part sub nom. National Parks and Conservation Ass'n v. Kleppe*, 547 F.2d 673 (D.C. Cir. 1976). Although the Defendants need not show actual competitive harm,

> the important point for competitive harm in the FOIA context . . . is that it be limited to harm flowing from the affirmative use of proprietary information by competitors. Competitive harm should not be taken to mean simply any injury to competitive position, as might flow from customer or employee disgruntlement or from the embarrassing publicity attendant upon public revelations concerning, for example, illegal or unethical payments to government officials or violations of civil rights, environmental or safety laws. *Connelly*, supra note 16, at 235-36 (emphasis in original).[5]

Public Citizen Health Research Group v. Food & Drug Admin., 704 F.2d 1280, 1291 n.30 (D.C. Cir. 1983). Explained another way, "for 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.'" 547 F.2d at 679. *Niagara Mohawk Power Corp. v. United States DOE*, 169 F.3d 16, 18 (D.C. Cir. 1999). With these standards in mind, we turn to the Defendants' allegations of competitive harm.

1. Defendants' Claims Concerning Competition and Substantial Competitive Injury are Insufficient.

a. Alleged competition

At this juncture, it bears repeating that

[5] Connelly, *Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data*, 1981 WIS.L.REV. 207, 230.

> [w]hen an agency's response to a FOIA request is to withhold responsive records, either in whole or in part, the agency 'bears the burden of proving the applicability of claimed exemptions.' *Am. Civil Liberties Union v. U.S. Dep't of Def. ("ACLU/DOD")*, 628 F.3d 612, 619, 393 U.S. App. D.C. 384 (D.C. Cir. 2011).

Nat'l Sec. Counselors v. CIA, 960 F. Supp. 2d 101, 132 (D.D.C. 2013). Defendant FDA, relying on declarations submitted by FDA staff and various sponsors, argues that disclosure of the information in Document 2 would reveal the market size and market shares for various drugs and categories of drugs, thereby enabling competitors to determine which drugs or types of drugs are worthwhile to target based on sales and potential profitability. *See* FDA Memo at 23 - 27. AHI makes the same argument, and adds that sponsors might mimic the marketing or pricing strategies of successful drugs. *See* AHI Memo at 15-19.

Defendants have presented declarations from ten (10) antibiotic animal drug sponsors, most of which allege, to some extent, the existence of competition within the antibiotic animal drug industry. In their declarations, many sponsors simply state that "the market for" these drugs "is highly competitive," "the data is highly competitive," "highly competitive business," and/or a "highly competitive field." *See* FDA Ex. C ¶ 15; Ex. F ¶ 12;[6] Ex. G ¶ 7; Ex. H ¶ 16; Ex. J ¶ 10; and Ex. K ¶ 6. These statements are conclusory, and are insufficient to meet Defendant's burden. *See Niagara Mohawk*, 169 F.3d at 18. Many sponsors refer to harms that might occur as a result of potential future

[66] As asserted by Dr. Elam and Mr. Bormann, the fact that there are 16 or 20 different companies selling antimicrobial drugs does not in itself establish that the industry is highly competitive. In fact, Dr. Elam attests that "[i]n the last ten years there have been no significant new competitors entering the antibiotics area in the animal health industry, and there have been few novel new products introduced." FDA Ex. C ¶18.

competitors who may or may not hold approved drug applications for similar products. *See, e.g.*, FDA Ex. F ¶ 12 (referring to "manufacturers who hold approved applications for products that are not currently distributed"). However, "the test explicitly requires that the submitter face *actual* competition." *Niagara Mohawk*, 169 F.3d at 19.

b. Alleged substantial competitive injury

The market for antimicrobial animal drugs has changed tremendously in the years since 2009. In the domestic market, sales of drugs in many of the classes skyrocketed in the two years following 2009, while sales of drugs in the remaining classes plummeted. Changes in the overseas market were even more dramatic. *See, e.g.*, P. Ex. 4, 2012 ADUFA Summary Report at 38 (Table 9). Though post-2012 data has not yet been released, recent events indicate that substantial changes continued to occur in 2013 through the present.

Consequently, any risk that might have been posed by contemporaneous release of the information in Document 2 has long since dissipated. Moreover, Defendants have failed to identify any potential, significant competitive harm not already posed by publicly available information. Nor have Defendants demonstrated that releasing the information in Document 2 would in any way increase the likelihood of competitive harm.

