United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

February 6, 2008

Via Electronic Transmission

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Andrew C. von Eschenbach M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Leavitt and Commissioner von Eschenbach:

As a senior member of the United States Senate and as Ranking Member of the Committee on Finance (Committee), it is my duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities at the Food and Drug Administration (FDA/Agency), a part of the Department of Health and Human Services (HHS). Previously, I wrote to Dr. von Eshenbach and his predecessor, Dr. Lester Crawford, regarding troubling allegations that a pharmaceutical company attempted to discredit the findings of Dr. Victoria Hampshire, an Agency employee and commissioned officer in the Public Health Service (PHS).

This Letter is based upon a comprehensive review of thousands of pages of documents obtained by my Committee staff. Portions of these documents were received by the Committee in response to letter requests to FDA, Wyeth Pharmaceuticals (Wyeth), its subsidiary division Fort Dodge Animal Health (FDAH), and Germinder and Associates, Inc. (GAI)—a public relations firm.[1] Wyeth hired GAI to handle public relations regarding its canine drug ProHeart 6. ProHeart 6 is a Wyeth Pharmaceuticals product designed to prevent canine heartworm and to treat both the larval and adult stages of the canine hookworm.[2] Additionally, this Letter contains information obtained by my Committee staff through interviews conducted with, among others, representatives of the aforementioned parties.

I. Background

On April 11, 2005, Committee staff received allegations from Dr. Victoria Hampshire that on January 7, 2005, she was wrongfully removed from her post at the Food and Drug

[1] Documents marked with Bates numbers beginning with the letters "FTDO" are documents obtained from Wyeth. Documents marked with Bates numbers beginning with letters "GA" came from Germinder and Associates. Please see the attached Appendix for descriptions of the cited documents.
[2] ProHeart 6 (moxidectin) background document, Fort Dodge Animal Health Presentation, January 2005, *available at* http://www.fda.gov/cvm/Documents/FINALVMACProHeart6.pdf (Attachment (Att.) 3).

Administration's Center for Veterinary Medicine (CVM) and was reassigned to another position.[3]

Dr. Hampshire informed Committee staff that she believed that she was removed and reassigned because of her work cataloging negative adverse drug events (ADEs) in conjunction with ProHeart 6. Her work demonstrated that the ProHeart 6 ADEs were increasing in frequency and in severity of associated safety signals. The ADE reports were sent to FDA from Fort Dodge Animal Health under the sponsor's mandatory reporting requirement and referred by Dr. Hampshire to her supervisors.[4] Dr. Hampshire believes that she was removed at the behest of Wyeth in an effort to minimize the impact of a presentation she was going to make at a Veterinary Medicine Advisory Committee (VMAC) meeting regarding her findings.[5] In 2005, I opened an inquiry into these allegations regarding ProHeart 6, issued document requests, and my staff began conducting interviews.

My staff has uncovered evidence supporting Dr. Hampshire's allegations, bringing into question the processes that FDA uses in response to industry allegations of wrongdoing by FDA employees. Their findings, as set out below, indicate that an industry sponsor may have used its resources to have the Adverse Events Coordinator removed in hopes of having its veterinary drug, ProHeart 6, returned to the market. Dr. Hampshire has offered credible evidence that the allegations Wyeth made against her to the FDA were misleading and easily refuted. Nonetheless, the FDA accepted Wyeth's allegations at face value and took actions against Dr. Hampshire that may have adversely affected the drug approval and recall processes. I offer the following findings and set forth a number of questions for the FDA.

A. Dr. Victoria Hampshire

The Committee obtained the following information about Dr. Hampshire through interviews, an April 11, 2005, letter she submitted to my staff, and documentation provided by various sources.

Dr. Victoria Hampshire, VMD, is a veterinarian and a Commander in the United States Public Health Service (PHS). In November 2003, Dr. Hampshire was promoted to Adverse Event Coordinator for CVM. This position required Dr. Hampshire to interact with pet owners whose animals were harmed and/or injured by products that are regulated by FDA through CVM. Among her major duties was the collection and analysis of thousands of adverse drug event reports. Dr. Hampshire's exemplary work at the FDA earned her a PHS Achievement Medal in June 2005 for her "significant achievements in post marketing veterinary drug surveillance."[6] Moreover, she was named Veterinarian of the Year in 2006 by the PHS.[7]

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[3] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005, with redactions (Att. 1).

[4] 21 CFR 514.80 requires companies to report veterinary or owner reports of suspect adverse drug experiences and product/manufacturing defects on Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report."

[5] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).

[6] Nomination for US PHS Achievement Medal CDR Victoria Hampshire (Att. 51).

Prior to joining the FDA in May 2001 as a Safety Reviewer, Dr. Hampshire worked at the National Institutes of Health (NIH) until 1999 and worked independently as a veterinarian for one year. During Dr. Hampshire's time as an independent veterinarian in 2000, she formed a company called Advanced Veterinary Applications (AVA). AVA operated through an internet website as a vehicle for providing veterinary services limited to to friends, family, and former clients. The website accommodated house calls, relief work, and/or the prescribing of veterinary medications for a limited number of clients including friends, relatives, and colleagues. AVA was not an internet pharmacy. The website had an affiliation with VetCentric, an independent third party prescription fulfillment house that fills orders generated by the website. This method is commonly used by veterinarians who have few clients or practice on a limited basis.

VetCentric prescribing accounts allow veterinarians to save on overhead and generate income by marking up prescriptions with a margin. In Dr. Hampshire's case, her margin was a maximum of $5.00 to cover her time spent. In many instances, she charged nothing at all. Thus, her website generated minimal income and was not designed to solicit general internet clients.[8] Over a period of three years, from 2003 until 2005, Dr. Hampshire told Committee investigators that she received approximately $200 as a result of the AVA website (but see fn. 154, below). Dr. Hampshire viewed this site as one of three outside activities she was allowed to undertake while employed at FDA.

