UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

PLAINTIFF'S REPLY IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

Plaintiff Government Accountability Project respectfully submits this reply in support of its Cross-Motion for Summary Judgment.

INTRODUCTION

Plaintiff filed a Freedom of Information Act ("FOIA") request seeking data concerning the 2009 sales volume for antimicrobial animal drugs, aggregated by antimicrobial class and broken down by route of administration. Defendant asserts that a single responsive document ("Document 2") was located, which containins a chart showing the aggregated 2009 sales volume for each class of antimicrobial animal drugs broken down by route of administration. While some of the numbers in Document 2 have been disclosed to Plaintiff, most have been withheld under FOIA Exemptions 3 and 4. As explained in Plaintiff's Memorandum in Opposition to Defendant's Motion for Summary Judgment and in Support of its Cross-Motion for Summary Judgment ("Pl's Mot."), Dkt. No. 9, and herein, Defendant has failed to meet its burden to establish that Exemptions 3 and 4 apply to the withheld information.

In its Memorandum of Points and Authorities in Support of its Motion for Summary Judgment ("Def's Mot."), Dkt. No. 8, Defendant argued that 21 U.S.C. § 360b(l)(3)(E)(i), a provision of ADUFA,

is a FOIA Exemption 3 withholding statute, and that the information concerning 2009 sales of antimicrobial animal drugs redacted in Document 2 was thus properly withheld under FOIA Exemption 3. *See* Def's Mot, at 7-13. As Plaintiff explained in its Motion, 21 U.S.C. § 360b(l)(3)(E)(i) does not qualify as a FOIA Exemption 3 withholding statute. *See* Pl's Mot., at 9-13. Furthermore, as Plaintiff explained, even if it did qualify, it would not apply to much of the information withheld in Document 2. *See Id.*, at 15-18. In Defendant's Reply in Support of its Motion for Summary Judgment and in Opposition to Plaintiff's Cross-Motion for Summary Judgment ("Def's Reply"), Dkt. No. 11, Defendant again argues that 21 U.S.C. § 360b(l)(3)(E)(i) qualifies as an Exemption 3 withholding statute, and that its broad interpretation of that statute's scope is entitled to deference. *See* Def's Reply, at 5-12. As explained previously and herein, 21 U.S.C. § 360b(l)(3)(E)(i) fails to meet the threshold requirement to qualify as an Exemption 3 withholding statute. Rather than broadly prohibiting public disclosure of information, 21 U.S.C. § 360b(l)(3)(E) mandates the publication, by FDA, of annual summary reports concerning antimicrobial animal drug sales, while 21 U.S.C. § 360b(l)(3)(E)(i) merely places limitations the content of those summary reports. Furthermore, as explained previously and herein, Defendant's interpretation of 21 U.S.C. § 360b(l)(3)(E)(i) is unreasonable, overly broad, and is not entitled to deference. Therefore, even if 21 U.S.C. § 360b(l)(3)(E)(i) were an Exemption 3 withholding statute, it would not apply to much of the information in Document 2.

In its Motion, Defendant also argued that the withheld information in Document 2 is subject to FOIA Exemption 4, because its disclosure is likely to cause substantial competitive harm. Specifically, Defendant argued that the remaining information in Document 2, if disclosed, would reveal the 2009 sales volume of individual drugs. Def's Mot., at 15-21. As a result, Defendant argued, competitors could use the information to estimate a sponsor's production capacity, identify other sponsor's customers, estimate sponsors' production costs, determine other sponsors' manufacturing techniques, product strengths, business emphases, and pricing strategies, ascertain which products' sales are

increasing or decreasing, hoard raw materials to increase production costs, imply overuse of competing drugs, and undercut other sponsors' prices. *Id*. In its Motion, Plaintiff explained that because significant changes had occurred in the industry and market for these drugs, the 2009 sales volume lacked any current competitive usefulness, and cannot be used to estimate the current sales volume or production capacity for a particular drug. Pl's Mot., at 24-29. Moreover, as Plaintiff explained, the information concerning 2009 sales volume could not be used to imply overuse, identify customers, estimate production costs, or determine manufacturing techniques, marketing strategies, pricing strategies, product strengths, business emphases, or sales trends. *Id*., at 31-41. Finally, as Plaintiff explained, many of the harms identified by Defendant were unlikely to occur, and a competitor wishing to cause the harms identified by Defendant in its Motion already has access to publicly available information of the sort needed to target customers, imply overuse, hoard raw materials, and undercut prices. *Id*. As Plaintiff explained, their ability to cause these harms would not be enhanced by having access to the 2009 sales volume information in Document 2. *Id*.

In its Reply, Defendant disputes that changes in the antimicrobial animal drug industry have diminished the current competitive significance of the 2009 sales volume information in Document 2. Def's Reply, at 17-21. Defendant supplements the record with multiple new declarations, which it argues establish that the 2009 information in Document 2, despite intervening changes, has nonetheless retained its competitive significance. *Id*. Specifically, Defendant argues that the 2009 information can be used in conjunction with publicly available information about events causing fluctuations to determine which drugs' sales have increased or decreased, and can be used to validate or improve statistical models to accurately estimate and forecast current and future information about the sales volumes, current market sizes, and current production capacities for particular drugs. *Id*. As a result, Defendant argues, the 2009 sales volume information is still likely to cause competitive harm. *Id.*, at 21-25. This dispute is not genuine, however, because as explained previously and herein, the evidence

on record, as supplemented by Defendant's Reply, fails to establish that the 2009 sales volume information in Document 2 can be used to derive competitively useful information or cause substantial competitive harm. For these reasons, the information in Document 2 is not exempt from disclosure under FOIA Exemption 4.

Defendant correctly notes that Plaintiff has withdrawn its objections to the withholding of information in Document 2 concerning the Tetracyclines, Penicillins, and Sulfas classes. *Id.*, at 2. Defendant is incorrect, however, that the information in Document 2 reflecting aggregate sales numbers for classes and routes of administration for which only one drug was sold in 2009 is no longer at issue. *Id.* Defendant is correct that Plaintiff's request only sought aggregate information for each class and route of administration. However, as Defendant well understood at the time it filed its Motion, Plaintiff seeks that information even where the aggregation reflects a single drug's 2009 sales volume, and addressed that information in particular. *See* Def's Mot., *passim*. Defendant's purported confusion about this is disingenuous. Indeed, in its Motion, Plaintiff repeatedly discussed *all* of the numbers withheld in Document 2, and made clear that the only ones not sought were certain numbers concerning Tetracyclines, Penicillins, and Sulfas. *See* Pl's Mot., at 43.

