UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GOVERNMENT ACCOUNTABILITY PROJECT	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 1:12-cv-01954 (KBJ)
	)	
U.S. FOOD AND DRUG ADMINISTRATION	)	
	)	
Defendant.	)	

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

Plaintiff Government Accountability Project respectfully submits this Memorandum in Opposition to Defendant's Motion 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 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* Def's Ex. 3; Def's Ex. A ¶ 9. 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* Def's Ex. 3; Def's Ex. A ¶ 10. 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* Def's 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. Therefore 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* Defendant's Memorandum in Support of its Motion for Summary Judgment ("Defendant's Motion") pg. 7. 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 Defendant's motion 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. (Pl's 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. *See* Price Decl. (Pl's Ex. 2) ¶ 13. Certain uses of antimicrobial drugs in food producing animals are believed to contribute more than others to the development of antimicrobial resistance. Pl's Ex. 1 ¶ 9; Pl's Ex. 2 ¶ 19-22. 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." Pl's Ex. 1 ¶ 9; Pl's Ex. 2 ¶ 18. Drugs administered in this manner are typically administered in medicated animal feed and drinking water. Pl's Ex. 1 ¶ 9; Pl's Ex. 2 ¶ 18. 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. Pl's Ex. 1 ¶ 10; Pl's Ex. 2 ¶ 21.

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 ingredient 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* Pl's 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 Pl's Ex. 1 ¶ 10-11; 2009 ADUFA Summary Report (Pl's Ex. 3); 2011 ADUFA Summary Report (Pl's Ex. 4). Unfortunately, these reports mask information concerning *how* these antimicrobial drugs are used, because these reports do not break down sales according to dosage form, strength, and route of administration, or otherwise indicate the uses for which they are sold. Pl's Ex. 1 ¶ 10; Pl's Ex. 2 ¶ 34; Pl's Ex. 3; Pl's 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. Pl's Ex. 1 ¶ 11; Pl's Ex. 2 ¶ 34.

In light of the significance of the data possessed by Defendant concerning the use of antimicrobial drugs in animals, and its 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. *See* Def's Ex. 1. 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 (Def's Ex. 3). 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* Pl's Ex. 2 ¶ 27-36.

As described above, Document 2 lists the aggregate 2009 total sales of antimicrobial active ingredient for each antimicrobial class, broken down by route of administration. *See* Def's Ex. 3. 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. Def's Ex. A ¶ 11, 28. In others, the totals reflect the aggregate total sales of two

or more sponsors of active ingredients in a particular antimicrobial class sold in drugs having a particular route of administration. Id. ¶ 31. While some of the totals listed in Document 2 have been disclosed by Defendant, most remain redacted. Def's Ex. 3. Defendant argues that these redacted totals are exempt from mandatory disclosure under FOIA Exemptions 3 and 4.

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 argues that Section 105 of the Animal Drug User Fee Act, 21 U.S.C. § 360b, is an Exemption 3 withholding statute. *See* Defendant's Motion, pg. 7-10. 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., Pl's Ex. 3; Pl's 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 3 distinct sponsors. 21 U.S.C. § 360b(l)(3)(E)(i). Defendant argues that this mandatory disclosure provision is an Exemption 3 withholding statute. *See* Defendant's Motion, pg. 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* Defendant's Motion, pgs. 13-15. In support of this claim, Defendant provides numerous declarations submitted by various drug sponsors and FDA personnel. *See* Def's Exs. C-O. 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

[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).

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, pg. 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 who 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

I. Defendant's Withholding of Information in Document 2 was Improper.

Defendant has claimed that the redacted information in Document 2 is subject to withholding under FOIA Exemptions 3 and 4. *See* Defendant's Motion, pg. 7. 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* Def's Exs. C-O. As explained below, the allegations in these declarations are largely conclusory and implausible. Moreover, as explained below, 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. 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 2 was improper. Section 105 does not qualify as an Exemption 3 withholding statute. Moreover, even if it did, it's scope would not be as broad as Defendant has claimed.

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

Defendant 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* Defendant's Motion, pgs. 7-10. 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., at 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 of these, 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. v. DOJ*, 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."). It cannot be found

"in the legislative history of the claimed withholding statute, nor in an agency's interpretation of the statute." *Reporters Comm. v. DOJ*, 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 TX SW Med. Ctr. v. Nassar*, No. 12-484, 570 U.S. ___ (2013) (June 24, 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. It would be absurd, for example, to believe that Congress intended

this limitation to apply to the disclosures made by the Secretary to the Antibiotic Resistance Task Force authorized by a separate provision of Section 105, which could scarcely perform its function if data about the use of several entire classes of antimicrobial drugs were withheld from it.

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. 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. That Congress didn't intend for these limitations to apply in the FOIA context is not 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 argues that the legislative history of Section 105 indicates that Congress intended for the limitations on the content of the Secretary's annual summary reports described in 21 U.S.C. § 360b(l)(3)(E) were intended 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. 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 734-735 ("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 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 certainly knew how to do 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.

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, its coverage would not extend to the majority of the information Defendant claims it would. Defendant claims that all of the

redacted information in Document 2 is exempt under Exemption 3. *See* Defendant's Motion, pg. 13. 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.

Defendant correctly notes that in 2009, fewer than three distinct sponsors distributed antimicrobial drugs in the following antimicrobial classes: Aminocoumarins, Amphenicols, Diaminopyrimidines, Fluroquinolones, Glycolipids, Pleuromutilins, Polypeptides, Quinoxalines, and Streptogramins. *See* Defendant's Motion, pg. 10. However, Defendant also 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* Defendant's Motion, pg. 11-13. 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* Defendant's Motion, pg. 11. 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 TX v. Nassar*, No. 12-484, 570 U.S., slip. op. at 13 (2013) (June 24, 2013) Courts should "give effect, if possible, to every clause and word of a statute, avoid, if it may be, any construction which implies that the legislature was ignorant of the meaning of the language it employed." Defendant's sweeping interpretation of § 360b(l)(3)(E)(i) unreasonably ignores Congress' deliberate word choice, and this Court should not give its interpretation deference or weight.