Dr. Hampshire filed disclosures for AVA during her employment with FDA.[9] In addition to AVA, Dr. Hampshire also disclosed two other outside activities, including limited employment at an emergency animal clinic and consultation work with the Humane Society of the United States. Dr. Hampshire also filed disclosures for other outside interests including speeches and talks that she gave outside of the Agency. All of these activities occurred outside of the scope of her government work and did not involve the use of FDA resources.

B. ProHeart 6 and Wyeth Pharmaceuticals

ProHeart 6, also known as moxidectin, is a Wyeth Pharmaceuticals product designed to treat both the larval and adult stages of the canine hookworm.[10] It is administered bi-annually with an injection at a veterinarian's office. ProHeart 6 was developed in part as a convenience to pet owners who want to protect their pets without using monthly pills or external creams and lotions. Further, the bi-annual injection was marketed as providing continuous protection against parasites.

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[7] See http://www.washingtonpost.com/wp-dyn/content/article/2006/05/11/AR2006051101883_2.html (Att. 52).

[8] Dr. Hampshire informed us that she received so little income from VetCentric and so much "junk mail" that she often threw away the VetCentric correspondence, including checks from time to time.

[9] See Att. 56 (Disclosure forms filed by Dr. Hampshire). Dr. Hampshire had no ownership interest in VetCentric, so filed no disclosures regarding that company.

[10] ProHeart 6 (moxidectin) background document, Fort Dodge Animal Health Presentation, January 2005, *available at* http://www.fda.gov/cvm/Documents/FINALVMACProHeart6.pdf (Att. 3).

ProHeart 6 was approved for use in the United States by the FDA in June 2001, based on laboratory studies that revealed no serious adverse drug events in healthy dogs.[11] ProHeart 6 is approved in several other countries, and a newer twelve-month version known as ProHeart SR12 has been approved for use in Australia since 2000.

Beginning in 2001, CVM and FDAH began receiving ADE reports from pet owners and veterinarians across the country. Initially, it appeared that many of the ADEs involved allergic-type reactions after administration of the drug.[12] The reactions that were cataloged as allergic reactions were attributed by FDAH to a manufacturing issue. FDAH allegedly resolved and "continu[ed] to optimize the manufacturing process."[13]

In the months following its approval, other problems plagued ProHeart 6. As a result, the label for ProHeart 6 was amended three separate times. The first amendment in June 2002 added anaphylaxis/anaphylactoid reactions, depression, lethargy, hives, and head and facial edema.[14] The label was amended a second time in November 2002 to include cardiopulmonary issues associated with dogs that were heartworm-positive.[15] Finally, the phrase "and rare reports of death" was added to the label in July 2003.[16] In addition to the label changes, the FDA required FDAH to send out two "Dear Doctor" letters noting the new information on the labels—one in July 2002, the second in June 2003.[17] As 2003 drew to a close, concerns began to arise among FDA safety reviewers about the increasing number of ADEs being reported by veterinarians and pet owners to both FDAH and CVM.

C. Removal of ProHeart 6 from the Market

In November 2003, Dr. Hampshire began noticing an increasing trend in ADEs being reported to CVM by FDAH, veterinarians, and pet owners across the country.[18] She alerted both the project manager and the team leader about this trend and suggested that the FDA should take some action to control the adverse impact that ProHeart 6 appeared to have on dogs in the United States.[19] Dr. Hampshire's initial outreach to her colleagues was heard, but no action was taken; in fact, Dr. Hampshire recalls that one of her colleagues stated, "The drug [ProHeart 6] will go away on its own after enough animals die."[20] However, this sentiment at the FDA changed in the spring of 2004 when consumer advocacy groups began to contact CVM en masse, lodging complaints about ProHeart 6.

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[11] FDA Veterinary Medicine Advisory Committee (VMAC) Meeting, January 31, 2005, Testimony of Dr. Lynn Post (Att. 4).
[12] ProHeart 6 (moxidectin) background document (Att. 3).
[13] *Id.* at p. 48.
[14] FDA VMAC Meeting, January 31, 2005 (Att. 4).
[15] *Id.*
[16] *Id.* Testimony of Dr. Margarita Brown (Att. 4).
[17] http://www.fda.gov/cvm/Documents/proheart6.pdf (Att. 47); http://www.fda.gov/cvm/Documents/Proheart6-062703.doc (Att. 48).
[18] Letter from Dr. Victoria Hampshire to Senate Finance Committee, dated April 11, 2005 (Att.1).
[19] *Id.*
[20] *Id.*

Consumer groups continued to press the FDA through the spring of 2004 and ultimately generated over 20 national news stories regarding the various adverse reactions pets had with ProHeart 6.[21] In response, FDA officials, including the head of the Office of New Drug Evaluation, began to ask when the FDA was going to act. FDA senior management, including the then-Director at CVM (Dr. Stephen F. Sundlof),[22] then-Deputy Director at CVM (Dr. Linda Tollefson), and the head of the Office of Surveillance and Compliance (OSC) (Dr. Dan McChesney), agreed to hear a presentation provided by Dr. Hampshire about the safety issues associated with the adverse drug event reports that CVM received. Dr. Hampshire made her presentation in July 2004. According to Dr. Hampshire, the CVM senior management staff unanimously agreed that ProHeart 6 was problematic and that it should be removed from the market, and that Wyeth should be asked to conduct additional studies.[23] In making this decision, Agency staff relied upon the nearly 5,000 ADE reports that were relayed to the FDA and the fact that there were large numbers of reports on relatively young, healthy dogs.[24]

Dr. Sundlof took the concerns that the management team raised and notified then-FDA Commissioner, Dr. Lester Crawford, who is also a veterinarian. According to Dr. Hampshire, Dr. Crawford asked Dr. Sundlof to speed up the process on ProHeart 6 in anticipation of the upcoming heartworm season and the potential increase in utilization. FDA officials at CVM scheduled a meeting with Wyeth officials to discuss concerns surrounding ProHeart 6. On August 11, 2004, FDA officials from CVM met with representatives of FDAH, a Wyeth subsidiary, to review the same presentation Dr. Hampshire gave to CVM management in July. Dr. Hampshire told Committee staff that she was unable to attend the August meeting. A follow-up meeting was set for September 1.

