

**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)
U.S. DEPARTMENT OF HEALTH AND)
HUMAN SERVICES,)**

Defendant.)

DECLARATION OF JOHN E. IKERD, Ph.D.

I, John E. Ikerd, Ph.D., declare as follows:

1. I am legally competent to make this declaration.

2. I hold a Ph.D. in Agricultural Economics from the University of Missouri, where I hold the rank of Emeritus Professor in the University's Agricultural and Applied Economics Department. I served as the Coordinator of Sustainable Agriculture Research and Education Programs at the University from 1995 to 2000. From 1993 to 1995, I served as the Liaison to States for the United States Department of Agriculture's Sustainable Agriculture Research and Education Program. Prior to that, I held the rank of Professor and served as the head of the Department of Extension Agriculture Economics at the University of Georgia from 1984 to 1988. From 1976 to 1984, I held the rank of Professor and Extension Economist in the Department of Agricultural Economics at Oklahoma State University and Associate Professor at North Carolina State University.

3. I have written and published numerous articles concerning agricultural science and sustainable agriculture in various academic and professional journals.

4. A primary focus of my 15 years of research and extension work as a livestock marketing specialist was to develop and use statistical models to forecast livestock prices and other economic phenomena. I published several journal articles and professional papers based on statistical analysis of time series data.

5. I submit this declaration in support of the Government Accountability Project's Motion for Summary Judgment.

6. I understand that the Government Accountability Project has sued the Food and Drug Administration under the Freedom of Information Act, seeking the disclosure of information concerning the 2009 sales volume of various antimicrobial animal drugs.

7. I understand that sponsors of these drugs do not publicly disclose information about the sales volume of these drugs, and that several of the individual drug sponsors have claimed that the public disclosure of this information would likely cause substantial harm to their ability to compete in the animal drug market. I further understand that publicly available information concerning sales in more recent years indicates that the sales volume for many of these drugs has fluctuated during the five years since 2009.

8. I understand that these sponsors use models to make predictions concerning future sales of individual drugs. I understand that because 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.

9. I understand that the disclosure of the information sought by the Government Accountability Project may reveal the true 2009 total sales volume for certain categories of drugs manufactured by these sponsors, and that some sponsors have claimed that these true values could be used to verify the accuracy of their existing models, or create new models to more accurately forecast a drug's sales volume in more recent and future years. I believe that these claims overstate the potential significance and usefulness of the 2009 sales volume data sought by the Government Accountability Project.

10. Models of the sort described by these sponsors are created by constructing an equation to "fit" multiple data points. Here, those points would be estimates of a drug's sales volume during recent years. 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 volume from year to year).

11. It is not possible to estimate coefficients of this sort using a single data point. You must have at least two data points (in this case, the annual sales volume for at least two years) to detect any sort of trend that may or may not extend into the future. In general, to develop a model of this sort that would have any degree of statistical reliability, you would need several data points—at least a dozen or more—as economic trends tend to fluctuate a good bit from year to year. Even then, market conditions are continually changing over time.

12. Because 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. There is no way of knowing 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. Nor would the addition of the true value from a single year cause any statistically significant improvement in the accuracy of such a model.

13. For the same reason, 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.

14. To estimate the effect of a particular event or market condition on a particular drug's sales, you need at least two data points: one providing an observation for one set of market conditions and another providing an observation for a different set of conditions. In an evolving and complex market where sales are affected by numerous factors, you really need a time series of several data points providing multiple observations to get a reliable and useful idea of how any particular factor affects sales, and even such estimates are unreliable as new causal factors are continually affecting real-world markets.

15. Even with a large set of accurate data to work with, it's quite difficult to predict future events, such as demand for a specific drug, with any useful degree of accuracy. 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.

16. Additionally, even where constructed using a robust set of accurate data points, the predictive accuracy of any model diminishes rapidly as the forecast moves further into the future beyond the last known value. I understand that the data requested is now over five years old. In today's business world, and in the agricultural industry in particular, five years ago is ancient history. Given their access to estimates derived from sophisticated market research and in-house information and expertise, I don't believe that the information about 2009 sales would

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 this industry. Nor do I believe that any of these companies, all of whom have a lot riding on their decisions, would change their behavior based on additional information about 2009 sales.

17. I base this opinion on 15 years of experience as a livestock marketing specialist using statistical models to forecast livestock prices. Seven years of this time was spent working with a team of other price forecasters, using large sets of historical and current data collected by the USDA. Despite all of our best efforts, our models had a standard deviation of around 5% to 7% for forecasts just three months in advance. For forecasts beyond six months in advance, our estimates plus or minus one standard deviation of our models' forecasts included the possible outcomes of striking it rich or going broke.

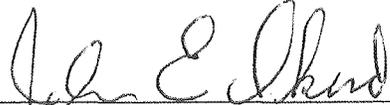
18. I understand that some sponsors have expressed concern that revealing the 2009 sales volume of these drugs could enable competitors to estimate the sponsor's production capacity, and in turn estimate their production costs. Again, I believe that these claims greatly exaggerate the significance and usefulness of this information.

19. While sales and production capacity are related to the extent that a sponsor can't very well sell more drugs than it is able to produce, it would be naïve to assume that a drug's annual sales, which is largely a function of consumer demand for the drug, is identical to the manufacturer's production capacity. Similarly, the production cost of a good depends on a number of variables other than production capacity and output.

20. Likewise, it would be naïve to assume that manufacturers have not adjusted their production capacity as annual sales have risen or fell.

21. Again, given their access to estimates derived from sophisticated market research and in-house information and expertise, and the amount of revenue at stake, I think it's very unlikely that these companies would change their behavior based on such assumptions.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.



John E. Ikerd, Ph.D.
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Executed on February 19, 2015 in Fairfield, IA.