Defendant's interpretation of § 360(l)(3)(E)(i) is also unreasonable because it renders §360(l)(3)(E)(ii)[2] 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

[2] 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.

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* Defendant's Motion, pg. 18. 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 of sponsor's in the antimicrobial class. *See* Defendant's Motion, pg. 11. As Defendant acknowledges in its Memorandum at page 12, 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." Defendant's interpretation of § 360b(l)(3)(E)(i) to include a prohibition on the disclosure of "confidential business information" thus unreasonably renders the same language in § 360b(l)(3)(E)(ii) superfluous, and is undeserving of any weight or deference.

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. These are: Aminocoumarins, Amphenicols, Diaminopyrimidines, Fluroquinolones, Glycolipids, Pleuromutilins, Polypeptides, Quinoxalines, and Streptogramins.

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

Defendant argues that the information withheld in Document 2 is exempt from mandatory disclosure under FOIA Exemption 4. *See* Defendant's Motion, pg. 13. 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, Defendant contends that the redacted information in Document 2 is exempt from disclosure under Exemption 4 because its release would reveal confidential commercial information. *See* Defendant's Motion, pg. 13. 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 Defendant 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. Defendant does not argue that disclosure of the information in Document 2 would impair the agency'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). Instead, Defendant argues that disclosure of the information would likely cause substantial

competitive harm to the various drug sponsors who submitted the information in Document 2. *See* Defendant's Motion, pg. 16. As explained below, Defendant has failed to demonstrate that disclosure of the information in Document 2 would likely cause substantial competitive harm.

In their declarations, several sponsors claim that information concerning sales is customarily kept confidential in this industry, and that its release would likely cause substantial competitive harm. However, while secrecy may be the norm in the animal antimicrobial drug industry, it is not the norm in the human pharmaceutical company. For example, Pfizer regularly reports the total revenue generated by sales of individual drugs in its portfolio, including drugs like Zoloft for which patent protection has expired and generic equivalents are marketed. See Pfizer Q4 2013 Performance Report (Ex. 5) [3] pg. 17. Pfizer even indicates whether sales of particular drugs have increased or declined over the previous year's sales. Id. Information concerning sales and production volume of particular products is routinely released by companies in other highly competitive industries as well. For example, car manufacturers routinely release such information. See Toyota 2012 Production Report (Ex. 6)[4]; General Motors July 2012 Sales Report (Ex. 7)[5]. Indeed, disclosure of such information can be quite beneficial, enabling suppliers of parts and other raw materials to accurately gauge future demand, thereby reducing the frequency of shortages.

Plaintiff does not doubt that antimicrobial animal drug sponsors desire to keep data concerning sales volume secret. However, as explained below, they have not demonstrated that

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[3] Retrieved at http://www.pfizer.com/files/investors/presentations/q4performance_012913.pdf

[4] Retrieved at http://www.toyota-global.com/company/profile/figures/pdf/2013/production.pdf

[5] Retrieved at http://www.gm.com/content/gmcom/home/company/investors/sales-production.content_pages_news_us_en_2013_jul_gmsales.~content~gmcom~home~company~investors~sales-production.html

their desire to withhold this information from the public stems from a legitimate fear of likely competitive harm flowing from its disclosure. As explained above, the public has long lacked sufficient data concerning the use of antimicrobial drugs in food animals to evaluate their public health impact. Indeed, drug companies have actively resisted proposed regulations that would require them to disclose more data, or that could otherwise limit use of their products. Ex. 1 ¶ 13-16. These sponsors therefore have a strong incentive to keep disclosure of data concerning their use to a minimum in order to stem public awareness that might result in limitations on use and other regulatory requirements. Indeed, Zoestis acknowledged this fear in the "Risk Factors" section its SEC Form S-1. Zoetis SEC Form S-1 (Ex. 8) pg. 22. These sponsors have other reasons to seek to maintain the confidentiality of sales volume information. For example, as one sponsor honestly noted, disclosure might prompt suppliers of raw materials, seeing their impact on the sponsor's profits, to increase their prices. Def's Ex. L, ¶ 14. Moreover, as several sponsors have noted, the number of large producers of particular species is relatively small. *See, e.g.,* Def's Ex. G ¶ 19. If information concerning sales volume were released publicly, customers who recognize that they are responsible for a significant portion of a sponsor's business might use that knowledge to obtain more favorable prices. None of these risks, however, are the sort protected by Exemption 4. See *Ctr. To Prevent Handgun Violence v. U.S. Dept. of the Treasury*, 981 F.Supp. 20, 23 (D.D.C. 1997) (denying competitive harm claim where agency failed to demonstrate that the alleged harm would "flow from *competitors' use* of the released information") (emphasis added).

1. Defendant's Evidence Concerning Competition is Insufficient.

To establish that the information qualifies for withholding under Exemption 4, the agency must find that the submitter of the information at issue faces "actual competition." Evidence

concerning the potential for future competitors to enter the industry is irrelevant, for "the test explicitly requires that the submitter face *actual* competition." *Niagara Mohawk*, 169 F.2d at 19.

Defendant has presented affidavits from numerous 2009 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," or "very" or "extremely" or "intensely competitive," and/or that these drugs "compete head-to-head across routes of administration and antimicrobial classes." *See* Def's Ex. D ¶ 18; Def's Ex. E ¶ 4; Def's Ex. F ¶ 18; Def's Ex. G ¶ 16; Def's Ex. I ¶ 18; Def's Ex. J ¶ 6; Def's Ex. L ¶ 11; Def's Ex. N ¶ 1. These statements are entirely conclusory, and are therefore insufficient to meet Defendant's burden. *See Niagara Mohawk* 169 F.3d at 18. Other affidavits provide even less detail, simply referring to "competitors" in passing, and are likewise insufficient. *See* Def's Ex. H ¶ 8-9; Def's Ex. M ¶ 4. Many sponsors refer to harms that might occur as a result of potential future competitors who may or may not hold approved drug applications for similar products. See, e.g., Def's Ex. F ¶ 6 (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.2d at 19.

