

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

**GOVERNMENT ACCOUNTABILITY PROJECT** )

**Plaintiff,** )

**v.** )

**U.S. FOOD AND DRUG ADMINISTRATION** )

**Civ. No. 1:12-CV-01954 (KBJ)**

**Defendant,** )

**and** )

**ANIMAL HEALTH INSTITUTE,** )

**Intervenor-Defendant.** )

**PLAINTIFF’S STATEMENT OF MATERIAL FACTS  
AS TO WHICH THERE IS NO GENUINE DISPUTE**

Pursuant to Local Rule 7(h), Plaintiff, Government Accountability Project, submits this statement of material facts as to which there is no genuine dispute. The facts discussed herein are based upon Plaintiff’s experts’ declarations and exhibits concerning the Freedom of Information Act (“FOIA”) request submitted by Plaintiff, and the redacted information in the responsive document identified by Defendant FDA as (“Document 2”).

1. Plaintiff has sued FDA under the Freedom of Information Act, seeking the disclosure of information concerning the 2009 sales volume of various antimicrobial drugs. *See* Compl. ¶ 1.

2. By letter dated February 10, 2011, Plaintiff requested, under FOIA:

(1) printed copies of all educational and outreach materials that FDA has prepared in order to inform and assist antimicrobial drug sponsors in fulfilling their duty to report the amount of antimicrobial active ingredient in their drugs that have been sold or distributed for use in food-producing animals pursuant to Sec 105 of the

Animal Drug User Fee Amendments of 2008; (2) FDA's data for use of antimicrobial drugs in food-producing animals in 2009 as broken down by container size, strength, and dosage form; and (3) FDA's data for use of antimicrobial drugs in food-producing animals in 2009 as broken down by class of animal.

FDA Ex. A ¶ 5.

3. FDA responded to the first part of Plaintiff's FOIA request on May 4, 2011, and FDA denied the remaining parts of the Plaintiff's request, citing Exemption 4 as the basis for its decision. FDA Ex. A ¶ 6-7.

4. Plaintiff subsequently modified its FOIA request with respect to the second and third parts of its request, to seek data collected under 21 U.S.C. § 360(b)(1)(3) containing the amount of antimicrobial drugs sold for use in food producing animals in 2009 aggregated by class, and broken down by container size, strength, dosage form, and class of animal, for each antimicrobial class. FDA Ex. A ¶ 8.

5. FDA conducted a search based on Plaintiff's request with respect to the second and third parts of its request and located two documents ("Document 1" and "Document 2"), at least one of which, Document 2, was partially responsive to Plaintiff's modified request. FDA Ex. A ¶ 9.

6. FDA produced Document 1 and Document 2 with redactions. FDA Ex. A ¶ 9-11.

7. Plaintiff does not challenge the scope or adequacy of FDA's search. *See* Joint Status Report, EFC No. 5, ¶ 1.

8. The information redacted in Document 2 was obtained from sponsors of new animal drug applications. These sponsors are corporations. FDA Ex. A ¶ 28-29.

9. The information redacted in Document 2 is sales data that is commercial or financial information. FDA Ex. A ¶ 30.

10. The information in Document 2 reflects sales volume information concerning antimicrobial animal drug sponsor's sales during the 2009 calendar year. FDA Ex. 3.

11. The total amounts of antimicrobial animal drugs in each class in 2011 and 2012 differ substantially from the amounts sold in 2009. FDA Ex. 4.

12. Plaintiff has designated Michael J. Blackwell, D.V.M., M.P.H. as an expert witness in this matter. A Declaration of Michael J. Blackwell, D.V.M., M.P.H. was completed by the expert on February 19, 2015. *See* Blackwell Decl. (P. Ex. 1).

13. The use of antimicrobial drugs in humans and food animal promote the development of antimicrobial resistance. P. Ex. 1 ¶ 9.

14. Antimicrobials are administered to food animals for purposes like growth promotion and to increase weight gain, and to prevent animal diseases. P. Ex. 1 ¶ 9.

15. Antimicrobials are administered to large groups of animals typically via feed or water for long durations and at low doses. This manner of use is especially effective at increasing selective pressure for antimicrobial-resistant bacteria and thereby promoting the evolution of antimicrobial resistance in bacterial populations. P. Ex. 1 ¶ 9.

16. In the United States, comprehensive data on food-animal use are not collected which makes it difficult to analyze and explain patterns of antimicrobial resistance, as these patterns are shaped largely by antimicrobial use. P. Ex. 1 ¶ 10.

17. The best indicators of antimicrobial use are antimicrobial sales data reported by animal drug sponsors under Animal Drug User Fee Act ("ADUFA"). P. Ex. 1 ¶ 11.

18. FDA does not release the majority of the data sponsors are required to submit, and only publishes annual summaries that contain broad aggregation of reported data. P. Ex. 1 ¶ 11.

19. In the FDA's 2009 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals ("2009 Summary Report"), the FDA states that because of confidentiality constraints, export sales and distribution date for antimicrobials approved for use in food-producing animals cannot be further reported. *See* 2009 Summary Report (P. Ex. 3, ¶ VI).

20. Plaintiff has designated another expert witness, John E. Ikerd, Ph.D. The Declaration of John E. Ikerd, Ph.D. was completed by the expert on February 19, 2015. *See* Ikerd Decl. (P. Ex. 5).

