

Dr. Papich has been asked to participate in official matters on the microbial food safety of an antimicrobial drug application submitted by Intervet and currently under review for use in food-producing animals in accordance with the Center for Veterinary Medicine's Guidance for Industry 152. At its September 25, 2006, meeting, the VMAC will be asked to advise FDA as to whether the Agency's assessment of the information and strategies for managing any potential microbial food safety risks are appropriate.

The function of the Veterinary Medicine Advisory Committee (VMAC) is to review and evaluate available data concerning the safety and effectiveness of marketed and investigational animal drug products and make appropriate recommendations to the Commissioner of the Food and Drug Administration (FDA).

Dr. Papich has advised the Food and Drug Administration (FDA) that he has financial interests that could potentially be affected by his participation in the matters described above. Dr. Papich serves as a consultant to [REDACTED] to [REDACTED]. The consulting topic is related to the issue at hand and [REDACTED] have competing products on the market for [REDACTED].

Dr. Papich also serves as a consultant with Intervet on the topic of [REDACTED]. According to Dr. Papich, although the consulting topic is unrelated to the meeting topic, Intervet is the sponsor of the meeting topic.

Dr. Papich serves as the principal investigator for a grant sponsored by [REDACTED]. The grant is to his employer, North Carolina State University. The topic of the grant is a competing product and the sponsor is a competing firm.

Dr. Papich reported receiving approximately [REDACTED] in royalties for a book published that relates to veterinary drugs, including [REDACTED]. Dr. Papich has a 2nd edition pending on the same topic. The publisher, [REDACTED] will continue to pay Dr. Papich royalties on the book. In addition, Dr. Papich has written a textbook, to be published by [REDACTED] publishing, on all aspects of veterinary pharmacology. The textbook will include [REDACTED]. Some of the topics in the book are related to competing products and indications of the upcoming Committee meeting. Dr. Papich has received no remuneration to date, the book is expected to publish in 2007.

Finally, Dr. Papich serves on the speakers' bureau for [redacted] [redacted] regarding antimicrobial use in animals. He receives moderate fees for his role. [redacted] are competing firms.

As a member of the Veterinary Medicine Advisory Committee, Dr. Papich potentially could become involved in matters that affect him or any other person whose interests are imputed to him under Title 18 U.S.C. § 208. Under U.S.C. § 208, he is prohibited from participating in such matters. However, as noted above, you have the authority under 18 U.S.C. § 208(b)(3) to grant a waiver permitting Dr. Papich to participate in such matters as you deem appropriate.

For the following reasons, I believe that it would be appropriate for you to grant Dr. Mark G. Papich a limited waiver that would allow him to participate in the committee's discussions without voting.

First, with regards to Dr. Papich's consulting for [redacted] [redacted] on [redacted] it is important to consider that although these companies manufacture a competing product, Dr. Papich's compensation is less than [redacted] per source.

Second, it is not clear that any current or future financial support from [redacted] to Dr. Papich would be directly and predictably affected by his participation in the issue at hand.

Third, there are more than 25 competing products on the market for [redacted] [redacted]

Fourth, Dr. Papich will be participating solely in an advisory capacity in which appropriate disclosure will be made of his interests. The FDA is not bound by the discussions and recommendations of the advisory committee or any votes taken and may take into account Dr. Papich's financial interests in assessing the advice he renders. In addition, any conflict or appearance of a conflict will be mitigated further by the fact that FDA has decided to limit Dr. Papich's participation. Under the terms of this limited waiver, Dr. Papich will be permitted to participate in the committee's discussions concerning official matters on the microbial food safety of an antimicrobial drug application submitted by Intervet and currently under review for use in food-producing animals in accordance with the Center for Veterinary Medicine's Guidance for Industry 152 but will be excluded from voting.

Moreover, the Agency has found it difficult to obtain the services of a qualified veterinarian who does not have similar or even worse, conflicts of interest. Given the large number of competing products and their sponsors, most qualified veterinarians have or have had involvement with Intravet, the competing products, and/or their sponsors. Dr. Papich is the only veterinary clinical pharmacologist participating in this meeting.

Further, the Federal Advisory Committee Act requires that committee memberships be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee. Also, the committee's intended purpose would be significantly impaired if the Agency could not call upon experts who have become eminent in their fields, notwithstanding the financial interests and affiliations they may have acquired as a result of their demonstrated abilities.

Mark G. Papich, D.V.M., M.S., Professor of Clinical Pharmacology, North Carolina State University, is a highly respected veterinarian whose expertise lies within the pharmacological framework of drug therapy. He is considered an articulate expert, whose opinions and recommendations are reflected in current scientific literature and post graduate texts. His concepts and views are based on the latest scientific technologies and information which address the issues and controversies surrounding the veterinary use of antimicrobial drug products.

Dr. Papich can deftly articulate real and theoretical implications for the potential for the development of antimicrobial resistance among bacteria of human health concern when using antimicrobial drugs in food producing animals. His science-based opinions on veterinary physiology and clinical pharmacology reflect his understanding of the current state of knowledge in pharmacokinetics/pharmacodynamics which is critical for his role on the Veterinary Medicine Advisory Committee. In particular, Dr. Papich will be able to synthesize the scientific issues and speak to the committee regarding the potential for the subject antimicrobial drug, [redacted] to promote antimicrobial resistance among bacteria of human health concern that might be in or on [redacted]

Dr. Papich's research and personal expertise on looking at the absorption, distribution, metabolism and excretion of drugs, including antimicrobial drugs, will allow him to address finer aspects of the specific interactions of [redacted] with the bacteria of concern. His numerous contributions to the literature in this area, as well as his outstanding credentials as a full professor and esteemed member of numerous committees, support his critical role in the participation and discussion of the use of [redacted]