Dr. Hampshire stated that she represented CVM at the September 1 meeting and presented the findings, which were supported by seven safety reviewers, as well as CVM management.[25] By the end of the meeting, CVM decided that it would ask FDAH to remove ProHeart 6 from the market.

Following the September 1, 2004, meeting, FDAH continued to appeal the decision of CVM senior management to FDA's then-Commissioner Crawford.[26] The appeal included arguments that the data was inconclusive and that other competitor heartworm products had similar adverse events.[27] CVM staff, including Dr. Hampshire, advised the FDA Commissioner that this comparison had been addressed previously by changes to dosage and new warnings on other competitor drugs.[28] The then-FDA Commissioner Crawford ultimately concluded that CVM's decision was fair and accurate and the FDA proceeded with the recall.[29] FDAH made one last appeal to the FDA Chief Counsel who

[21] See, *e.g.*, http://www.dogsadversereactions.com (moxidectin link).
[22] Dr. Sundlof is now the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN).
[23] Letter from Dr. Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[24] See FDA VMAC Meeting, January 31, 2005, Testimony of Dr. Margarita Brown, pp. 16 and 34-52. Dr. Brown was one of four veterinarians who initially reviewed adverse drug events for CVM. She synopsized why the adverse reports were serious (Att. 4).
[25] Letter from Dr. Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*

also rejected the appeal and upheld the recall.[30] Finally, on September 3, 2004, FDAH voluntarily recalled ProHeart 6 from the market,[31] provided that CVM would convene an outside panel of experts to reevaluate the data.

II. Findings

Set forth below are my Committee staff's findings with regard to ProHeart 6 and Dr. Hampshire.

A. Wyeth Pharmaceuticals' Investigation of Dr. Victoria Hampshire

1. Initial Disputes with FDA and Dr. Hampshire

Internal emails from FDAH following the September 3, 2004, recall of ProHeart 6, show that it requested a copy of the September 2004 slide presentation prepared by Dr. Hampshire.[32] Dr. Hampshire and CVM officials initially withheld the slide presentation because of particular concerns regarding the confidentiality of outside consultants that the FDA utilized in preparing the data. Dr. Hampshire believed the FDA needed the approval of the outside consultants before divulging their names to a drug sponsor because the use of the consultants was "pre-decisional."

On September 20, 2004, the President of FDAH, Dr. Thomas Corcoran, asked that Dr. Sundlof provide FDAH with the September 1 slide presentation.[33] Three days later, on September 23, 2004, Dr. Corcoran wrote a formal letter to Dr. Sundlof in which he continued to request the September slide presentation, asked for a narrative to accompany the slide presentation, and requested "the list of academics Dr. Hampshire consulted with in evaluating ProHeart 6."[34] On September 24, 2004, Dr. Sundlof responded to the Dr. Corcoran and provided a redacted copy of the September 1 slide presentation prepared by Dr. Hampshire. In the response, Dr. Sundlof stated, "[i]n considering your request for the names of the experts outside the Agency which Dr. Hampshire referred to during her presentation, CVM has determined that the information is pre-decisional and therefore considered confidential, thus we are declining to provide their names."[35]

Internal FDAH emails indicate that Dr. Corcoran sought internal guidance from FDAH Corporate Counsel regarding the ability of CVM to withhold this information as "pre-decisional."[36] Based on these internal discussions, Dr. Corcoran continued to ask the then-CVM director for the unredacted slides. In an email dated October 4, 2004, Dr. Corcoran stated, "In going through the presenttion [sic] slides were omitted. Would you look into this and let me know if the missing slides were omitted for a specific reason?"[37] Dr. Corcoran continued, "I need to understand the context of the 'predecisional' [sic]

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[30] *Id.*
[31] http://www.fda.gov/cvm/PH6QA.htm (Att. 49).
[32] FTDO 001391 (Att. 5).
[33] FTDO 000845 (Att. 6).
[34] FTDO 000846-848, at 847 (Att. 7).
[35] FTDO 00929 (Att. 7a).
[36] *See* FTDO 0000845 (Att. 6).
[37] FTDO 001075 (Att. 10).

statement that guides you to withhold the information from whom in the academic world you received advice on ProHeart 6. Obviously the nature of the advice is also key."[38] Finally, Dr. Corcoran commented on conversations with CVM, "The confrontational tone exhibited by some of the CVM personnel at the September 1 meeting seems to be continuing. Why?"[39]

As a follow-up to the October 4 email, Dr. Corcoran called Dr. Sundlof the following day to discuss the September 1 slide presentation. Contemporaneous notes of the conversation prepared by Dr. Corcoran provide a narrative of the call. Specifically, Dr. Corcoran wrote:

> On the issue of the "missing" slides from Dr. Hampshire's September 1 presentation, Dr. Sundlof stated he was told we were given all slides with data. Slides with commentary and conclusions were omitted. I told him this was totally unacceptable. If CVM presented this information as factual and it was the basis of their decision to demand we voluntarily recall ProHeart 6, we had an absolute right to see the complete presentation and they had an obligation to provide***. I further told him that unless we received the entire presentation, I was going to make a big issue of initially withholding the presentation and then submitting only a portion of the presentation. I assured him this would be carried to the highest levels, and I wasn't speaking of FDA. He stated, "Message received."***[40] (emphasis added).