21. Sponsors of the antimicrobial animal drugs do not publicly disclose information about the sales volumes of these drugs and several of the individual drugs sponsors have claimed that the public disclosure of this information would likely cause harm to their ability to compete in the animal drug market. P. Ex. 5 ¶ 7.

22. As sponsors use models to make predictions concerning future sales of individual drugs and as sponsors do not publicly disclose information concerning the annual sales volume of drugs in their portfolios, these models are based upon estimates derived from polling of customers and end-users and other publicly available information. P. Ex. 5 ¶ 8.

23. A model's ability to accurately predict future values depends primarily upon the extent to which the coefficients of the equation constructed from the set of data accurately depict changes in sales over time, in this case, the increase or decrease in sales volumes from year to year. P. Ex. 5 ¶ 9.

24. It is not possible to estimate coefficients of this sort using a single data point, and to develop a model of this sort that would have any degree of statistical reliability, you would

need at least a dozen or more data points as economic trends tend to fluctuate year to year. P. Ex. 5 ¶ 11.

25. As multiple data points are required to detect any trend, the accuracy of a model of this sort cannot be significantly improved by comparison of a single estimate with a single true value, whether the single true value was the result of a random occurrence, unlikely to reoccur in the future, or was a reflection of more normal market conditions. P. Ex. 5 ¶ 12.

26. For the reasons listed above, learning the aggregate sales volume for a particular drug in 2009 won't enable a competitor to discern how that drug performs under varying market conditions, or how the drug's sales respond to particular events. P. Ex. 5 ¶ 13.

27. Another expert witness designated by the Plaintiff is, Richard A. Levins, Ph.D. The Declaration of Richard A. Levins, Ph.D. was completed by the expert on February 20, 2015. *See Levins Decl.* (P. Ex. 6).

28. There is no way to develop a model or trend based solely on the 2009 sales data. P. Ex. 6 ¶ 7.

29. The period during which the inferences are being made must be relatively stable. A number of major shocks have impacted the livestock and poultry industries since 2009 to include the general economic crisis during the years since 2009, which affected consumer demand for livestock and poultry products as well as availability of farm credit, and increased uncertainty in all business decisions. P. Ex. 1 ¶ 8 and 9.

30. An extensive drought resulted in record-high feed prices and, in turn, significantly reduced the number of animals being raised and therefore the number of animals that might receive antimicrobials or other inputs and forced modifications to animal production practices. P. Ex. 5 ¶ 9.

31. Models that reflect a high degree of accuracy in “explaining” actual past occurrences rarely are accurate in “forecasting” future occurrences. It’s virtually impossible to anticipate the impacts of an uncommon event like a severe drought or a major disease outbreak. P. Ex. 5 ¶ 15.

32. The shocks mentioned are difficult to incorporate into a forecasting model and the 2009 sales data would not be useful in validating a model in 2015 and subsequent years. Changes in industry since 2009 have diminished sharply the value any possible accurate prediction for 2009. P. Ex. 6 ¶ 10.

33. Even where constructed using a robust set of accurate data points, the predictive accuracy of any model diminished rapidly as the forecast moves further into the future beyond the last known value. The information about 2009 sales would not enable any of these companies to produce an estimate of current sales that would be any more reliable or useful than an intuitive estimate based on in-house data and years of experience working in the industry. P. Ex. 5 ¶ 16.

34. At least one sponsor has claimed that disclosure of the redacted information in the 2009 Summary Report could enable a competitor to encourage the sponsor’s customers to switch to one of the competitor’s products by implying that the sponsor’s product is being overused. P. Ex. 1 ¶ 17.

35. Over-use of an antimicrobial will, over time, promote the development of antimicrobial resistance in bacteria; the development of antimicrobial resistant will reduce the efficacy of the over-used antimicrobial. P. Ex. 1 ¶ 18.

36. The development of antimicrobial resistance is driven by local patterns of antimicrobial use. P. Ex. 1 ¶ 19.

37. No sales data that are reported under ADUFA refer to particular geographic locations where antimicrobials are purchased or used. Therefore, it is impossible to use ADUFA sales data to determine antimicrobial use in particular regions, states, or counties, let alone particular herds of animals. P. Ex. 1 ¶ 20.

38. Different species of food animals are produced for different markets and in different regions of the country with different disease ecologies, resulting in a high degree of variability in antimicrobial use among sponsors' clients. P. Ex. 1 ¶ 20.

39. At least one declarant suggested that while sales of these drugs have fluctuated since 2009, those fluctuations are often due to disease outbreaks to derive more current estimate of drug sales from the 2009 data. P. Ex. 1 ¶ 21.

40. There are many approaches as to how a veterinarian may treat the sick animals including segregating the sick animals, providing a low or high dosage of an antimicrobial, or a combination of the three. The approach will be based upon the particular circumstances, and the amount of a given drug used will vary depending on the severity of the outbreak and the approach used to treat it. P. Ex. 1 ¶ 23.

41. While it is reasonable to expect that an outbreak of a particular disease would cause a spike in sales of drugs used to treat that disease, information about disease outbreaks could not be used to derive useful estimates of current sales volume from the 2009 data. P. Ex. 1 ¶ 24.

42. Therefore, as there are multiple variables in creating a forecasting model, public disclosure of the redacted information of the 2009 Summary Report is highly unlikely to cause substantial competitive harm. P. Ex. 1, P. Ex. 5, and P. Ex. 6.

Dated: April 2, 2015

Respectfully Submitted,

*/s/ Richard E. Condit*

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