Only a few sponsors provide any detail at all concerning the identity of competitors and scope of competition. In her declaration, the Regulatory Manager for the sponsor Huevepharma states that its medicated feed products compete with medicated feed products produced by Alpharma and Elanco and "other companies." Def's Ex. C ¶ 4. In his declaration, the Senior Vice President of Global Marketing for Phibro identifies other manufacturers of "Medicated Feed Additives" as competitors of for its own medicated feed drugs. Def's Ex. G ¶ 16. An employee of PennField Oil Co. identifies ADM Alliance Nutrition, Phibro Animal Health and

Zoetis as competitors for its medicated feed drugs. Def's Ex. K ¶ 9. Finally, the General Counsel for Hanford identifies its Penicillin G Procaine mastitis product as a drug with respect to which other manufacturers "directly compete." Def's Ex. O ¶ 5, 10. Plaintiff does not contest Defendant's allegations concerning competition with respect to medicated feed drugs in all classes or mastitis products in the pencillins class. Moreover, the declarations from Huevepharma, Phibro, Pennfield and Hanford indicate that particular drugs do not compete with all other drugs in the industry, such that the existence of competition within the industry, without more, is sufficient to determine whether a given sponsor faces actual competition with respect to its products. *See, e.g.* Def's Ex. K ¶ 9 (indicating that Pennfield's medicated feed drugs only face competition from similar drugs manufactured by ADM Alliance, Phibro and Zoetis). However, aside from those products specifically identified by Huevepharma, Phibro, Pennfield and Hanford, Defendant has failed to provide anything more than conclusory allegations that competition exists in this industry. Defendant has thus failed to meet its burden to demonstrate actual competition with respect to all other drugs, and has failed to provide the Court with sufficient information to evaluate which information concerning these drugs properly qualifies for withholding under Exemption 4, and which does not and should be disclosed.[6]

2. Disclosure of the Information in Document 2 is not Likely to Cause Substantial Competitive Harm.

As explained below, 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

[6] FOIA requires the segregation and disclosure, where reasonably possible, of non-exempt information where both types appear in the same document. 5 U.S.C. § 552(b). *See* also *Krikorian v. Dept. of State*, 984 F.2d 461, 467 (D.C. Cir. 1993) (remanding to district court for segregability determinations); *Hall v. U.S. Dept. of Justice*, 551 F.Supp.2d 23, 31 (D.D.C. 2008) (denying agency's motion for summary judgment where agency failed to provide sufficient information to determine whether reasonably segregable information had been disclosed).

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. Though post-2011 data has not yet been released, recent events indicate that substantial changes continued to occur in 2012 and 2013. As a result, any risk that might have been posed by contemporaneous release of the information in Document 2 has long since dissipated. Moreover, Defendant has failed to identify any potential competitive harm not already posed by publicly available information. Nor has Defendant demonstrated that releasing the information in Document 2 would in any way increase the likelihood of competitive harm.

a. <u>Any risk of competitive harm that might have resulted from contemporaneous public disclosure of the information has dissipated.</u>

Defendant argues 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* Defendant's Motion at pg. 16. In turn, Defendant argues, competitors could use that information to obtain a competitive advantage over or otherwise harm the sponsor's competitive position. Id. For example, Defendant argues, 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," to "identify other companies' customers," to "estimate a company's production costs," to ascertain "the amount of antimicrobial active ingredient distributed by a sponsor," and to identify profitable markets for particular drugs and/or markets where sales are flagging. Id., pgs. 16-19. 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 four

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 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."). Here, the market for animal antimicrobial drugs has changed dramatically in the years since 2009. In light of these tremendous 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, etc., could be derived from historical data concerning its sales given that sales volume has apparently changed substantially across all classes, particularly given that no information is publicly available concerning the distribution of these changes among particular drugs within those classes. After all, 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 current market

intelligence reports. *See* Def's Ex. F ¶ 22 (discussing the availability of "market intelligence reports" containing "valuable information" about sponsors in the industry).

Demand for antimicrobial animal drugs has shifted tectonically in the intervening years since 2009. As the following charts derived from FDA's 2009 and 2011 ADUFA Summary Reports illustrate, this shift has occurred across all antimicrobial classes, and in both the domestic and export markets:

Antimicrobial Class	**2009 Domestic Sales**[7]	**2011 Domestic Sales**[8]	**% Change**
Aminoglycosides	339,678 kg	214,895 kg	-36.736%
Cephalosporins	41,328 kg	26,611 kg	-35.611%
Ionophores	3,740,627 kg	4,123,259 kg	+10.229%
Lincosamides	115,837 kg	190,101 kg	+64.111%
Macrolides	861,985 kg	582,836 kg	-32.385%
Penicillins	610,514 kg	880,163 kg	+44.167%
Sulfas	517,873 kg	371,020 kg	-28.357%
Tetracyclines	4,611,892 kg	5,642,573 kg	+22.348%
All others	2,227,366 kg	1,510,572 kg	-32.181%

Antimicrobial Class	**2009 Export Sales**[9]	**2011 Export Sales**[10]	**% Change**
Tetracyclines	515,819 kg	15,321 kg	-97.03%
All others	1,115,728 kg	185,333 kg	-83.39%

By 2011, domestic sales of antimicrobial animal drugs containing aminoglycosides, cephalosporins, macrolides and sulfas had dropped by nearly 1/3. Similarly, between 2009 and 2011, domestic sales of antimicrobial drugs containing ionophores, penicillins and tetracyclines