Defendants argue that public disclosure of the information withheld in Document 2 would enable competitors to ascertain the sales volume of particular sponsors, and to estimate other information about particular sponsors. *See* FDA Memo at 23 - 25; AHI Memo at 17 - 20. In turn, Defendants argue, competitors could use that

information to obtain a competitive advantage over or otherwise harm the sponsors' competitive positions. *Id.*

For example, Defendants argue, as many sponsors have alleged, that competitors could use the information in Document 2 to "more accurately estimate a company's production and/or manufacturing capacity,"[7] to "identify other companies' customers,"[8] to "estimate a company's production costs,"[9] to ascertain "the amount of antimicrobial active ingredient distributed by a sponsor,"[10] and to identify profitable markets for particular drugs and/or markets where sales are flagging.[11] FDA Memo at 23-30; AHI Memo at 14-23. However, any such risk that might have been presented by the contemporaneous public disclosure of the information at issue here at the time it was submitted to FDA has undoubtedly dissipated in the nearly five years that have elapsed since then. The courts have repeatedly recognized that the risk of competitive harm diminishes with the passage of time and with changes in the market. *See, e.g., Lee, et al. v. F.D.I.C.*, 923 F.Supp. 451, 455 (S.D.N.Y. 1996) (reversing agency's Exemption 4 claim with respect to two year old financial information concerning two banks because "the financial information in question is given for the 1994 year and any potential detriment which could be caused by its disclosure would seem likely to have mitigated

[7] FDA Ex. H ¶ 19 (Mlodzik).

[8] FDA Ex. C ¶ 26 (Elam).

[9] FDA Ex. C ¶ 29 (Elam).

[10] FDA Ex. E ¶ 25 (Harper).

[11] FDA Ex. D ¶s 19-20 (Uppal).

with the passage of time."); *Ctr. for Pub. Integrity v. Dept. of Energy*, 191 F.Supp.2d 187, 195 (D.D.C. 2002) (rejecting claim that information pertaining to bids for government land purchases would cause competitive harm because a competitor would "be naïve to assume that . . . business strategies and valuation methodologies remain the same over time in the face of changing market conditions.").

The market for animal antimicrobial drugs has changed dramatically in the years since 2009. P. Ex. 4 at 38 (Table 9). In light of these changes, which indicate that the 2009 data concerning sales volume is no longer accurate for competitive purposes, it would be unreasonable to expect that any actual or potential competitors would rely on or obtain any competitive advantage from the redacted 2009 sales volume data in Document 2, or any estimates of other information they could derive from that data. No useful predictive judgments about a particular sponsor's *current* market share, production capacity, and the like could be derived from 2009 data concerning its sales given that sales volume has apparently changed substantially across all classes. P. Ex. 5 ¶¶ 9 – 17 (Ikerd). Sponsors are not competing with their rivals under 2009 conditions. It is especially unlikely that a competitor would rely on this 2009 data given the availability of more current market intelligence reports. P. Ex. 5 ¶¶ 18 – 21; P. Ex. 6 ¶¶ 6 – 7 (Levins).

Despite the continuing reduction in value of the 2009 information contained in Document 2 due to the passage of time, unexpected events, and changed circumstances for consumers and sponsors, the Defendants offer a myriad of rationales purporting to justify their claims of competitive harm. For example, one sponsor argues, competitors

could use their insights into the market size or share to "predict how the sponsor will react to . . . aggressive competition" based on how important the particular drug is to the sponsor's overall business. FDA Memo at 25. However, it is unlikely, if not impossible, to develop any reliable market analyses solely from 2009 data. As Dr. Levins explains:

> It is clear enough that a single observation, or even multiple observations from a single point in time *(e.g.*, 2009), cannot be useful in any type of forecasting model. The *development* of a model or trend used to determine current sales and/or forecast future sales depends upon having observations from at least two points in time. This is obvious when one visualizes a trend line: a line connects two points; if there is just one point, there cannot be a line. As I understand that only data from 2009 are disputed in this lawsuit, and that the same data for other years are not publicly available, there is no way to develop a model or trend based solely on the 2009 sales data.