Following this conversation with FDAH's president, Dr. Sundlof emailed an un-redacted version of the complete September 1 slide presentation to FDAH on October 7, 2004.[41] In transmitting the slides, Dr. Sundlof noted, "The set I sent previously mostly omitted the conclusion slides because I thought, and still do think, that it is more important for FDAH to draw their own conclusion from the data in the reports FDAH sent to CVM rather than focusing on what FDAH considers problems with CVM's conclusions."[42]

2. Initial Complaints about Dr. Hampshire

One week following the September 3, 2004, removal of ProHeart 6 from the market, evidence suggests that individuals at FDAH received concerns regarding the possibility that Dr. Hampshire had a "vendetta" against FDAH and ProHeart 6. On September 10, 2004, Dr. Rocky Bigbie, Director of Field Veterinary Services at FDAH, received an email from M. Gatz Riddell, Jr., then-professor at Auburn University, who stated, "I have also heard that Tori Hampshire might have been on a mission with some type of ax to grind or a vendetta to carry out."[43]

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[38] *Id*.
[39] *Id*.
[40] FTDO 001654 (Att. 11).
[41] FTDO 001803 (Att. 12).
[42] *Id*.
[43] FTDO 000878 (Att. 13). Dr. Riddell was a source of information to FDAH that Dr. Hampshire may have a personal "vendetta" against ProHeart 6, and he was also an "Invited, Voting Consultant" to the VMAC

Further, that same day, a representative of the American Veterinary Medical Association forwarded an email from Larry Glickman, VMD, a professor at Purdue University, which discussed Dr. Hampshire.[44] The email concluded that Dr. Hampshire's actions were important because they "reflect[] a deliberate attempt by Victoria Hampshire to exclude veterinarians in the decision making process."[45]

3. Hiring Consultants to Investigate Dr. Hampshire

During September 2004, FDAH began an effort to get ProHeart 6 back on the market. Disclosures made to Committee staff indicate that on September 5, 2004, FDAH Director of Marketing Craig Wallace contacted Lea Ann Germinder of Germinder & Associates, Inc. (GAI),[46] an independent public relations specialist affiliated with FDAH since 1998. FDAH contacted GAI in an effort to begin a "communications outreach plan to respond to the recall."[47] This outreach effort included contact with "veterinarians, veterinary medical associations and key contacts in the animal health community and members of Congress and others believed to have influence at FDA and to continue to monitor and provide online coverage of the recall."[48]

Ms. Germinder informed Committee staff that she recalled receiving instructions from Craig Wallace "sometime between September 6, 2004 and October 12, 2004,"[49] to google Victoria Hampshire."[50] GAI began forwarding internet research on Dr. Hampshire to Mr. Wallace on September 16, 2004.[51] In response to the information on Dr. Hampshire, the Vice President of

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meeting held on January 31, 2005, to examine the voluntary recall of ProHeart 6**.** See FDA Veterinary Medicine Advisory Committee (VMAC) Meeting, January 31, 2005, Committee Deliberations on Question 1 (Att. 4). Further, Dr. Riddell voted "YES" to the question "is ProHeart 6 safe for use in dogs?" *Id.* Whether or not the contacts that Dr. Riddell had with FDAH were disclosed to the FDA prior to his voting on the January 31, 2005, VMAC meeting is unknown. However, it appears that the contact he had with FDAH representatives was a component in FDAH's investigation of Dr. Hampshire.

[44] FTDO 001849 (Att. 14).

[45] Dr. Glickman was introduced by FDAH at the September 1, 2004, meeting as a consultant for FDAH. In addition, Dr. Glickman presented FDAH's study data at the January 31, 2005, VMAC meeting. See, VMAC January 31, 2005 Meeting Transcript (Att. 4). Dr. Glickman had gathered data used by FDAH to support the position that Pro Heart 6 was safe. It is unknown whether Wyeth informed FDA that FDAH had these contacts with Dr. Glickman.

[46] According to disclosures made by Ms. Germinder, FDAH has "utilized the services of Germinder & Associates, Inc. in a wide variety of projects since approximately 1998." Further, GAI has also contracted some projects with Wyeth Animal Health since 2004. However, GAI has "never had a general written contract with either of Wyeth's animal health divisions governing their relationship" and serves as "an independent contractor and executes projects with Fort Dodge Animal Health according to signed estimates which set forth a scope of work as directed by the Vice President of Marketing, Craig Wallace." *See* Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, to Senator Charles E. Grassley, May 16, 2006, at 5 (Att.15).

[47] *Id*. at 11.

[48] *Id*.

[49] *Id*.

[50] *Id*.

[51] FTDO 000879-881, 879 (Att. 16).

Pharmaceutical Research (Rami Cobb) for FDAH concluded that the information "helps to point towards there being a personal agenda on her part."[52]

Based on the information made available to my staff, FDAH hired more than one person to look into Dr. Hampshire's activities. In fact, the Senior Vice President of North American Marketing at FDAH wrote to the Vice President of North American Marketing regarding the GAI research and said, "I had already hired an investigator to do the same."[53] Ms. Germinder then sought further help and entered into a written contract with her nephew, Dan O'Hare, for independent consulting.[54]

4. Failed Attempts to Purchase Competitors' Prescription Products from AVA

The key portion of the investigation into Dr. Hampshire occurred in early October 2004 and revolved around Dr. Hampshire's affiliation with a website she operated known as Advanced Veterinary Applications (AVA), http://www.advancedvet.com. As stated earlier, this was the website portal that Dr. Hampshire had created in 2000, prior to joining FDA. GAI and FDAH researchers came across AVA after Mr. Wallace asked for a google search of Dr. Hampshire.[55]

Ms. Germinder stated that, once directed to the AVA website, she saw that it offered Heartguard, a competitor drug to ProHeart 6.[56] According to Ms. Germinder, once he became aware of this, Mr. Wallace instructed her to research this matter further and directed Ms. Germinder to attempt to make a purchase from the AVA website. In response, Ms. Germinder assigned one of her direct staff members, Catherine Couch, to "mystery shop" the AVA website.[57] Ms. Couch determined that the website was live and operational. Ms. Germinder noted that she then instructed her nephew Dan O'Hare, an independent consultant hired by GAI, to conduct internet research and attempt to make a purchase.[58]

Mr. O'Hare made his first purchase of products from the AVA website on October 8, 2004. Mr. O'Hare placed an initial order for a product, Bitter Apple Spray—a non-prescription product—and paid $6.08 for the product plus shipping cost. He used the business name XC Direct, billed the purchase to his father's credit card and shipped it to his father's home.[59] This order was shipped to Mr. O'Hare from VetCentric on October 11, 2004.[60]

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[52] FTDO 000882-887 (Att. 17).
[53] FTDO 000888-893 (Att. 18).
[54] GA-9-00001-03 (Att. 19).
[55] *See* Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 11 (Att. 15).
[56] *Id*.
[57] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 11 (Att. 15).
[58] *Id*. at 11.
[59] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12 (Att. 15)
[60] FTDO 000045-000049 (Att. 21).