ARGUMENT

Defendant argues that the information withheld in Document 2 is properly withheld under FOIA Exemptions 3 and 4. FOIA Exemption 3 exempts information from mandatory disclosure under FOIA where that information 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 Exemption 4 exempts information from mandatory disclosure "commercial or financial information obtained from a person" that is "privileged or confidential." 5 U.S.C. § 552(b)(4). Where, as here, the information was required to be submitted to

the government, information is considered "confidential" under FOIA Exemption 4 where its disclosure is "likely to cause substantial harm to the competitive position of the person from whom the information was obtained." *National Parks & Conservation Assn. v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974).

I. EXEMPTION 3 DOES NOT APPLY TO THE INFORMATION IN DOCUMENT 2.

Defendant argues that 21 U.S.C. § 360b(l)(3)(E)(i) is a FOIA Exemption 3 withholding statute, and applies to all of the withheld information in Document 2. As explained in Plaintiff's Motion and herein, 21 U.S.C. § 360b(l)(3)(E)(i) is not an Exemption 3 withholding statute. Moreover, even if it were, it would not apply to many of the withheld numbers in Document 2.

A. 21 U.S.C. § 360b(l)(3)(E)(i) is Not an Exemption 3 Withholding Statute.

ADUFA, 21 U.S.C. § 360b(l)(3)(E)(i) provides that "no class with fewer than 3 distinct sponsors of approved applications shall be independently reported" in the FDA's annual summary of information concerning antimicrobial animal drugs sold or distributed during the prior year. Defendant argues that this limitation on the content of the agency's annual summary report qualifies as a FOIA Exemption 3 withholding statute. FOIA Exemption 3 excuses from mandatory disclosure information that is "specifically exempted from disclosure by statute … if that statute" either "requires that the matters be withheld from the public" or "establishes particular criteria for … or refers to particular types of matters to be withheld" from the public. 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).

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. Dept. of Justice*, 816 F.2d 730, 734 (D.C. Cir. 1987). As Plaintiff

explained in its Motion, 21 U.S.C. § 360b(l)(3)(E)(i) fails to meet this threshold requirement. *See* Pl's Mot., at 9-15. Rather than broadly prohibiting disclosure to the public, 21 U.S.C. § 360b(l)(3)(E) imposes a mandatory publication requirement, requiring the Secretary to publish annual summary reports of the previous year's sales, and 21 U.S.C. § 360b(l)(3)(E)(i) merely imposes a limitation on the content of that summary report. The structure of § 360b(l)(3)(E) and Congress' choice of words indicate that the limitation on publication described in § 360b(l)(3)(E)(i) was intended to apply only to the FDA's annual summary report, and was not intended to broadly prohibit disclosure of information in other contexts. 21 U.S.C. § 360b(l)(3)(E) requires the FDA to publish summaries of the data concerning sales of antimicrobial animal drugs that it receives from the drug sponsors each year. *See* 21 U.S.C. § 360b(l)(3)(E). Subsection (i) of 21 U.S.C. § 360b(l)(3)(E) further provides 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). The fact that § 360b(l)(3)(E)(i) is included as a subsection of § 360b(l)(3)(E), which ends with the words "except that," and the fact that both are parts of a single sentence, indicates that § 360b(l)(3)(E)(i) was intended to modify the content of the summary report mandated by § 360b(l)(3)(E). *See Univ. of TX SW Med. Ctr. v. Nassar*, No. 12-484, 570 U.S. __ (2013) (June 24, 2013) ("Just as Congress' choice of words is presumed to be deliberate, so too are its structural choices.") (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, indicates 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). Furthermore, the phrase "the summary data shall be reported" in § 360b(l)(3)(E)(i) makes clear that Congress intended the word "reported" in this subsection to refer to the mandatory annual summary report published FDA.[1] The meaning of words should be informed by their context within a statute,

1 21 U.S.C. § 360b(l)(3)(E)(i) does not use the phrase "publicly reported" as Defendant erroneously claims on page 5 of its Reply.

and are presumed to bear the same meaning where they appear multiple times within the same sentence. *Jerecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961) ("[A] word is known by the company it keeps"); *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.").

As Plaintiff explained in its Motion, had Congress intended to create a broad prohibition on public disclosure sufficient to create an Exemption 3 withholding statute, it certainly knew how. *See* Pl's Mot., at 13-14. Congress has repeatedly demonstrated its ability to craft broad prohibitions on public disclosure of information sufficient to exempt information from disclosure under FOIA Exemption 3. See, *e.g.*, 2 U.S.C. § 437g(a)(12)(A) ("Any notification or investigation made under this section shall not be made public …"); 7 U.S.C. § 136i-l(b) ("in no case may a government agency release data … that would directly or indirectly reveal the identity of individual producers."). Likewise, Congress has demonstrated its ability to explicitly exempt information from disclosure under FOIA Exemption 3. See, *e.g.*, 39 U.S.C. § 39 U.S.C. § 3016(d) ("Any documentary material provided pursuant to any subpoena issued under this section shall be exempt from disclosure under section 552 of title 5, United States Code."). Here, Congress instead crafted the limitation in 21 U.S.C. § 360b(l)(3)(E)(i) narrowly so as to limit only the content of the FDA's annual summary reports. Indeed, it had no need to create a broader prohibition on public disclosure or otherwise exempt the information from disclosure under FOIA, because the very risk that Defendant argues Congress intended to mitigate in § 360b(l)(3)(E)(i), the risk of competitive harm, is adequately mitigated under FOIA by Exemption 4. [2]

Defendant argues that 7 U.S.C. § 136i-l, which was found to qualify as an Exemption 3 withholding statute in *Doe v. Veneman*, 380 F.3d 807 (5th Cir. 2004), is analogous to 21 U.S.C. § 360b(l)(3)(E)(i). *See* Def's Reply, at 6-7. However, these two statutes are significantly different

2 Disclosure in contexts other than FOIA would be prohibited by 18 U.S.C. § 1905, which, while not an Exemption 3 withholding statute, does also prohibit disclosure under FOIA of information subject to Exemption 4. See CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1151-1152 (D.C. Cir. 1987).