P. Ex. 6 ¶ 7. No competitive harm regarding competitor market analyses can result solely from the release of the information in Document 2.

Another sponsor asserts that a competitor, having used its insights into the market sizes and market shares of particular drugs or sponsors to identify a profitable drug or market segment to target, might "take advantage of significant investments made by other sponsors by 'contracting with third-party manufacturers for production on existing lines . . . that were built, licensed, and brought on-line with considerable investment'" by the sponsor being targeted. FDA Memo at 25 - 26. However, the ability to predict production capacity and costs of a particular sponsor utilizing 2009 data in order to implement a strategy to disrupt the availability of production facilities

is highly speculative. Dr. Ikerd opined that such hypothetical concerns "greatly exaggerate the significance and usefulness of . . . [the 2009] information." P. Ex. 5 ¶ 18.

Some sponsors also complain that release of the 2009 data would enable competitors to determine which drugs have an "increasing market share," or assess whether particular drugs' or sponsors' market shares are increasing relative to the competitors. *See* FDA Memo at 24-25. This concern is more imagined than real as the 2009 data would only reveal the aggregate sales for a single year. Trends cannot be extrapolated from a single data point concerning a single point in time, or even multiple observations from a single point in time. P. Ex. 6 ¶ 7.

Other sponsors claim that the 2009 data, by revealing the sales volume for particular drugs or sponsors, will enable competitors to estimate sponsors' production capacities, an in turn deduce their manufacturing costs, selling prices, and profit margins. *See* FDA Memo at 28; AHI Memo at 17. While sales and production capacity are related to the extent that a sponsor can't very well sell more than it is able to produce, it would be naive 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. Likewise, it would be naive to assume that manufacturers have not adjusted their production capacities as annual sales have risen or fallen. P. Ex. 5 ¶¶ 19 - 20. Production cost depends on a number of variables aside from production capacity and output. P. Ex. 5 ¶ 19.

Finally, AHI argues that revealing the 2009 sales volume for drugs will enable competitors to identify sponsors' customers, because only a few large companies

dominate the livestock production industry. AHI Memo at 23. In fact, many, if not most, of these drugs are indicated for use in multiple species of animals. P. Ex. 3 at 3 (2009 ADUFA Summary). Moreover, many of these drugs are used to treat a variety of conditions beyond those for which they're labeled, and there's considerable overlap in how these drugs are used, even among drugs in different classes and routes of administration, in addition to variability in the amount of drug used to treat outbreaks among different herds. P. Ex. 1 ¶¶ 22 - 23 (Blackwell).

Further complicating the Defendants' theoretical concerns about the competitive harm that may result if the 2009 Document 2 data is released is the fact that since 2009 the market conditions have changed significantly creating instability.[12] Dr. Levins explains:

- The reasons for this instability are many and varied, and include the general economic crisis during the years since 2009, which affected consumer demand for livestock and poultry products as well as the availability of farm credit, and increased uncertainty in all business decisions.

- More recently, an extensive drought resulted in record-high feed prices and, in turn, significantly reduced the number of animals being raised (and therefore the number of animals that might receive antimicrobials or other inputs) and forced modifications to animal production practices. Beef production and prices have been especially volatile, resulting in shifts away from beef production and toward poultry and pork production.

- Global policies and business have rapidly entered livestock production decision making-the two largest dairy processors are foreign-owned, and Smithfield, a dominant processor and producer of pork in the United States, has been acquired by Chinese interests.

[12] Of course, FDA and AHI assert that the drug market and industry have not undergone dramatic changes since 2009. FDA Memo at 33; AHI Memo at 24. However, the bases for their assertions fail to reflect the events described by Dr. Levins.

- Consumer demand for organic and related products (natural, GMO-free, antibiotic-free) has continued to grow since 2009, and producers have responded. For example, two of the largest poultry producers, Tyson Foods and Perdue Farms, have eliminated certain uses of antibiotic drugs and started antibiotic free brands.

- Economic concentration at the retail level has increased, forcing changes in business practices by livestock companies.

- Additionally, since 2009 there has been a great deal of consolidation among the livestock producers who purchase and use these drugs, so that just a handful of large companies are now buying a majority of these drugs. These companies have preferences just like any other consumer, and I think it's reasonable to expect that on-farm practices have become more standardized as ownership has consolidated.