Ms. Germinder's employees then attempted to purchase prescription products from AVA website that were direct competitors to ProHeart 6. Ms. Germinder asked Mr. O'Hare to purchase Heartguard, a competitor product to ProHeart 6. Mr. O'Hare was unable to purchase the product through the AVA website.[61] After being denied the product because he did not have a prescription for Heartguard and was not a friend, family member or former client that Dr. Hampshire worked with on the AVA website,. O'Hare instead purchased $1,197.65 worth of non-prescription pet products through the product link on the AVA website, including shampoos and pet treats.[62]

Later, GAI enlisted the help of Dr. Steven A. Levy, a veterinarian at Durham Veterinary Hospital in Durham, Connecticut.[63] Since 1990, Dr. Levy has been a canine-lyme disease consultant for FDAH.[64] Dr. Levy, according to the information presented to the Committee, worked with Ms. Germinder in the past and agreed to attempt to purchase Heartguard from the AVA website. However, Dr. Levy was unsuccessful in purchasing Heartguard from AVA.[65] Documents produced to my staff show that Dr. Levy then requested assistance from a person named "Kelly." Kelly was to obtain Heartguard using a prescription issued by Dr. Levy on October 18 and October 19, 2004.[66] According to GAI's documents, Kelly had a prescription from Dr. Levy and also requested a prescription through AVA.[67] Kelly had problems accessing the VetCentric ordering site, so she called VetCentric.[68] She told VetCentric that she "had a prescription from [Dr. Levy] and a request for a prescription through Advanced Vet [AVA]"but that she wanted a prescription from AVA.[69] She told VetCentric that AVA was her.[70] This statement was false; according to Dr. Hampshire, neither "Kelly" nor Dr. Levy were clients of AVA. Ultimately, VetCentric did not fill any prescription through AVA.[71] VetCentric personnel told Kelly that she could, however, purchase the Heartguard product using Dr. Levy's prescription.[72] Therefore, both of Dr. Levy's attempts to purchase Heartguard through AVA without an AVA prescription were unsuccessful.

In addition to the attempts by Mr. O'Hare and Dr. Levy, Ms. Germinder initiated an attempt to purchase Heartguard from AVA by enlisting the help of a pet owner in Maine. That individual was also unsuccessful.[73] Ultimately, GAI failed in its attempts to purchase products competitive with ProHeart 6 from Dr. Hampshire's AVA website.

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[61] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12 (Att. 15).
[62] FTDO 000799-0000801 (Att. 22). According to Dr. Hampshire, the friends, family and former clients who used the AVA website to obtain prescription medication seldom, if ever, purchased non-prescription products.
[63] FTDO 000050-000053 (Att. 23).
[64] Resume of Dr. Steven Levy, found at http://www.durhamveterinary.com/cv.html (Att. 20).
[65] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12. (Att.. 15).
[66] FTDO 000054-55 (Att. 24).
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] *Id.* The letter from Kelly to Dr. Levy states that "I'm not sure about identifying Advanced Vet as my vet, but this seemed the only way to proceed with the order."
[71] *Id.*
[72] *Id.*
[73] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12 (Att. 15)..

5. Interim Report Provided to Wyeth by Germinder & Associates

GAI produced its first report to Wyeth regarding Dr. Hampshire on October, 12, 2004.[74] This interim report consisted of information and research conducted, "in accordance with standard public relations research practices for background use only to determine the stakeholders who are conducting a negative communications campaign against ProHeart 6."[75] The report was designed with the "hope that understanding who these stakeholders are, what motivates them, the tactics they use, and the key messages they wish to convey will assist you in executing your business strategy regarding this matter."[76]

The interim report produced by GAI contains (1) screen prints of internet searches of the terms "Victoria Hampshire" and "Tori Hampshire;"[77] (2) various scholarly articles authored and/or peer reviewed by Dr. Hampshire;[78] (3) screen prints of the AVA website operated by Dr. Hampshire and information about VetCentric;[79] and (4) information on the "Dogs Adverse Reactions" website and other websites that appeared critical of ProHeart 6.[80]

6. Hiring a Private Investigator to Research Dr. Hampshire

In the days following the transmittal of the GAI interim report to FDAH, Ms. Germinder was in contact with Mr. Wallace on a daily basis.[81] However, she realized that she needed some experienced assistance in furthering the investigation. Consequently, Ms. Germinder contacted a longtime acquaintance, Ms. Donna Dauite, a licensed private investigator.[82] Ms. Dauite was tasked with tracking down proper legal ownership of the AVA website and was contracted by GAI to conduct this work.[83] During interviews with Committee staff, Ms. Germinder recalled that the decision to hire and contract with Ms. Dauite was discussed with Mr. Wallace and representatives of Wyeth prior to signing the contract. Specifically, Ms. Germinder told Committee staff on March 12, 2007, that she advised Mr. Wallace that further research would be done by a researcher who had credentials as a private investigator.