structurally and linguistically such that *Veneman* is inapposite. Defendant correctly notes that 7 U.S.C. 136I-l contains a mandatory publication requirement, which requires the Secretary of Agriculture and Administrator of the EPA to "publish annual comprehensive reports concerning agricultural and nonagricultural pesticide use." 7 U.S.C. § 136i-l(f). 7 U.S.C. § 136i-l(f) also contains a provision limiting the publication of certain information. See 7 U.S.C. § 136i-l(b). However, quite unlike 21 U.S.C. § 360b(l)(3)(E)(i), this prohibition appears prior to, and in an entirely different subsection of 7 U.S.C. § 136i-l that does not address the agency's mandatory reporting obligation. Furthermore, unlike § 360b(l)(3)(E)(i), § 136i-l(b) incorporates language indicating intent to broadly prohibit any public disclosure of certain information to the public, and not merely to limit the content of the "annual comprehensive reports" published under 7 U.S.C. § 136i-l(f). 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.") (emphasis added). *Consumer Product Safety Comm. v. GTE Sylvania, Inc.*, 447 U.S. 102 (1980), cited by Defendant in its Reply, does not even concern Exemption 3 and is likewise inapposite. There the Court merely found that the terms "public disclosure" used in Section 6 of the Consumer Products Safety Act encompassed disclosures of information to the public under FOIA. No such broad language indicating intent to regulate all public disclosures was used in § 360b(l)(3)(E)(i). In fact, both of these cases and the statutes they concern demonstrate that, had Congress intended for § 360b(l)(3)(E)(i) to apply broadly to disclosures under FOIA or in other contexts, it knew how to do so.

Defendant again argues that the legislative history of 21 U.S.C. § 360b indicates that Congress intended for the limitation on the FDA's annual summary report described in § 360b(l)(3)(E)(i) to apply broadly to all disclosures of information to the public. *See* Def's Reply, at 7-8. However, the required

intent to prohibit or otherwise exempt information from public disclosure must be expressed explicitly in the text of the statute itself, and may not 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 734. Not one of the cases cited by Plaintiff on page 8 of its Reply has overruled or abrogated this requirement.[3]

B. Even if it Applied, Exemption 3 Would Not Cover Much of the Information.

Even if 21 U.S.C. § 360b(l)(3)(E)(i) were an Exemption 3 withholding statute, it would only exempt from disclosure data concerning those antimicrobial classes for which there were fewer than 3 distinct sponsors of antimicrobial animal drugs sold in 2009.[4] As Plaintiff explained in its Motion, Defendant's more sweeping interpretation of § 360b(l)(3)(E)(i) is unreasonable and overly broad, because it ignores the plain, unambiguous language used therein, and Congress's apparent awareness of the limited meaning of the term "antimicrobial class." *See* Pl's Mot., at 15-18. Additionally, Defendant's interpretation of the scope of § 360b(l)(3)(E)(i) improperly renders § 360b(l)(3)(E)(ii) superfluous. *Id.*

In its Reply, Defendant argues that the limitation on the annual summary report's content imposed by § 360b(l)(3)(E)(i) must logically extend to publication of data concerning classes with three or more sponsors where that data is broken down further to the "more granular level of route of administration." *See* Def's Reply, at 10-11. This is so, Defendant argues, because the same risk presented by the publication of information concerning classes with fewer than three distinct sponsors would also be present where data concerning classes with three or more distinct sponsors is further broken down by container size, strength, dosage form, or route of administration. *Id.*, at 10-12. In fact, however, given that § 360b(l)(3)(E)(i) expressly requires that "the summary data" reported in the

3 In *Essential Information, Inc. v. U.S. Information Agency*, 134 F.3d 1165 (D.C. Cir. 1998), the only decision from this Circuit cited by Defendant, the Court merely noted, after determining that the statute qualified as an Exemption 3 withholding statute, that the statute's legislative history reinforced its decision.

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

FDA's annual summary report "shall be reported by antimicrobial class," it is far more logical to conclude that Congress didn't even contemplate, when drafting that section, the need to regulate publication of summary reports containing data broken down to the "more granular level of route of administration." *See* 21 U.S.C. § 360b(l)(3)(E)(i).

Defendant further argues that 21 U.S.C. § 360b(l)(3)(E)(ii), which excludes from the annual summary report data that would reveal "confidential business information," supports its broad interpretation of 21 U.S.C. § 360b(l0(3)(E)(i) because both sections are intended to prevent the publication of data that may cause competitive harm to a particular sponsor. *See* Def's Reply, at 10-12. As Plaintiff explained previously, however, Defendant's unreasonably broad interpretation of 21 U.S.C. § 360b(l)(3)(E)(i) improperly renders 21 U.S.C. § 360b(l)(3)(E)(ii) superfluous. *See* Pl's Mot., at 17-18. Defendant contends that its interpretation does not render § 360b(l)(3)(E)(ii) superfluous, because under its interpretation, both sections require FDA to redact the same information, *i.e.* information that might cause competitive harm by revealing a particular drug's sales volume to a competitor, with § 360b(l)(3)(E)(ii) establishing "another criterion for withholding" that same information. *See* Defendant's Reply, at 11-12. However, this sort of interpretation, under which one section subsumes the effect of another, is the very sort of superfluous construction that must be avoided. *See Corley v. U.S.*, 556 U.S. 303, 304 (1991) (statutes "should be construed … so that no part will be inoperative or superfluous, void or insignificant") (finding that government's interpretation of 18 U.S.C. § 3501(a) improper where it rendered § 3501(c) without any unique effect).

Finally, Defendant argues that that the of the scope of § 360b(l)(3)(E)(i) advanced by it in this case is entitled to deference. *See* Def's Reply, at 9, FN 4. However, such deference to an agency's interpretation of a statute administered by it is only appropriate where the statute in question is ambiguous, and the agency's interpretation is reasonable. *See Chevron U.S.C., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842-845 (1984). As explained in Plaintiff's Motion, the text

of § 360b(l)(3)(E)(i) is unambiguous, and the interpretation advanced by Defendant in this case is manifestly unreasonable and inconsistent with the statute's plain language. *See* Pl's Mot., at 15-18. Moreover, an agency's interpretation of a statute is not entitled to *Chevron* deference where, as here, the interpretation was not made pursuant to a delegation of rulemaking authority through adjudication, notice and comment rulemaking, or some other comparable adjudicatory exercise of rulemaking authority. *See United States v. Mead Corp.*, 533 U.S. 218, 226-227 (2001). In fact, the interpretation of the scope of § 360b(l)(3)(E)(i) reached by Defendant after notice and comment, which was published in the Federal Register at the end of last month, is quite different from the one advanced by Defendant in this case, and is in fact consistent with Plaintiff's.[5] For these reasons, the broad interpretation of § 360b(l)(3)(E)(i)'s scope advanced by Defendant here is not entitled to deference, and should be rejected. Instead, the Court should, consistent with the plan language of that section and fundamental principles of statutory construction, hold that § 360b(l)(3)(E)(i), if it is found to qualify as an Exemption 3 withholding statute, only applies to data concerning those antimicrobial classes with fewer than three distinct sponsors.