[7] Source: 2009 ADUFA Summary Report (Ex. 3)

[8] Source: 2011 ADUFA Summary Report (Ex. 4)

[9] Source: 2009 ADUFA Summary Report (Ex. 3)

[10] Source: 2011 ADUFA Summary Report (Ex. 4)

increased tremendously. Even domestic sales of lincosamides, which underwent the smallest change, increased substantially. Likewise, the aggregate total sales of antimicrobial drugs in those classes with fewer than three sponsors, which includes aminocoumarins, amphenicols, fluoroquinolones, diaminopyrimidines, glycolipids, pleuromutilins, polypeptides, quinoxalines and streptogramins, indicates that the domestic market for drugs in those classes has also morphed greatly. As the 2011 sales figures also indicate, in just the two years since 2009, the overseas market for these drugs became virtually unrecognizable when compared to itself in 2009, with export sales of tetracyclines dropping by over 97%, and overseas sales of all other classes dropping by more than 80%.

Although FDA has not yet released its Summary Report for 2012, it is reasonable to expect that the market for these drugs has continued to change substantially. In the 19 months since 2011 ended, record-breaking droughts have caused livestock producers to place their cattle on feed at lower weights as pasture availability has decreased and feed prices have increased. *See* U.S. Drought 2012: Farm and Food Impacts, U.S. Dept. of Agriculture Economic Research Service (Ex. 9)[11] pgs. 1, 9. In light of these conditions, it's reasonable to expect that demand has increased for those antimicrobial drugs used to obtain greater feed efficiency. Likewise, it's reasonable to expect that, as livestock producers have cut the size of their herds, demand for those drugs used to treat infections has decreased. Indeed, Zoetis, the dominant sponsor in this industry, recently acknowledged the impact that these conditions have had on its sales of livestock drug products in the U.S. and abroad in its April 30, 2013 report of its First Quarter 2013 Results. See Zoetis Q1 2013 Results (Ex. 10)[12] pg. 2.

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[11] Retrieved at http://www.ers.usda.gov/topics/in-the-news/us-drought-2012-farm-and-food-impacts.aspx

[12] Retrieved at http://investor.zoetis.com/press-release/financial/zoetis-reports-first-quarter-2013-results

Other recent changes have also undoubtedly affected, and continue to affect, demand for antimicrobial animal drugs in the U.S market. For example, in 2012, the FDA published guidelines for the livestock industry recommending the phase-out of non-therapeutic uses in agriculture of medically important antimicrobial drugs. *See* Guidance for Industry on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals, 65 Fed. Reg. 22328 (April 13, 2012). Similarly, Zoetis recently came to an agreement with the FDA to remove the indication for growth promotion from many of its antimicrobial animal drugs in the U.S. *See* Zoetis Q1 2013 Earnings Call Transcript, (Apr. 30, 2013) (Ex. 11)[13] pg. 15 (noting that sales of livestock drugs have increased in the U.S. And abroad, though total sales in the U.S. Have been tempered by the drought's effect on livestock production). Additionally, since 2009, there has been significant consolidation and acquisition of companies among the pool of 2009 sponsors. *See* Def's Ex. D ¶ 10 (indicating that BIVI acquired products from Fort Dodge); Def's Ex. E ¶ 2 (indicating that Bayer has acquired Teva Animal Health, Inc.); Def's Ex. F ¶ 2 (indicating that Merck has acquired Intervet Schering-Plough); Def's Ex. H ¶ 1(indicating that Zoetis, as Pfizer, acquired Pharmacia & Upjohn, Forth Dodge and Alpharma LLC). Likewise, there has been ongoing consolidation and change on the demand side of the market for antimicrobial animal drugs. *See* Def's Ex. G ¶ 19 ("The livestock production industry is very concentrated and has become more and more consolidated… Phibro has seen consolidation of customers (farms and producers) over the past several years.")

Given the tremendous changes in the market for these drugs that occurred between 2009 and 2011, and the changes that have likely continued to occur since, it is extremely unlikely that

[13] Retrieved at http://seekingalpha.com/article/1386171-zoetis-ceo-discusses-q1-2013-results-earnings-call-transcript?source=nasdaq

any information revealed by or estimates derived from the redacted data in Document 2 would be accurate for competitive purposes or at all useful to any sponsors. These sponsors must compete in the present, and so information that does not reflect *current* conditions is unlikely to be of any competitive use. To whatever extent *contemporaneous* public disclosure of the information in Document 2 might have caused competitive harm, any such risk has since dissipated. Any estimates about the *current* state of affairs in this industry derived from the 2009 sales volume information contained in Document 2 could hardly be more reliable than unguided guesses, particularly since no information is available concerning how the changes in demand across antimicrobial classes since 2009 have been allocated among particular sponsors and drugs. It is therefore extremely unlikely that any harm to a sponsor that might result from changes in behavior made by other sponsors following disclosure of the information contained in Document 2 would in fact flow from any use of the information revealed. In fact, given the availability of current "valuable information" in market intelligence reports, and the alleged constant efforts of sponsors to obtain accurate information about their peers, it is exceedingly implausible that any sponsor would base any decisions on or otherwise rely on the outdated information in Document 2 or any estimates derived therefrom. *See* Def's Ex. F ¶ 22 (discussing the availability of "market intelligence reports" containing "valuable information" about sponsors in the industry). As Zoetis noted in its SEC Form S-1, "the breadth of a business's product portfolio and a *real-time* understanding of regional and local trends are key success factors" in this industry. Pl's Ex. 8 pg. 117 (emphasis added).

b. Disclosure of the information in Document 2 is not likely to cause substantial competitive harm.