Ultimately, the GAI investigators, including Ms. Dauite, created a substantial investigative file on Dr. Hampshire. This file included property records for Dr. Hampshire's personal residence,[84] business search records related to AVA,[85] taxation

[74] GA-4-00009 (Att. 25); GA-4-00134-231 (Att. 26).
[75] GA-4-00009 (Att. 25).
[76] *Id*.
[77] *See* GA-4-00135-00138 (Att. 26).
[78] GA-4-00159-00184 (Att. 26).
[79] *Id.*
[80] *Id.*
[81] Letter from Pamela B. Stuart, Attorney for Lea Ann Germinder, at 12 (Att. 15).
[82] *Id*.
[83] *Id*.
[84] GA-4-00041 (Att. 27).
[85] GA-4-00043 (Att. 28); 00045 (Att. 29).

records related to both Dr. Hampshire and AVA,[86] as well as records related to the VetCentric Prescription fulfillment site.[87]

This information and over $1,000 in over-the-counter, non-prescription animal products that Mr. O'Hare purchased from the VetCentric component linked to the AVA website and provided to GAI were given to Wyeth in two separate packages. The first package was delivered by Ms. Germinder on October 20, 2004,[88] and included "the latest correspondence and documentation in attempting to order Heartguard from Advanced Veterinary Applications"[89] as well as two boxes of "product and paperwork." GAI delivered the remaining information to Wyeth on October 27, 2004.[90]

7. Meeting between Wyeth and Former FDA Commissioner

Emails produced to my staff detail at least two phone calls between Wyeth and senior FDA officials following Wyeth's receipt of GAI's October 27 production.[91] Specifically, internal Wyeth documents show that Geoffrey Levitt, Vice President & Chief Counsel, Regulatory and Research at Wyeth, spoke with then-FDA Chief Counsel Dan Troy on November 5, 2004, in an effort to follow up on a call made to then-FDA Commissioner Crawford by Wyeth Chairman, Robert Essner.[92] Based upon documents provided by FDA, it appears that the topic of conversation for both calls was "the apparent conflict of interest issue."[93] Further, emails obtained from FDA show that Wyeth prepared company-wide talking points on the issue, and that Wyeth believed they had "information to show not only that there was a strong appearance of conflict and bias, but also that these issues had influenced the data and analysis on which FDA's position was based."[94] The emails also show that Wyeth requested a meeting to discuss the issues with then-FDA Commissioner Crawford.

Wyeth created a 29-page slide presentation titled, "ProHeart 6: Apparent Conflict of Interest" and a 10-page appendix slide presentation with supporting documentation.[95] Both slide presentations appear to have been created based upon information obtained from the GAI investigation and Wyeth's own investigation of Dr. Hampshire.[96] Wyeth offered the slide presentations to FDA at a meeting on November 19, 2004.[97] This

[86] GA-4-00044 (Att. 30); 00047-52 (Att. 31); 00055-57 (Att. 32).
[87] GA-4-00053 (Att. 33).
[88] GA-4-00031 (Att. 34).
[89] *Id*.
[90] GA-4-00058 (Att. 35).
[91] *See* FTDO 002613 (Att. 36).
[92] *Id*.
[93] *Id*.
[94] *Id*.
[95] See Wyeth's November 19, 2004 slide presentation (Att. 8).
[96] Similar web searches and document searches on Dr. Hampshire were conducted concurrently to the investigation conducted by GAI. One noteworthy portion of this Wyeth investigation is the involvement of FDAH Senior Vice President & Chief Counsel C.T. Newsum, as many documents related to Mr. Newsum were withheld from the Committee by Wyeth under Attorney Client Privilege related to Mr. Newsum's capacity as FDAH's Chief Counsel. The Committee is not subject to such common law privilege, but took no action to force production.
[97] *See* Letter from Douglas Dworkin, Wyeth Pharmaceuticals, to Senator Charles Grassley, December 16, 2005, at 3 (Att. 37).

meeting took place at the FDA. Representing Wyeth were "Bob Essner, Chairman, President, and Chief Executive Officer; Jeff [sic] Levitt, V.P. and Chief Counsel Regulatory and Research; Gerald Fisher, Senior V.P., Drug Safety and Metabolism."[98] The FDA was represented by then-FDA Commissioner Crawford, then-Chief Counsel Dan Troy, and Policy Analyst Dana Delman.[99] The topic of conversation was "issues surrounding the September 3, 2004, withdrawal from the market of ProHeart 6" and included discussion of "a potential conflict of interest issue."[100] This portion of the meeting included Wyeth's slide presentation regarding Dr. Hampshire.[101] The presentation alleged, among other things, that (1) public records revealed that AVA was an "active internet veterinary pharmacy" selling products competing with ProHeart 6, which raised the appearance of a conflict of interest; (2) Dr. Hampshire was biased because she had been in contact with anti-ProHeart6 activists; and (3) Dr. Hampshire presented adverse events data in a biased fashion."[102]

8. FDA Investigation of Dr. Hampshire

Following the meeting between representatives from Wyeth and FDAH, then-FDA Commissioner Crawford and then-Chief Counsel Troy provided Wyeth's slide presentation to Dr. Steven Sundlof, then-Director of CVM. Dr. Sundlof relayed the contents of the presentation via telephone to a Special Agent within the FDA's Office of Internal Affairs (OIA) Office of Criminal Investigations (OCI) on November 22, 2004. According to the FDA, OIA "is a subordinate office within OCI which conducts administrative and criminal investigations of alleged employee misconduct."[103] Based on this referral phone call, Special Agents within OIA opened an initial investigation into Dr. Hampshire on November 24, 2004, alleging that Dr. Hampshire was operating an internet pharmacy.[104]

In the meantime, Dr. Hampshire continued to work with CVM staff on ProHeart 6 and began preparing for a January VMAC meeting.[105] She was unaware of Wyeth's allegations and the FDA/OIA investigation. However, Dr. Hampshire informed Committee staff that her colleagues began to give her "a cold shoulder treatment," but she did not know why.[106]

Throughout December 2004, Dr. Hampshire continued to help select candidates for the January 2005 VMAC meeting. However, Dr. Hampshire was kept away from preparing the CVM presentation that would be given to the VMAC, despite her long history of working on ProHeart 6. During this same time, Mr. C.T. Newsum, Senior Vice President and Chief Counsel for FDAH, was working closely with the OIA agents.

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[98] FDA Memorandum of Meeting prepared by Dana Delman, Policy Analyst, November 19, 2004 (Att. 38).
[99] *See id*.
[100] *Id*.
[101] *See* Letter from Douglas Dworkin, Wyeth Pharmaceuticals, at 3 (Att. 37).
[102] Wyeth's November 19, 2004 slide presentation (Att. 8).
[103] Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, at 1 (Att. 39).
[104] FDA Office of Internal Affairs, Case Initiation and Fact Sheet, November 24, 2004 (Att. 42E).
[105] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[106] *Id*.