II. EXEMPTION 4 DOES NOT APPLY TO THE INFORMATION IN DOCUMENT 2.

Defendant argues that, despite changes in the market for these drugs since 2009, the data in Document 2 can be used to estimate current market trends, and is therefore likely to cause competitive harm. As explained in Plaintiff's Motion and herein, Defendant has failed to establish that the information in Document 2 can in fact be used to ascertain reliable current information about these drugs. Its disclosure is therefore unlikely to cause substantial competitive harm, and it is therefore not subject to withholding under FOIA Exemption 4.

A. The 2009 Sales Volume Data in Document 2 is Not Competitively Useful.

5 *See* 79 Fed. Reg. 59308, 59309 ("While the 'no class with fewer than 3 distinct sponsors' requirement of section 512(l)(3)(E)(i) of the FD&C Act specifically applies to the summary reporting by antimicrobial drug class, FDA notes that it is also obligated to comply with the more broadly written requirement of section 512(l)(3)(E)(ii) of the FD&C Act that such 'data shall be reported in a manner consistent with protecting … confidential business information.'") (discussing the agency's authority to release annual ADUFA Summary Reports with aggregate sales data broken down by route of administration, indications and dispensing status).

As Plaintiff explained in its Motion, the potential for the disclosure the 2009 sales volume information in Document 2 to cause competitive harm depends on the extent to which that data could be used by competitors to derive reliable current and future information about particular sponsors and market conditions. *See* Pl's Mot., at 24-25. The various drug sponsors are not, after all, competing under past conditions to re-perform past transactions. For this reason, courts have repeatedly recognized that the potential for competitive harm is mitigated by the passage of time where, as here, conditions have changed significantly as time has passed. *See Lee, et al. v. F.D.I.C.*, 923 F.Supp. 451, 455 (S.D.N.Y.) (reversing agency's Exemption 4 determination with respect to two year old financial data 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) (finding substantial competitive harm unlikely 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."); *Teich v. FDA*, 751 F.Supp. 243, 253-254 (D.D.C. 1990) (finding that agency failed to demonstrate the "*current* significance" of the information where the industry had "changed substantially in the intervening years") (emphasis added).

Here, nearly four years have passed since 2009. Significant changes in the market for these drugs have occurred in the intervening years, as reflected in the 2011 ADUFA Summary Report published by the FDA, which shows significant shifts in the sales volume for these drugs across all classes.[6] *See* Pl's Mot., at 23-28. As a result, the 2009 sales volume data in Document 2 cannot be used to derive reliable information about the current sales volume of any particular drug. See *Id.* As Dr. John E. Ikerd, Professor Emeritus in the University of Missouri's Agricultural Economics

6 Defendant argues that these changes have not been significant, citing the opinion of Dr. Bataller, the Director of the Division of Surveillance at the FDA's Center for Veterinary Medicine. Regardless of Dr. Bataller's opinion, however, as explained in Plaintiff's Motion and herein, these changes are significant for purposes of resolving this case in that they have rendered the 2009 sales volume data in Document 2 useless for competitive purposes.

Department succinctly states, "this data will be over four years old by the time it is released," and "in the agricultural industry, in particular, four years ago is ancient history." Decl. of John E. Ikerd, Pls. Ex. 13, ¶ 12. In its Reply, Defendant supplements the record with additional declarations which it argues establish that, despite these changes, the 2009 sales volume data can still be used by competitors to estimate the current sales volume of particular drugs. *See* Def's Reply, at 17-21. In turn, Defendant argues, those estimates can be used to ascertain the current market-size (i.e. demand) and production capacity for these drugs. *See Id.* However, the evidence on record, as supplemented by Defendant's Reply, fails to establish that disclosure of the information in Document 2 can be used to derive current information about the sales volume, demand, or production capacity for any particular drug.

As Plaintiff illustrated on page 26 of its motion, between 2009 and 2011, the most recent year for which data about sales of these drugs has been published, significant changes occurred across all classes of antimicrobial animal drugs. These changes are reflected in the 2011 ADUFA Summary Report, which only lists the aggregate sales for entire classes (or groups of classes) of antimicrobial animal drugs. For most classes, the aggregate change in domestic sales exceeds 30%.[7] The changes in export sales reflected in the 2011 ADUFA Summary Report are even greater, exceeding 97% for Tetracyclines, and exceeding 80% for all other classes combined.[8] To derive a reliable estimate of a particular drug's more recent information using the FDA's ADUFA Summary Reports, in which sales volume information is aggregated by class, a competitor would need to know far more than just the 2009 sales volume for that drug. They would need to know how the aggregate changes in the report

7 Aggregate changes for each reported class or group of classes are shown on page 26 of Plaintiffs Motion. The information therein was derived from the 2009 and 2011 ADUFA Summary Reports published by the FDA (Pls. Ex. 3; Pls. Ex. 4).

8 In his declaration, Dr. Bataller attributes the changes in export sales reflected in the 2011 ADUFA Summary Report to a change in the way export sales are reported by the sponsors. *See* Def's Ex. Q, ¶17. According to Dr. Bataller, the sponsors now only report a small fraction of their export sales to the agency under ADUFA. Id. As a result, Dr. Bataller says, the changes reflected for export sales were "attributable mainly to how the sponsors submitted data." Id. In fact, however, since only a tiny fraction of export sales were reported to the agency for 2010 and 2011, Dr. Bataller has no way of knowing the extent to which export sales have changed since 2009. Moreover, this claim is incredible on its face, as it's unlikely that overseas markets haven't experienced similar fluctuations to those experienced in the domestic market. As Dr. Bataller acknowledges, demand for these drugs is subject to fluctuations in response to environmental conditions like weather events and disease outbreaks, and it is unreasonable to assume that such events don't occur outside of the United States. Id., at ¶16-18.

were allocated among the numerous drugs in each class or group of classes.[9] Because the rates of change reflected in the ADUFA Summary Reports for each class are so significant, and because the number of sponsors in each class is so great, it would be impossible for any competitor to accurately figure out how much the sales volume of any particular drug has changed since 2009. Defendant has presented no evidence that any information is available to the various sponsors that would enable them to determine how the aggregate changes reflected in each year's ADUFA Summary Report were distributed among the various drugs in each class or group of classes such that the change in sales volume for any particular drug could be reliably estimated. Indeed, because information concerning particular drugs' sales volumes is so jealously guarded by each sponsor, the ADUFA Summary Reports published by the FDA contain the only accurate publicly available information about sales of these drugs. For these reasons, the 2009 sales volume data in Document 2 cannot be used to make reliable estimates about the current or even more recent sales volume of any particular drug.