Defendant bears the burden of establishing that the withheld information in Document 2 is "likely to cause substantial competitive harm" if released. Given FOIA's presumption in favor of disclosure, this burden is appropriately high. Conclusory and generalized allegations by the agency are insufficient to meet this burden. *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291 (D.C. Cir. 1983). A detailed economic analysis is not required, but an agency "must provide affidavits that contain more than mere conclusory statements of competitive harm." *Gilda Indus., Inc. v. U.S. Customs & Border Protection Bureau*, 457 F.Supp.2d 6, 10 (D.C. C. 2006). While an agency need not demonstrate actual competitive harm, to meet its burden, Defendant must establish that competitive harm is reasonably *likely* to occur. *See Frazee v. United States Forest Serv.*, 97 F.3d 367, 371 (9th Cir. 1996) (finding that the alleged risk of competitive harm was already posed by publicly available information, thereby making it unlikely that disclosure of the contractor's operating plan would cause competitive harm). Moreover, the competitive harm risked must be substantial. *Martin Marietta Corp. v. Dalton*, 974 F.Supp. 37, 41 (D.D.C. 1997) (upholding decision to release information where disclosure was not "likely to result in such egregious injury to [the submitter] as to disable as an effective competitor"). Finally, this burden is not met where the alleged risk competitive harm is already posed by publicly available information, and where the withheld information would not otherwise enhance the likelihood of the alleged harm. Rather, the alleged harm must flow from the release and use by competitors' of the alleged confidential information. *See Public Citizen Health Research Group v. FDA*, No. 96-1650, slip op. at 1-2 (D.C.C. Nov. 3, 1997) (ordering information released where no competitive harm would "flow from the release" of the information); *Ctr. To Prevent Handgun Violence v. U.S. Dept. of the Treasury*, 981 F.Supp. 20,

23 (D.D.C. 1997) (denying competitive harm claim where agency failed to demonstrate that the alleged harm would "flow from *competitors' use* of the released information") (emphasis added).

Defendant has alleged that he information withheld in Document 2 could be used to derive numerous other pieces of sensitive, competitively useful information, and has presented many scenarios whereby such information could allegedly be used to cause substantial harm to the competitive interests of existing sponsors of antimicrobial animal drugs. *See* Defendant's Motion, pgs. 15-19. However, these allegations dissolve under scrutiny. Moreover, to the extent any of the allegations are plausible, Defendant has not and cannot demonstrate that disclosure of the information contained in Document 2 will increase the likelihood of competitive harm posed by information already readily available to any competitors.

Defendant argues that disclosure of the information Document 2 would enable competitors to "more accurately estimate a company's production and/or manufacturing capacity." *See* Defendant's Motion, pg. 16. As discussed above, however, to whatever extent the 2009 sales volume information in Document 2 could have been used to ascertain a particular sponsor's production capacity in 2009 had it been disclosed contemporaneously, these sponsors' production capabilities have apparently changed considerably in the years since. Any estimate regarding a sponsor's current production capacity derived from the information Document 2 would be inaccurate and unreliable. Furthermore, Defendant does not explain how knowing a sponsor's production capacity could enable a competitor to gain any advantage or otherwise cause substantial competitive harm.

Defendant argues that competitors could use the information in Document 2 to "identify other companies' customers based on the types of antimicrobial drugs sold." Id. Defendant fails to explain, however, how information about a company's 2009 sales, the information in

Document 2, could possibly be used to identify a sponsor's particular customers. However, a competitor wishing to identify consumers of a particular drug can already do so using publicly available information. As one sponsor noted, the list of large producers of each species of food animal has become quite small. Def's Ex. G ¶ 19. A competitor wishing to narrow the list of possible customers of a particular drug need only look at the list of species for which the drug is indicated for use in. This information is already publicly available. It is listed on each drug's application, which can be easily accessed online using the FDA's database[14]. Defendant has not demonstrated how revealing the information in Document 2 would enhance a competitor's ability to identify particular customers beyond what can already be accomplished using publicly available information, or would otherwise increase the likelihood of this particular sort of competitive harm. In fact, it is extremely unlikely that a competitor could, using the information in Document 2, narrow the list of potential customers any further than it could using this publicly available information. To engage in any further matching of quantities with particular producers, a competitor would need to know how much of a particular species each producer raises, and how much of the drug is used per animal, and would need additional information about the regional disease ecology. *See* Pl's Ex. 1 ¶ 20. Defendant has failed to demonstrate that such information is publicly available. *See Jurecwicz*, 891 F.Supp.2d, at 155 (finding that disclosure would not cause competitive harm where dog breeders alleged that the information could be used in combination with other information, but failed to demonstrate that the other information was available to competitors). Moreover, most of these drugs are indicated for use in multiple species, and so any further attempts at narrowing the list of possible customers would likely amount to little more than a blind guess.

[14] Accessed at: http://www.accessdata.fda.gov/scripts/animaldrugsatfda/index.cfm?gb=1

Defendant further argues that competitors could "estimate a company's production costs," and use that information to "undercut another company's prices" to steal customers. *See* Defendant's Motion, pg. 16. In price-driven markets like this one, Plaintiff does not doubt that undercutting a competitor's prices could indeed cause some customers to change their purchasing habits. *See* Def's Ex. However, a competitor wishing to undercut another sponsor's prices already has all the information they need to do so. As several sponsors noted, information about particular drugs' prices is already readily available to any competitors. *See* Def's Ex. D ¶ 19; Def's Ex. F ¶ 20; Def's Ex. G ¶ 20. A competitor can surely already look at these publicly available prices and pick lower numbers. The ability of a competitor to lower its price will not depend on some other sponsor's production costs. Rather, it will depend on whether the competitor's own production costs allow it to charge less, and whether the revenue generated by customer gains will sufficiently offset the foregone revenue from existing customers. Even if knowledge of another sponsor's production costs were in any way useful for this purpose, as discussed above, it is unlikely that a competitor could accurately estimate any sponsor's current production costs using the 2009 data in Document 2, and even less likely that it would rely upon any estimates derived from that information. None of the industry representatives claimed in their declarations that they could accurately estimate a competitor's *current* production capacity based on the 2009 data. Furthermore, production costs depend on numerous variables, including costs of raw materials, labor costs and other overhead costs, none of which would be revealed by disclosure of the information in Document 2. *See Jurecwicz v. U.S. Dept. of Agriculture*, 891 F.Supp.2d 147, 154 (finding insufficient risk of competitive harm posed by disclosure of dog breeder' net income where "too many other variables" affected prices charged for dogs to make "revenue-divided-by-dogs-sold" estimates of prices reliable).