Documents and information show that Mr. Newsum reached out to FDA agents on December 9, 2004, and was interviewed by OIA agents on December 16, 2004.[107] According to one of the FDA agents interviewed by Committee staff, Mr. Newsum called frequently regarding this matter. In fact, one written investigative report stated that Mr. Newsum spoke to an agent on "numerous occasions over the course of this investigation."[108] Eventually, OIA agents pulled Dr. Hampshire's ethics filings from the Office of Ethics at FDA where they learned that she filed three separate outside activity reports (OAR), including one for AVA Consulting.[109]

The FDA/OIA investigation into Dr. Hampshire included (1) pulling Dr. Hampshire's ethics forms; (2) reviewing the materials prepared by Wyeth; (3) interviewing the Chief Counsel for FDAH, (4) pulling all emails and internet activity from Dr. Hampshire at FDA; and (5) requesting the Department of Health and Human Services, Office of the Inspector General (HHS/OIG)[110] to issue a subpoena to VetCentric for records related to AVA.[111] Based on this information, the OIA presented investigative facts relating to Dr. Hampshire's alleged conflicts to officials at CVM on January 6, 2005.[112]

On January 7, 2005, Dr. Hampshire was called into a meeting with then-CVM Deputy Director Tollefson and OSC Director McChesney.[113] Dr. Hampshire informed my staff that, during this meeting, Dr. Tollefson told her that Wyeth had "pulled all plugs" at the level of the Commissioner and that Dr. Hampshire was being reassigned.[114] Dr. Hampshire agreed that if the industry sponsor had questions about her involvement that it was ultimately better to leave the role of lead reviewer for ProHeart 6 and let the data speak for itself. Accordingly, Dr. Hampshire then asked if she could be reassigned within CVM instead of being transferred out of the Center.[115] Dr. Hampshire was granted a move within CVM, but was no longer a lead reviewer on ProHeart 6. She

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[107] Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, Documents at Tab C (Att. 40).
[108] OIA Investigative Report January 31, 2005, at 3 (Att. 42B).
[109] *Id.*
[110] It is important to note that during the time-frame discussed in this Letter, FDA held a distinction within the Department of Health and Human Services (HHS) not afforded to other subordinate agencies. The FDA had a written memorandum of understanding (MOU) with HHS/OIG regarding the investigation of internal misconduct by FDA employees. Att. 41. This MOU was executed in July 1998 and allowed FDA to continue to have Criminal Investigators, Federal Series 1811 employees, on staff in the Office of Internal Affairs to conduct investigations into employee misconduct. *Id.* Further, the MOU provided that both FDA/OIA and HHS/OIG would hold concurrent responsibility for investigating employee misconduct at FDA with FDA/OIA taking a lead role unless it was preempted by the HHS/OIG's right in all cases to pursue a case jointly with OIA or after consultation replace OIA as the primary Agency. *Id.* Because of this right of preemption retained by HHS/OIG, FDA/OIA utilized the services of HHS/OIG whenever it needed to issue a subpoena duces tecum, as was the case here. The MOU was, however, withdrawn as of November 30, 2007, and the function of criminal investigation of FDA employees was returned to HHS/OIG "[t]o ensure integrity in the process of conducting sensitive employee misconduct investigations." Att. 53. According to HHS/OIG, "this function is more appropriately placed in an investigative office with statutory independence." *Id.*
[111] OIA Investigative Report, January 31, 2005, at 4 (Att. 42B).
[112] *Id.*
[113] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[114] *Id.*
[115] *Id.*

continued, however, to provide advice to CVM to keep continuity in CVM as they moved toward the advisory committee hearing.

During the next few weeks, CVM prepared for the January 31, 2005,VMAC to discuss the safety of ProHeart 6. One of Dr. Hampshire's colleagues was selected to make the presentation in place of Dr. Hampshire. On January 30, 2005, the Director of OSC called Dr. Hampshire at home and asked her to help prepare a statement for the VMAC in the event that questions arose about why Dr. Hampshire was not presenting.[116] In response to this request, she helped prepare a statement that said she was on vacation and had been reassigned within FDA to different projects.[117]

On January 31, 2005, the VMAC met to discuss the safety of ProHeart 6 and the earlier recall. The panel heard data from both FDA and Wyeth. The presentation by FDA included testimony from CVM employees who relayed the same concerns that were presented by Dr. Hampshire at the September 1, 2004, meeting with Wyeth. The panel, by an 8-7 vote, ultimately concluded that safety concerns based on serious adverse events warranted the continued recall of ProHeart 6.[118]

With the VMAC complete, and following her reassignment to another division within CVM, Dr. Hampshire was still unaware of the investigation into her activities. However, on February 8, 2005, she was contacted by the FDA Office of Ethics regarding her outside activities reports.[119] The Ethics staff asked Dr. Hampshire why she did not include her AVA website on her December 14, 2004, HHS Form 520-1 "Request for Approval of Outside Activity,"or OAR.[120]

Dr. Hampshire told my staff that she informed the ethics staff that the AVA website account was not included on her OAR because, even though it was still open, she had not been using it over the past year. She believed that she did not have to disclose an activity that was not producing income.[121] This belief was wrong, and the Director of Ethics informed Dr. Hampshire that "receipt of income" was not the standard for filing an approved outside activity request. Dr. Hampshire was also told that because she had not ended the AVA activity, she also needed to file a new OAR in order to close the 2004 file.[122] Dr. Hampshire agreed to file a new OAR report.[123] Dr. Hampshire did not know