To illustrate the competitive uselessness of the 2009 sales volume sought by Plaintiff, the Macrolides class, which contains relatively few distinct drugs and which experienced a relatively modest change in aggregate domestic sales volume between 2009 and 2011, provides an apt example. In that class, there were 10 distinct drugs sold domestically. Aggregate domestic sales volume for the Macrolides class decreased by approximately 32.385% between 2009 and 2011. *Compare* Pls. Ex. 3 *and* Pls. Ex. 4. This means that the sum total of the rates of change for each of the 10 drugs in the Macrolides class would equal approximately -323.85%.[10] Therefore, even in the unlikely event that all

9 Domestically, 21 different drugs were sold in the Aminoglycosides class, 10 were sold in the Cephalosporins class, 9 were sold in the Ionophores class, 15 were sold in the Lincosamides class, 10 were sold in the Macrolides class, 21 were sold in the Pencillins class, 24 were sold in the Sulfas class, 41 were sold in the Tetracyclines class, and 21 different drugs were sold in the group of classes for which aggregate sales are combined in a single reported total. In the export market, 7 different drugs were sold in the Tetracyclines class, and 26 different drugs were sold in the group of classes for which aggregate sales are combined in a single reported total. *See* Def's Ex. 2 to Def's Ex. A.

10 The aggregate change for each class reflects the mean weighted change for each drug, weighted according to the proportion of the total sales volume for the class made up by each drug's sales volume. In this example, there are 10 drugs, all of which are assumed, for the purpose of this illustration, to have the same 2009 sales volume. Therefore, -32.385%, the mean weighted average, is one-tenth of the sum of the rates of change for each drug., -323.85%. In reality, the rate of change for each drug would be weighted differently according to its proportion of the total sales volume for the entire class.

of the drugs in that class experienced decreases in sales between 2009 and 2011 and had the same sales volume in 2009, to determine the change in sales volume of any particular drug in the Macrolides class during the two intervening years, a competitor would have to accurately allocate -323.85 percentage points among the 10 drugs. Thus, even if all 10 drugs experienced decreased sales during the two years, there's tremendous room for error in any estimate of the change for any particular drug. This potential for inaccuracy is obviously even greater when it is taken into account that sales of some drugs likely increased while others decreased, and that each drug had a different sales volume in 2009. Similarly, the potential for error is compounded as the aggregate change in sales for the class increases, and as the number of distinct drugs within the class increases. Of course, it is especially great for those classes which are grouped together and not independently reported in the FDA's ADUFA Summary Reports.

As illustrated in the foregoing paragraph, because significant changes occurred across all classes of drugs, and because those changes would need to be accurately allocated among the numerous drugs in each class to ascertain any reliable estimate about a drug's 2011 sales volume, the 2009 sales volume cannot be used to ascertain more recent estimates of any particular drug's sales volume. Put another way, trying to ascertain the more recent sales volume of a particular drug using the 2009 data sought by Plaintiff in conjunction with the publicly available information about more recent years contained in the ADUFA Summary Reports published by the FDA would be "tantamount to attempting to solve for x in the equation x + y + z = $3.65 billion without knowing the other variables." *Ctr. for Pub. Integrity v. Dept. of Energy*, 191 F.Supp.2d at 194. It would of course be even less feasible to derive reliable estimates about any particular drug's current sales volume, since data concerning sales in a given year are not reported to the FDA until the following year. Moreover, as Defendant acknowledges, demand for these drugs is volatile, changing in response to unpredictable environmental conditions like weather events and disease outbreaks. *See* Def's Ex. Q, ¶16, 19. Under these

conditions, any estimate by a competitor about a particular drug's current or even recent sales volume based upon the 2009 data in Document 2 would scarcely be any more reliable than a guess. *See* Pl's Mot., at 29.

Again, Defendant has not presented any evidence or information concerning the more recent sales volumes for these drugs, other than the FDA's ADUFA Summary Reports, that a competitor could use to reliably estimate how much the sales volume for any particular drug has changed since 2009. Indeed, because every sponsor keeps information about its own sales confidential, the only accurate information about annual sales volumes for these drugs available to competitors is found in the FDA's annual summary reports, in which the sales volumes reported are aggregated by entire classes or groups of classes. *See* Pls. Ex. 3; Ex. 4. Defendant argues that the 2009 data is still useful for competitive purposes because, according to Dr. Bataller, "many individualized animal drug products saw little change" since 2009. *See* Def's Reply, at 17. However, unlike Dr. Bataller, competing sponsors do not have access to the information about other sponsors' drugs' sales volumes that would enable them to determine which drugs' sales volumes remained static. Novartis claims that, because it was the only manufacturer of Pleuromutilins in 2009, the 2009 data is "still an excellent indicator of size of the tiamulin market." *See* Def's Ex. V, ¶ 8. This claim does not make sense, however, as the fact that Novartis was the only manufacturer of the drugs in 2009 is in no way indicative of whether and to what extent annual sales volume for those drugs has changed. Moreover, the evidence on record shows that the size of the Tiamulin market has likely not remained static since 2009. According to their labeling information, Novartis's Tiamulin products, Denagard and Denagard 10 Medicated Premix, are indicated for the treatment of swine dysentery. *See* Pls. Ex. 14[11]; Pls. Ex. 15[12]. As Dr. Bataller noted, outbreaks of clostridial dermatitis and swine dysentery have caused fluctuations in demand for the drugs used to treat those conditions in the years since 2009. *See* Def's Ex. Q, ¶ 18.