Defendant correctly notes that courts have found risk of competitive harm where the release of information could enable competitors to "estimate and undercut bids." *See* Defendant's Motion, pg. 17. In these cases, the submitters of the information at issue have been companies that regularly contract with the government to supply goods and services. *See, e.g., Gulf & W. Indus., Inc. v. United* States, 615 F.2d 527 (D.C. Cir. 1979) (FOIA request for information regarding defense contractor); *Abou-Hussein v. Mabus,* 2010 U.S. Dist. LEXIS 115032 (D.S.C. 2010) (FOIA request for information concerning six government contractors). In this peculiar procurement context, where procurement is carried out by soliciting bids from different companies, and where the prices and other content of companies' bids is kept secret from competitors, knowledge of competitor's pricing capabilities may indeed be quite advantageous. In that peculiar context, any information that would enable a company to predict the content of a competitor's secret bid would obviously make it easier to craft a winning bid. Here, however, none of the sponsors have presented evidence of government procurement of animal drugs, or that any analogous procurement process is used by customers in this industry. To the contrary, this is a price driven industry, and prices in this industry are already disclosed publicly. *See* Def's Ex. D ¶ 19; Def's Ex. F ¶ 20; Def's Ex. G ¶ 20-21 ("price is one of the key elements of concern" in this industry). A competitor wishing to undercut another sponsor's price and take customers from them already has all the information they need to do so.

Defendant argues that release of the 2009 sales volume data in Document 2 would "eliminate the need for competitors to do market research for certain products," and enable them to forego purchasing "market intelligence reports" which contain "valuable information" about other sponsors in the industry. *See* Defendant's Motion, pg. 17. As discussed above, the market for these drugs has changed so substantially since 2009 that any information in Document 2, and

any estimates derived therefrom, would be unreliable. It is inconceivable, particularly given the apparent availability of sophisticated , current market intelligence reports, that any sponsor would rely upon the information contained in Document 2 or any estimates derived therefrom in making business decisions. *See* Def's Ex. F ¶ 22 (discussing the availability of "market intelligence reports" containing "valuable information" about sponsors in the industry).

Defendant argues that the release of sales volume data about particular drugs could prompt others holding approved, but dormant, applications for identical or near identical drugs to decide to begin manufacturing and marketing the drug. *See* Defendant's Motion, pg. 17. These potential competitors, Defendant argues, could forego the purchase of costly market intelligence reports, and could contract for production on equipment built with significant investment from an active sponsor. Id. However, as discussed above, the existence of "future or potential" competitors is insufficient to establish Exemption 4's applicability. To establish that the information qualifies for withholding under Exemption 4, "the test explicitly requires that the submitter face *actual* competition." *Niagara Mohawk* 169 F.2d at 19 (D.C. Cir. 1999) (emphasis in original). Moreover, Defendant has not presented any evidence demonstrating that any active participants in this market with approved but dormant applications actually exist. Additionally, as discussed above, it is extremely unlikely that any sponsor considering manufacturing and marketing a new drug, with all the risk that entails, would even consider relying on the information in Document 2 or any estimates derived from it, particularly given the availability of current market intelligence reports. *See* Def's Ex. F ¶ 22 (discussing the availability and use of "market intelligence reports" containing "valuable information" about sponsors in the industry).

In any event, deciding whether to start manufacturing a particular product depends on an analysis of multiple factors aside from demand for the product or the success of other

manufacturers. For example, a potential manufacturer must consider the availability of capital, raw materials and other inputs, availability and cost of labor, and generally whether production costs will enable competitive pricing. Moreover, they must consider whether, in light of all those factors, the potential profits justify the risk and investment. The existence of an approved application alone is certainly insufficient to establish that competitive harm is *likely* to occur for the reasons alleged by Defendant. This possibility is even less likely where a potential competitor does not already hold an approved application, and would therefore have to invest considerable time and capital at great expense to even become eligible to compete. Whether any new market or sub-market entrant would take a competitor's market share or otherwise cause substantial competitive harm is even less predictable, and would depend on a host of unknown factors and hurdles that would be considerably difficult to clear, including competitors' existing customer loyalty, brand recognition, and manufacturing advantages gained through experience.

Defendant argues that disclosure of the information withheld in Document 2 would "reveal the amount of active antimicrobial ingredient distributed by a sponsor," and "could be used by competitors to purchase a significant volume of that active antimicrobial ingredient to limit production by the sponsor." *See* Defendant's Motion, pgs. 17-18. This claim, like the others, falls apart under scrutiny. A competitor seeking to limit another sponsor's production or increase its production costs by choking the supply of a needed active ingredient already has all the information necessary to do so. To cause competitive harm in this way, a competitor need only know the identity of the necessary active ingredient used by a sponsor to manufacture the competing drug. This information is already public. It is reflected in Document 1. It is likewise reflected in the drug applications publicly available on the FDA's website[15]. Defendant has not

[15] Accessible at http://www.accessdata.fda.gov/scripts/animaldrugsatfda/index.cfm?gb=1

explained or otherwise demonstrated how disclosure of any information in Document 2 would improve the ability of a competitor to cause competitive harm in this way or otherwise increase the likelihood of this sort of competitive harm. In fact, it is extremely unlikely that, in a price driven market where profit margins are thin, a competitor would hoard substantial quantities of an ingredient for which it has no need, or would purchase substantial quantities of an ingredient beyond what it needs to meet current demand for its products. *See* Def's Ex. G ¶ 21 ("price is one of the key elements of concern" in this industry); Def's Ex. O ¶ 3.