- Finally, federal farm policy, a perennial source of stability in difficult times, has all but disappeared from that role. Instead, federal policy now relies on subsidized insurance programs for farmers that, while compensating farmers for losses due to instability, do nothing to prevent that instability.

P. Ex. 6 ¶ 9. As a result, Dr. Levins concludes,

> These shocks would be difficult to incorporate into a forecasting model, and it is difficult to see how 2009 sales data would be useful in validating a model in 2015 and subsequent years. Even if the model did accurately "predict" sales in 2009 (i.e., if the values it generated for 2009 were found to be reasonably accurate when compared to the redacted actual data for 2009), changes in the industry since 2009 will have diminished sharply the value of this accurate prediction.

P. Ex. 6 ¶ 10. Thus, the likelihood of competitive harm from the release of the data in Document 2 is quite remote.

With respect to the changing market conditions and industry shakeups since 2009, some declarants explain that competitors in this industry are knowledgeable about the events that affect demand for these drugs, like disease outbreaks and weather

patterns, and how they affect sales.[13] *See* FDA Memo at 34 - 35 n. 23; AHI Memo at 25 - 26. Even if sponsors could make reliable intuitive judgments about whether sales of a particular type of drug would increase or decrease in response to a disease outbreak or severe weather pattern, to reliably estimate the magnitude of the change in sales in response to a particular condition or event, one needs at least two data points: one providing an observation for one set of conditions, and a second providing an observation for the different conditions (*i.e.*, a "before" and an "after"). In a complex and evolving market, like this one, where multiple factors and events effect sales, one needs even more data points to get any sort of reliable analysis about how one particular event affects sales. P. Ex. 5 ¶ 14. Moreover, it's virtually impossible to anticipate, with any useful degree of accuracy, the impact of an uncommon event like a severe drought or a major disease outbreak. *Id.*

Lastly, the Defendants complain that GAP is pursuing a similar FOIA request covering periods after 2009. They argue that the Court should, in evaluating whether to permit withholding in the instant case, account for the possibility that that information might be used in combination with the 2009 sales information sought in this proceeding to cause competitive harm. *See* AHI Memo at 15; FDA Memo at 34 n. 23. Of course, the Defendants speculation about FDA's compliance with other pending FOIA requests in no way demonstrates that disclosure of the 2009 data is "likely" to cause competitive

[13] Antimicrobials are used in a variety of species for many purposes, including controlling illness. Thus, the correlation of events such as disease outbreaks and severe weather problems with anticipated usage/sales is far too speculative to make reliable predictions. P. Ex. 1 ¶¶s 21 – 24.

harm. Any effort to compel FDA to disclose the more recent information would occur in a separate proceeding, raising a distinct factual situation requiring a separate analysis, whose outcome may well depend on the outcome of this litigation. *See, e.g.*, *Biles v. HHS*, 931 F.Supp.2d 211, 227 (D.D.C. 2013) ("Speculative assertions do not serve as affirmative evidence.").

2. Evidence Offered by the Defendants is Objectionable

The declarations offered by the Defendants to establish that competition and competitive injury would likely result from the release of the redacted in formation in Document 2 are often conclusory, offer legal conclusions, provide bare allegations of fact, and lack foundation for the statements made. In general, facts stated in summary judgment declarations/affidavits must be specific and constitute admissible evidence. Fed.R.Civ.P. Rule 56(c)(4); *Lujan v. National Wildlife Federation*, 497 U.S. 871, 888 (1990). The affiant's or declarant's statement must be based on personal knowledge. *See, e.g.*, Fed.R.Civ.P. Rule 56(c)(4). The basis for the assertion of personal knowledge should be contained in the affidavit or declaration. Finally, it is well settled that,

> 'ultimate or conclusory facts and conclusions of law . . . cannot be utilized on a summary judgment motion.' 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 2738, at 486 & 489 (1983); see also Fed. R. Civ. P. 56(e). Such conclusory statements are insufficient to raise a triable issue of material fact, and hence were properly disregarded.

BellSouth Telecomms. v. W.R. Grace & Co., 77 F.3d 603, 615 (2d Cir. 1996); *see also*, *TIG Insurance v. Sedgwick James*, 276 F.3d 754, 759 (5th Cir. 20002).