11 Retreived at: http://www.livestock.novartis.com/pdf/denagard2011/DEN110004A_Denagard_Dysentery_Sell_Sheet.pdf

12 Retrieved at: http://livestock.novartis.com/literature_library/Swine/4600000698_MAY09.pdf

BIVI asserts that no significant change in sales volume has occurred for those drugs listed in Document 1 whose sponsor is listed as Boehringer Ingelheim or Fort Dodge. *See* Def's Ex. T, ¶ 6. However, as Document 1 reveals, those sponsors only produced drugs in the following five classes: Macrolides, Cephalosporins, Penicillins, Sulfas and Tetracyclines. *See* Def's Ex. 2 to Def's Ex. A. Three of these classes- Penicillins, Sulfas and Tetracyclines- are no longer sought by Plaintiff. In the Macrolides class, its sole drug has the "Injection" route of administration, the number for which has already been revealed. *Id.* Finally, in the Cephalosporins class, both drugs implicated have the "Mastitis" route of administration. *Id.* So, the only number this would support withholding would be the number for Cephalosporins in the Mastitis route of administration.

Defendant argues that, because variables causing changes in the market for some of these drugs, such as weather events and disease outbreaks, are readily identifiable, "sophisticated industry participants" can readily determine why changes occurred for some of the drug products. *See* Def's Reply, at 18. In turn, Defendant argues, industry participants can discern whether those drugs were likely to have seen sales increases or decreases. *Id.* However, to ascertain the current or even recent sales volume of any particular drug using the 2009 data in Document 2, a sponsor would need to know more than just whether sales of that drug likely increased or decreased. They would need to know the magnitude of the increase or decrease in order to make a reliable estimate of the drug's current or more recent sales volume. Defendant has presented no evidence of available information that would enable competitors to reliably determine the magnitude of the response by the market for any particular drug to any particular event affecting demand for that drug. Many of these drugs are used for multiple purposes.[13] Additionally, as Dr. Bataller acknowledges, numerous drugs are used to treat the same conditions, with overlap occurring even among drugs in different classes. *See* Def's Ex. Q, ¶ 8-11. Moreover, as reflected in the most recent ADUFA Summary Report, significant changes in sales have

13 See, e.g., Pls. Ex. 16; Pls. Ex. 17 (retrieved at: http://www.accessdata.fda.gov/scripts/animaldrugsatfda/index.cfm?gb=1) (last viewed on Oct. 11, 2013)

occurred across all classes of antimicrobial drugs since 2009. Finally, as Zoetis noted in its SEC filings, the net effect on sales of these drugs from disease outbreaks, weather events and other environmental conditions is not as predictable as Dr. Bataller speculates.[14] It's therefore unlikely that any sponsor could reliably estimate how much the sales volume of any particular drug changed in response to any particular event. For these same reasons, it's also implausible that the 2009 sales data in Document 2 could be used by a competitor to make the sort of baseline determinations about why each drug's sales volume was what it was in 2009 that would be required to predict how the market for that drug might have responded to subsequent events.

Defendant contends, quoting Dr. Bataller, that because demand for these drugs responds to events like disease outbreaks, "the individual sales data for each of these years … even if variable, directly conveys important insights into each company's business performance under varying environmental and market conditions." *See* Def's Reply, at 19. However, Dr. Bataller's concerns over the potential outcome of releasing data of the sort reflected in Document 2 for multiple years are irrelevant in this case. *See* Def's Ex. 4 to Def's Ex. A. The data in Document 2 covers the 2009 calendar year as a whole, and only the 2009 calendar year. *Id.* The data in Document 2 does not contain sales volume information for 2010, 2011 or any subsequent years. *Id*. Nor does the information in Document 2 reflect sales volume information broken down by months or other units of time. *Id.* By definition, "trends" and comparisons of a drug's performance under "varying environmental and market conditions" cannot be derived from the single data point about each drug or pair of drugs 2009 sales volume reflected in the redacted portions of Document 2.

14 While Dr. Bataller states that an outbreak of a particular disease or a weather event impacting the supply of animal feed can be expected to drive up sales of drugs used to treat the disease or increase feed efficiency, as Zoetis acknowledges, those events may well have the opposite effect. *See* Pls. Ex. 8, at 20 (noting that livestock producers may instead reduce their herds to control the disease or reduce their operation's need for animal feed, and that while a weather event affecting feed supply might cause a short term increase in sales of certain drugs, it may also cause a decrease in demand over the longer term, as livestock producers reduce their herds). This practice is not a remote, speculative possibility, but is apparently a sufficiently established practice to be discussed in Novartis' labeling materials for its Denagard drugs. *See* Pls. Ex. 14 (noting that farmers facing an outbreak of swine dysentery have three options, their choice of which will impact their demand for antimicrobial drugs and will depend on the economic impact of the disease, extent of the disease, and potential for its spread: 1) eradication through killing infected animals; 2) control with antimicrobial drugs like Denagard,; or 3) treatment with antimicrobial drugs like Denagard).

Defendant argues that the various sponsors use models/trend-lines based on estimates to develop predictions of future market activities. *See* Def's Reply, at 19. The addition of the true 2009 sales volume numbers from Document 2 could, Defendant argues, be used with estimates to make "significantly more" accurate predictions of future market activities. *Id*. Defendant elaborates on this argument on page 24 of its Reply, claiming that market intelligence providers and competing sponsors could use the 2009 sales volume data in Document 2 to validate or improve their current forecasting models, or to make new models. *Id*., at 24. These more accurate models, Defendant argues, could be used to more accurately estimate the current sales volume or market share of a particular drug. *Id*. Defendant does not explain how the 2009 sales volume information in Document 2 could be used to develop forecasts or improve the accuracy of existing predictive models. In any event, this claim, like Defendants other arguments concerning the use of the 2009 sales volume totals in Document 2 to ascertain trends, cannot be true.