Defendant argues that if the information withheld in Document 2 is disclosed, "competitors who produce drugs with the same active ingredient" as other sponsors might use their knowledge of other sponsors to "gain an advantage in negotiating annual agreements with the active ingredient suppliers." *See* Defendant's Motion, pg. 18. Plaintiff doesn't doubt that under certain conditions, manufacturers using the same raw materials might be able to leverage knowledge that they are a primary source of a supplier's business to obtain more advantageous contract terms. However, this risk could not possibly be posed where only one sponsor uses a particular ingredient. As Document 1 reveals, this is frequently the case. As Document 1 reveals, this risk could not be posed by releasing the numbers in Document 2 for domestic sales of the following class/route combinations: Aminocoumarins/Mastitis; Aminoglycosides/Mastitis; Cephalosporins/Mastitis; Diaminopyrimidines/Medicated Feed; Fluroquinolones/Injection; Glycolipids/Medicated Feed; Lincosamides/Mastitis; Macrolides/Oral; Macrolides/Injection; Pleuromutilins/Water; Pleuromutilins/Medicated Feed; Polypeptides/Topical; Polypeptides/Oral; Polypeptides/Medicated Feed; Quinoxalines/Medicated Feed; and Streptogramins/Medicated Feed. *See* Def's Ex. 2. Nor could this risk be posed by releasing the numbers in Document 2 for export sales of the following class/route combinations:

Aminocoumarins/Mastitis; Aminoglycosides/Water; Aminoglycosides/Injection; Amphenicols/Medicated Feed; Amphenicols/Injection; Cephalosporins/Injection; Cephalosporins/Mastitis; Ionophores/Medicated Feed; Lincosamides/Water; Lincosamides/Mastitis; Lincosamides/Medicated Feed; Lincosamides/Injection; Macrolides/Injection; Polypeptides/Topical; Polypeptides/Medicated Feed; Tetracyclines/Topical; and Tetracyclines/Injection. *See* Def's Ex. 2

Nor has Defendant demonstrated that this risk would be increased in any way by releasing any of the other information in Document 2. For a sponsor using a particular ingredient to use information about other sponsors' use of the same ingredient to obtain more favorable terms, the two sponsors would have to be using the same supplier. Moreover, the competing sponsors would have to *know* that they use a common supplier, or the supplier would have to reveal this information. Defendant has presented no evidence showing that any two sponsors use a common supplier, or that the identity of any suppliers' customers is available. In fact, it is unlikely that any suppliers of active ingredients would reveal their customers for the very reason that that information might be used by particular sponsors to obtain lower prices where the supplier only has a few customers, or to pressure the supplier into cutting ties with competing sponsors. Finally, as discussed previously, the information in Document 2 concerns 2009 sales, and is unlikely to provide any useful information about any sponsor's *current* use of a particular ingredient.

Defendant argues that competitors could use the 2009 sales volume information Document 2 to "encourage customers to switch products by implying over use of another sponsor's product." *See* Defendant's Motion, pg. 18. This sort of competitive harm is unlikely to result from disclosure of the information in Document 2 for a number of reasons. Certain uses

of a particular antibiotic drug could indeed motivate a livestock producer to switch drugs. Pl's Ex. 1 ¶ 20. This is so because over time, bacteria within populations exposed to antimicrobials, particularly in lower doses, develop resistances due to survival and reproduction of bacteria with mutations that allow them to resist the antibiotic's lethal effect. Id. ¶ 21. However, where a population forms a resistance to a particular antibiotic, that resistance is typically class-wide, meaning that other antibiotics within the same class will concurrently lose effectiveness. Pl's Ex. 2 ¶ 14. As a result, the sponsors' most direct competitors, those within the same class, will not benefit from alleging overuse of another sponsor's drug. For this same reason, competitors wishing to imply over use already have more useful, current information for this purpose. In its 2011 ADUFA Summary Report, FDA lists the total amount of antimicrobial active ingredient sold domestically in 2011 for 8 of the antimicrobial classes. Indeed, one sponsor appears to indicate that this practice already occurs. *See* Def's Ex. C ¶ 10.

Additionally, resistance occurs due to exposure of particular populations to antimicrobial drugs. As Dr. Blackwell states in his declaration, "for example, administering penicillin to a pig in North Carolina does not expose bacteria in a chicken in Arkansas or a dairy cow in Pennsylvania to that penicillin. Pl's Ex. 1 ¶ 21. Rather the effect of over use is a localized issue depending on a particular producer's use of a given drug, and it is doubtful that any producer would be swayed to switch by evidence concerning industry-wide use. Id. ¶ 21-22. As discussed above, a competitor wishing to suggest "shuttling" in his drug in place of another sponsor's drug can already look at the list of indicated species for the target drug using the FDA's database, contact the relatively few major producers of each species, and suggest replacement. Each producer will understand the extent of his own use of the target drug. If the producer has noticed decreased effectiveness and/or the price is lower, he may switch to the

competitor's drug. If not, he probably won't. As discussed above, nor would the information in Document 2 enable a competitor to identify or further narrow the list of a drug's potential customers, let alone determine how much of the drug each customer uses. Indeed, Dr. Blackwell states in his declaration that he knows of no collection of information reported under ADUFA concerning the locality of sales or use of particular antimicrobial drugs. Pl's Ex. 1 ¶ 22.