In light of these standards, Plaintiff objects to the following sponsor's statements because they are conclusory, lack foundation, lack personal knowledge, and/or state a legal conclusion.

- "The customer base for antimicrobial-containing animal drugs is very concentrated. For example, the top five broiler chicken producers controlled 59% of the 2013 volume of the top 35 producers and the top five turkey producers controlled 75% of the 2013 volume of the top 11 producers . . ." FDA Ex. C ¶s 19 -20.

- "If FDA were to reveal the information described above, knowledge of detailed product volumes would increase a competitor's ability to target specific markets and customers . . ." FDA Ex. C ¶s 26 – 29.

- "Competitors who are known to have significantly lower production costs than manufacturers currently competing in a particular market segment—for example, overseas manufacturers with lower labor costs—could use the volume sales data redacted in revised Document 2, together with information on prices and production costs, to identify market segments where existing products generate relatively low profit margins . . ." FDA Ex. C ¶s 33 – 39.

- "Competitors could thus generate accurate estimates of current volume sales data using precise, accurate 2009 data as a baseline and adjusting for known market trends. Absent the information redacted from revised Document 2, competitors must rely on estimates of the current market in conjunction with projections from estimates of the past market, neither of which would be as accurate as the information in revised Document 2 adjusted for the known market trends . . ." FDA Ex. C ¶ 42.

- "Although it relates to 2009 sales, the data in Revised Document 2 is highly relevant to understanding the current marketplace. If the currently redacted information were disclosed, it would allow Zoetis's competitors (alone or through data vendors), both within specific market segments and in the animal drug industry generally, to predict accurately current Zoetis market share and sales volume for certain products. In general, historical sales data is extremely valuable in predicting current and future trends in the market . . ." FDA Ex. D ¶ 11.

- "Sales and distribution data from 2009 remains extremely valuable for forecasting purposes because the animal drug market has not changed significantly in the intervening years . . ." FDA Ex. D ¶s 15 - 17.

- "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 . . ." FDA Ex. D ¶s 19, 20, 22.

- "If the redacted information in Revised Document 2 were to become publicly disclosed, market actual sales information from 2009 to validate existing predictive models, or to develop new, more reliable models . . . FDA Ex. D ¶s 24 – 25.

- "I understand that 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 . . ." FDA Ex. E ¶s 16 – 25.

- "The aggregate information redacted in revised Document 2 would allow Merck's competitors to determine Merck's and its competitors' respective market shares and sales volume . . ." FDA Ex. F ¶s 14 – 20.

- "Someone with industry knowledge could extract significant understanding and knowledge of the Elanco business from the Redacted Information . . ." FDA Ex. G ¶s 13 – 19, 22, 23.

- "Competitive injury to BIVI will result from the disclosure of the Redacted Information . . ." FDA Ex. H ¶s 19 – 24.

- "While more recent information about competitors' sales volumes is always desired, having the correct sales numbers from five years ago, in this case 2009, still has substantial value . . ." FDA Ex. I ¶s 6 – 8.

- "The release of this information could cause substantial competitive harm to Bayer and harm to the industry as a whole . . ." FDA Ex. J ¶ 10.

- "Norbrook hereby affirms that disclosure of Norbrook's sales and distribution data would likely cause Norbrook significant competitive harm . . ." FDA Ex. K ¶ 7.

- "Disclosure of the information redacted by the FDA in the documents regarding the amount of Medicated Articles disturbed, or disclosure of the data set forth in the reports referenced above, would enable a competitor to determine the amount of each product distributed by Pharmgate during the time frame represented by the data . . ." FDA Ex. L ¶ 10, 12.

Plaintiff moves to strike the referenced statements and asks that the Court reject them.

CONCLUSION

For the foregoing reasons, the Court should deny Defendants' motions for summary judgment, grant Plaintiff's motion for summary judgment, and order Defendant FDA to produce the redacted information contained in Document 2, except for corresponding totals for the following class/route combinations: Penicillins/Mastitis; Penicillins/Medicated Feed; Sulfas/Oral; Sulfas/Water; Sulfas/Oral/Water; Tetracyclines/Injection; Tetracyclines/Oral; Tetracyclines/Topical.

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Respectfully submitted,

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