Plaintiff does not doubt Defendant's claim that the various sponsors and market research consultants use predictive models to forecast future market activity, including sales volumes for particular drugs. Such models are created by developing an equation, which depicts a trend line when graphed, to "fit" a set of multiple data points. Pls. Ex. 13, ¶ 9. In the case of these drugs' annual sales volumes, because the actual values for each year have been kept confidential by each sponsor, the set of data points used to develop the equation would consist of estimates of the sales volume for each year. As Jeet Uppal explains in his supplementary declaration, these estimates are based upon polling of customers and other publicly available information. *See* Def's Ex. S, ¶ 10. Generally, to develop a statistically reliable predictive model, "several data points—at least a dozen or more" would be need to be used, particularly where, as here, the trend being depicted tends to fluctuate from year to year. Pls. Ex. 13, ¶ 10; *See also* Decl. of Richard A. Levins, Pls. Ex. 18, at ¶ 7 (noting that the years since 2009 have "been one of the least stable times for the agricultural economy" in the past 40 years. The ability

of such a model to accurately predict future values "depends primarily upon the extent to which the slope of the equation constructed from the set of data accurately depicts the rate of change over time (in this case, the increase or decrease in sales volume over the years) and not on its fit with any single data point." Pls. Ex. 13, at ¶ 9. For this reason, and because it is not possible to estimate a trend using a single data point, an accurate model depicting a drug's annual sales over multiple years cannot be developed using only the 2009 sales volume information in Document 2. *Id*., at ¶ 10-11. .Nor can the accuracy of a model of this sort cannot be assessed by comparing the model with a single true value, here the actual 2009 sales volume for a particular drug that would be revealed by disclosure of the information in Document 2. *Id*., at ¶ 11. *See also* Pls. Ex. 18, at ¶ 7-9 (nothing that the value, for purposes of assessing the accuracy of a model, of a single true value for 2009 annual sales would be particularly diminished in light of numerous recent changes to the agricultural industry). Likewise,"the addition of a true value for a single year" would not result in any "statistically significant improvement in the accuracy" of a predictive model of this sort. Pls. Ex. 13, ¶ 11; As a result, the information in Document 2, even where it would reveal the actual 2009 annual sales volume for a particular drug, cannot, as Defendant argues, be used to develop or improve the accuracy of models used to forecast the current or future sales volume of that drug.

Defendant argues that courts have consistently held that sales data are exempt from disclosure under Exemption 4 even when the data are five or more years old. *See* Def's Reply, at 20-21. In support of this argument, Defendant cites three cases, *Braintree Elec. Light Dept. v. Dept. of Energy*, 494 F.Supp. 187 (D.D.C. 1980), *Timken Co. v. U.S. Customs Serv.*, No. 79-1739, 1983 WL 486442 (D.D.C. June 24, 2983) (unpublished opinion), and *Zenith Radio Corp. v. Matsushita Elec. Corp.*, 529 F.Supp. 866 (E.D. Pa. 1981). *Id.* Inasmuch as Defendant intends to argue that the passage of time alone may be insufficient to mitigate the risk of competitive harm presented by the disclosure of information, Defendant's characterization of these cases is correct. However, Defendant's description

of these decisions ignores key distinctions between these cases and those cited by Plaintiff.

For example, in *Braintree Elec.*, the Court found that the 1980 market was so similar to the 1973 and 1974 markets that the older data could easily be adjusted for cost of living and interest rate increases to extrapolate accurate data about the 1980 market. *See Braintree Elec.*, 494 F.Supp., at 291. In *Timken Co.*, the plaintiff sought a broad swath of detailed comprehensive information, including hundreds of documents, covering five years. *Timken Co.*, at *2. In *Zenith Radio Corp.*, the court addressed a motion seeking the wholesale declassification of "millions of pages of documents containing detailed technical and commercial information exposing the very heart of [plaintiff's] business operations," including "production and sales plans and techniques; marketing, pricing, and advertising plans and philosophy; customer information, long term plans, product development patters; and other vital competitive information." *Zenith Radio Corp.*, at 885. Moreover, the court simply concluded, after acknowledging case law noting that the risk of competitive harm may be mitigated over time, that "wholesale declassification" of so many millions of pages of documents "cannot meaningfully be attained unless the necessary determinations can be made by some sweeping rule of thumb, e.g., documents over "x" years of age are conclusively ineligible for continued protection." *Id.*, at 891-893. Put another way, the court merely rejected a bright line rule that information becomes stale for competitive purposes simply because a certain amount of time has passed. In contrast, as explained on page 12, *supra*, this Court has consistently held that the risk of competitive harm dissipates over time where, as here, significant changes occur in the intervening years.

B. Disclosure of the 2009 Sales Data in Document 2 is Not Likely to Cause Substantial Competitive Harm.

As explained in Section II.A. above, the information in Document 2 concerning the 2009 sales volume of particular drugs and groups of drugs cannot be used to derive reliable estimates of the current sales volume for any particular drug. For the same reasons, the 2009 sales volume information

in Document 2 cannot be used to derive reliable estimates of the current market share or sponsor's current production capacity for any particular drug.[15] As a result, public disclosure of the 2009 sales volume data in Document 2 is unlikely to cause substantial competitive harm. In fact, given that operating decisions in this industry are already fraught with risk[16], it's unlikely that any sponsor would base any decisions on the outdated information or any unreliable extrapolations they might attempt to derive from it. Instead, a sponsor is far more likely to base any operating decisions on current market intelligence reports derived from end-user data and other more current publicly available information.

Defendant argues that "knowing a sponsor's production capacity and limitations would allow a competitor to "adjust either their price and or volume of production," which Defendant argues would "either force the sponsor to lower its price or decrease its production volume and drive up manufacturing costs." *See* Def's Reply, at 22. If a competitor knows a sponsor's production capacity, Defendant argues, and knows that the sponsor is operating at or near capacity, the competitor "can be assured that additional sales volumes will not be sought" and can "increase prices for additional units as demand increases." *Id*. However, as Plaintiff explained in its Motion, whether a competitor can lower its own price depends on whether its own production costs allow it to do so while continuing to profit. *See* Pl's Mot., at 33. Similarly, whether a company can increase its own production depends on its own production capacity, and not on its knowledge of other sponsors' production capacity. Moreover, Defendant fails to explain how a sponsor would be harmed by a competitor's ability to profit from sales which that sponsor lacked the capacity to fulfill anyway. Finally, the 2009 sales volume information in Document 2 will not enable a competitor to determine or reliably estimate a sponsor's

15 Defendant has never explained how the sales volume for a particular drug in a given year could be used to estimate the sponsor's production capacity for that drug, or the market-size (i.e. demand) for that drug. Unless it is assumed that all demand for a particular drug was met in 2009, and that the manufacturer produced and sold every drug it had the capacity to produce, then the 2009 sales volume for that drug in no way reflects its market-size and production capacity. Defendant has not established that either assumption is warranted. Moreover, to the extent the 2009 sales volume for any particular drug accurately reflected the drug's production capacity or market-size, those numbers have apparently changed, as the 2011 ADUFA Summary Report reflects. Indeed, it would be naïve to assume that a sponsor retained the same production capacity (facilities, equipment, labor, etc.) for a particular drug in the face of a significant increase or decrease in sales of that drug.