Defendant also argues that the information in Document 2 could be used to ascertain information about "manufacturing specifics" and "pricing strategies." See Defendant's Motion, pg. 18. As discussed above, information about prices of particular drugs is already readily available to any actual or potential customers. Defendant does not explain how the outdated information about 2009 sales volume in Document 2 would reveal anything about current "pricing strategies" than is revealed by this current, publicly available information about particular drugs' prices. Nor does Defendant present any plausible reason why a competitor in this industry would care *how* or *why* a sponsor arrived at a particular price for its drugs. As discussed above, in a price-driven market, a competitor will care about the actual price, whether their own production costs enable them to charge a lower price, and whether the revenue gained by adding customers would offset the foregone revenue from current customers such that lowering the price would be profitable. Finally, Defendant does not explain how the information in Document 2 would reveal anything useful about "manufacturing specifics" than can be deduced from already public information. On its face, this claim is not credible. A competitor wishing to learn about a particular drug's "manufacturing specifics" can already learn a wealth of such information merely by analyzing the drug itself, its packaging, and its labeling, on which an exhaustive list of ingredients, a detailed description of the active ingredients' chemical structure,

preparation, and more. For example, the labeling of Zoetis' DRAXXIN antibiotic drug describes its preparation in considerable detail, stating:

> DRAXXIN Injectible Solution is a ready-to-use sterile parenteral preparation containing tulathromycin, a semi-synthetic macrolide antibiotic of the subclass triamilide. Each mL of DRAXXIN contains 100 mg of tulathromycin as a free base in a 50% propelyne glycol vehicle, monothioglycerol (5 mg/mL), with citric and hydrochloric acids added to adjust pH. DRAXXIN consists of an equilibrated mixture of two isometric forms of tulathromycin in a 9:1 ratio.

DRAXXIN Technical Bulletin (Ex. 12)[16] pg. 7. Defendant's allegation that any useful further information about "manufacturing specifics" could be learned from knowing how much DRAXXIN was sold in 2009 is simply incredible.

Defendant also claims that the information in Document 2 would reveal sponsors' market shares, "strengths and weaknesses within the market," companies' "business emphasis," and "which product line are receiving more focus" and which "lines appear to be flagging." As discussed above, any information of this sort derived from the 2009 sales volume information in Document 2 would be grossly inaccurate and unreliable. Defendant does not allege any addition sorts of competitive harm that may occur through use of this information. Furthermore, as explained above, the sorts of competitive harm Defendant alleges could result from information revealed by the numbers in Document 2 are unlikely to occur and already risked by far more useful, publicly available information.

c. <u>Disclosure of certain information concerning Penicillins, Tetracyclines and Sulfas would not cause substantial competitive harm.</u>

Defendant notes certain information in Document 2 concerning domestic sales of class/route combinations with three or more sponsors has been withheld under Exemption 4

[16] Retrieved at https://online.zoetis.com/us/en/products/publishingimages/drx_bulletin.pdf

despite that disclosure of these amounts would not enable a particular sponsor's 2009 sales volume to be determined. See Defendant's Motion, pgs. 20-21. These class/route combinations are: Penicillins/Injection, for which there were three distinct sponsors; Tetracyclines/Injection, for which there were three distinct sponsors in 2009; Penicillins/Mastitis, for which there were five distinct sponsors in 2009; Sulfas/Medicated Feed, for which there were three distinct sponsors in 2009; Tetracyclines/Medicated Feed, for which there were three distinct sponsors in 2009; Penicillins/Water, for which there were three distinct sponsors in 2009; Sulfas/Water, for which there were six distinct sponsors in 2009; and Tetracyclines/Water, for which there were nine distinct sponsors in 2009.

Defendant does not argue that the information in Document 2 concerning these particular sponsors would cause competitive harm if disclosed. *See* Defendant's Motion, pg. 20-21. Indeed, disclosure of these numbers would not even enable any particular sponsor's 2009 sales volume to be determined. Instead, Defendant argues that disclosure of the information concerning these class/route combinations would enable competitors to ascertain the 2009 sales volume for sponsors of drugs in the Penicillins, Sulfas and Tetracyclines classes having other routes of administration. *See* Defendant's Motion, pg. 21. Therefore, Defendant argues, this information is subject to Exemption 4 even though it would not, in and of itself, cause substantial competitive harm if released. Id. However, this alleged risk would not be presented by disclosure of just two of these three class/route combinations for Penicillins. Nor would this alleged risk be presented if only one of these class/route combinations were disclosed for Sulfas. Likewise, this alleged risk would not be presented by the release of just two of these three class/route combinations for Tetracyclines. In light of this, and because certain numbers in Document 2 have more public health significance than others, Plaintiff has chosen not to contest

Defendant's decision to withhold information in Document 2 concerning domestic sales of the following class/route combinations: Penicillins/Mastitis; Penicillins/Medicated Feed; Sulfas/Oral; Sulfas/Water; Sulfas/Oral/Water; Tetracyclines/Injection; Tetracyclines/Oral; Tetracyclines/Topical. Because Plaintiff no longer seeks disclosure of these numbers in Document 2, disclosure, the risk that disclosure of the remaining data concerning these classes would reveal sales volume information about a particular sponsor has been eliminated\. For this reason, Defendant should be required to disclose information concerning domestic distribution of the following class/route combinations in Document 2: Penicillins/Injection; Penicillins/Water; Sulfas/Medicated Feed; Tetracyclines/Medicated Feed; Tetracyclines/Water.

CONCLUSION

For the foregoing reasons, the Court should deny Defendant's motion for summary judgment, grant plaintiff's motion for summary judgment, and order Defendant to produce the redacted information 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,

/s/ Richard E. Condit

Richard E. Condit
Senior Counsel
Government Accountability Project
DC Bar # 417786
1612 K Street, NW, Suite 1100
Washington, DC 20006
Tel. 202-457-0034 ext. 142
Fax. 202-457-0059
RichardC@whistleblower.org

/s/ Jeffrey S. Gulley

Jeffery S. Gulley
Food & Public Health Counsel
DC Bar # 1013071
1612 K Street, NW, Suite 1100
Washington, DC 20006
Tel. 202-457-0034 ext. 142
Fax. 202-457-0059
JeffG@whistleblower.org