16 See Pls. Ex. 8, at 19-27 (listing various significant operational risks in the animal drug industry).

current production capacity for any particular drug.

In its Motion, Defendant argued that the 2009 sales volume data in Document 2 would enable competitors to identify and target a sponsor's customers for particular drugs. *See* Def's Mot., at 16. As Plaintiff explained in its Motion, the 2009 sales volume information in Document 2 would not enhance the ability of a competitor to identify a drug's customers beyond publicly available information about the drug's target animals and indications. *See* Pl's Mot., at 32. In its Reply, Defendant instead contends that "the release of the sales data would allow a competitor to determine which products and customers" are "worthwhile to target." *See* Def's Reply, at 22. For example, Defendant argues, sales data "would provide … competitors with insight into how much money they should invest in specific areas" to compete with another sponsor, and use the information to determine whether the market share of another sponsor's drug is increasing relative to its own such that aggressive marketing steps might be advantageous. *Id*. Again, however, neither scenario is likely to result from the disclosure of the information in Document 2, since, as explained above, the *current* sales volume or demand for a particular drug can't be determined using the 2009 sales volume data in Document 2. Similarly, just as the current sales volume for a particular drug cannot be determined, relative rates of sales volume growth among different drugs can't be identified based on the 2009 sales volume data in Document 2, which merely reflects the total 2009 annual sales volume for each drug or group of drugs.

Defendant further argues that sponsors could use the sales volume information to determine which animal drug products are most profitable, identify products to replicate, and evaluate the value of adding a competing product to their own portfolio. *Id.* at 22-23. While the information in Document 2 might reveal whether replicating a particular drug or otherwise targeting a particular drug would have been worthwhile in 2009, it would not be useful for competitors today. As explained above, these drugs' sales volumes have shifted significantly in the years since 2009, and reliable estimates of any

particular drug's *current* annual sales volume cannot be derived using the 2009 information in Document 2.

In its Motion, Defendant argued that the release of the 2009 sales volume information in Document 2 would enable competitors to undercut other sponsors' prices. *See* Def's Mot., at 16. As Plaintiff pointed out in its Motion, however, pricing information in this industry is already publicly available, and all a competitor needs to undercut another sponsor's price. *See* Pl's Mot., at 33. In its Reply, Defendant argues that knowledge of a sponsor's sales volume will increase the likelihood that a competitor will lower its price, because it can use the sales volume information to more accurately demand for the product, and hence make more accurate calculations concerning whether the added revenue from additional sales will offset the lost revenue due to the lower price. *See* Def's Reply, at 23-24. However, the information in Document 2 cannot be used to assess *current* demand for any particular drug. In turn, it cannot be used to make reliable estimates about the number of additional units it can expect to sell by decreasing its per-unit price.

In its Motion, Defendant argued that the sales volume information in 2009 could enable competitors to estimate or undercut bids. *See* Def's Mot., at 17. In its Motion, Plaintiff noted that while procurement through confidential bids is the norm in some contexts, there was no evidence that an analogous procurement process was used in the antimicrobial animal drug industry. *See* Pl's Mot., at 34. In its Reply, Defendant argues that in this industry, some procurement is in fact carried out through an analogous bidding process whereby sponsors submit confidential bids to potential customers. *See* Def's Reply, at 24, FN 13. However, the prices charged by sponsors to most customers for particular drugs is already publicly available, and Defendant has again failed to demonstrate how the 2009 sales volume information could possibly be used to better ascertain a sponsor's "pricing capability." As Plaintiff explained previously, pricing capability depends largely on production cost, which in turn depends on a variety of variables, including labor costs, equipment costs, raw materials

costs, overhead costs (i.e. facilities), etc. *See* Pl's Mot., at 33. Indeed, "the Courts of this Circuit have viewed such arguments with skepticism, generally requiring agencies to disclose information under Exemption 4's competitive harm prong unless they are able to demonstrate that the release of the information would be of substantial assistance to competitors in estimating a bidder's future bids." *Ctr. for Pub. Integrity v. Dept. of Energy*, 191 F.Supp.2d, at 194 (rejecting agency's argument that disclosure of records concerning previous years would enable competitors to estimate and undercut future bids) (citing *Gulf & Westaern Indus., Inc. v. U.S.*, 615 F.2d 527, 530 (D.C. Cir. 1979). Moreover, given the significant changes in the market for these drugs, which Defendant has acknowledged is subject to ongoing fluctuation, a competitor "would therefore be naïve to assume that" any sponsor's "business strategies and valuation methodologies" have remained constant "over time in the face of changing market conditions. *Id.*, at 195.

Finally, Defendant argues that its judgment as to the likelihood of competitive harm resulting from disclosure of the information in Document 2 is entitled to deference. *See* Def's Reply, at 25, FN 14. In support of this argument, Defendant cites *United Technologies Corp. v. U.S. Dept. of Defense*, 601 F.3d 557, 563 (D.C. Cir. 2010). *Id.* However, Defendant fails to recognize that *United Tech* is distinguishable because it is a reverse-FOIA case, and in such cases the standard of review of the agency's decision to release records is "arbitrary and capricious." *See United Tech,* 601 F.3d 557, 559 (D.C. Cir. 2010) ("When an agency determines, pursuant to a FOIA request, to disclose information gathered from a non-governmental source, that source may contest the disclosure as arbitrary and capricious or not in accordance with law under the Administrative Procedure Act."). To the contrary, where a party seeks to enjoin an agency from wrongfully withholding records under FOIA, the agency bears the burden of establishing that the claimed exemption applies, and "the court shall determine the matter de novo." 5 U.S.C. § 552(a)(4)(B) . Deference is therefore not appropriate in the instant case.

CONCLUSION

As explained in Plaintiff's Motion and herein, the information in Document 2 is not subject to withholding under FOIA Exemption 3. Likewise, Defendant has failed to establish that the information is subject to withholding under FOIA Exemption 4. Accordingly, Plaintiff respectfully requests that this Court deny Defendant's Motion for Summary Judgment and grant Plaintiff's Cross-Motion for Summary Judgment.

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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/ Jeffery 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