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[116] *Id.*
[117] *Id.*
[118] VMAC meeting minutes, January 31, 2005 (Att. 50).
[119] Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, Documents at Tab A – Email from Office of Ethics to Dr. Hampshire Feb. 8, 2005 (Att. 42).
[120] *Id.* at p. 14 (Att. 42).
[121] *Id.* Because Dr. Hampshire seldom checked the website, she had no idea that GAI had ordered thousands of dollars of non-prescription supplies from the website, which gave it the appearance of being active. See Letter from Dr.Victoria Hampshire to the Senate Finance Committee dated April 11, 2005 (Att. 1).
[122] Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, Documents at Tab A – Email from Office of Ethics to Dr. Hampshire Feb. 8, 2005 (Att. 42, Exh. 6).
[123] *Id.*

that the request from the Office of Ethics was not initiated by that office, but was requested as part of the investigation being conducted by OIA.[124]

a. Re-Submission of Dr. Hampshire's Ethics Filings

Dr. Hampshire submitted her updated OAR on February 8, 2005 pursuant to the Office of Ethics request.[125] She continued to correspond with the Director of Ethics and other officials within the Office of Ethics and CVM regarding her disclosures.[126] On the morning of February 11, 2005, Dr. Hampshire was still unaware of the ongoing investigation into her activities. Later that day, Dr. Hampshire had lunch with a friend who was also employed at the CVM, who informed her that there was an investigation ongoing and that she should consider other employment.[127] This colleague informed Dr. Hampshire that representatives from Wyeth had obtained information about AVA and that they were looking into her outside activity.[128]

Dr. Hampshire told Committee staff that, upon hearing this, she began to fear that she did not adequately detail the AVA website on her disclosure forms.[129] As a result of this, Dr. Hampshire said that she returned to her office and called Dr. Sundlof's assistant to ask if it was too late to attach a new comment sheet to her OAR.[130] She was informed that Dr. Sundlof had not reviewed the OAR yet.[131] Dr. Hampshire then retrieved the disclosures she had prepared and given to Dr. Sundlof as a result of the February 8th conversations from the pile of OARs that were waiting to be signed by CVM Director Sundlof.[132] Dr. Hampshire told Committee staff that she thought that, in responding to questions by Office of Ethics staff, she should add a new comments page indicating that AVA website contained an internet pharmacy component.[133] Dr. Hampshire placed a pink note on the documents noting the new detailed version of the OAR.[134] According to Dr. Hampshire, she was under the mistaken impression that her supervisors and officials in the Office of Ethics had not yet read the form and that submitting it as amended was insignificant.

On Monday, February 14, 2005, after receiving the copy of Dr. Hampshire's amended outside activities form, the OIA agent called the Office of Ethics that had reviewed Dr.

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[124] Specifically, one of the Agents wrote in the OIA investigative report that he asked Ethics to request an update from Dr. Hampshire on her outside activities. OIA Investigative Report January 31, 2005, at p. 3 (Att. 42B). This request initiated the exchange on February 8, and all documents obtained and communications with Dr. Hampshire were transmitted by Ethics to OIA. Individuals within the Office of Ethics were prohibited from replying to Dr. Hampshire's inquiries until Ethics personnel consulted with OIA Agents investigating Dr. Hampshire. (Letter from David Boyer, Documents at Tab A—Email from Office of Ethics to Dr. Hampshire Feb. 8, 2005) (Att. 42).

[125] Dr. Hampshire's OAR form (Att. 42A).

[126] Letter from David Boyer, Documents at Tab A—Emails between Dr. Hampshire and various FDA personnel. (Att. 42).

[127] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).

[128] *Id.* This friend was later disciplined for advising Dr. Hampshire of the on-going investigation.

[129] Dr. Hampshire's OIA statement (Att. 42A).

[130] *Id.*

[131] *Id.*

[132] *Id.*

[133] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).

[134] *Id;*, Dr. Hampshire's OIA statement (Att. 42A)

Hampshire's OAR and asked "why four members in the chain of command would sign off on that document."[135] Dr. Wardrop, CVM's Chief Executive Officer, replied that he had not seen an OAR with such language and pulled a copy from his personal safe that did not include the additional language that Dr. Hampshire included in her amended form.[136] These originals without the additional language were sent to OIA on February 17, 2005, by the Office of Ethics.[137]

b. Criminal Referral to the United States Attorney's Office for the District of Maryland

At this point the OIA Agents still had not spoken with Dr. Hampshire. Aside from the information her colleague provided to her at lunch, Dr. Hampshire said she had no knowledge of the ongoing criminal investigation, and that she changed the OAR because of her concern over her co-worker's warning.[138] She erroneously believed that amending the form was innocuous.[139]

OIA agents prepared and submitted a referral letter to the United States Attorney for the District of Maryland (USAO).[140] This referral recommended prosecution of Dr. Hampshire for criminal violations of conflict of interest statutes, as well as for false statements to government officials.[141] The language of the referral letter indicates that OIA was unaware of some of the facts, however. For instance, the referral letter stated, "Through the web portal of Advanced Veterinary Applications (AVA), the subject [Dr. Hampshire] also advertises heartworm medications which compete with Pro Heart 6. An agent acting on behalf of Fort Dodge Animal Health had two orders filled through AVA."[142] This statement is inaccurate. FDAH had failed to get any orders for heartworm medication filled through AVA.

The referral letter also notes that, of the $774.55 received from 2002 through 2005 for VetCentric orders, $472.57 was paid to Dr. Hampshire from the orders placed by the agent for Fort Dodge Animal Health "to cement their Conflict of Interest Allegation. In this regard it is the opinion of the investigating agent that although the dollar amount may seem minimal, as an employee of the FDA, the subject has a grave and continuing conflict of interest."[143] This statement is also inaccurate.

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[135] OIA Investigative Report, March 7, 2005, at 3 (Att. 42A).
[136] *Id.*
[137] *Id.*
[138] *Id.*
[139] *Id.* (Dr. Hampshire's OIA statement); Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1)
[140] Referral Letter from FDA Office of Internal Affairs to Assistant United States Attorney Dunne dated Feb. 23, 2005 (Att. 2).
[141] *Id.*
[142] *Id.*
[143] *Id.* The items ordered from the website were ordinary items not requiring a prescription. Moreover, Dr. Hampshire informed Committee staff that she was never paid for the VetCentric order, because she apparently threw away the check for that order, thinking it was junk mail. See Dr. Hampshire's Letter to Senate Finance Committee (Att. 1).

OIA told the USAO that "When an order is placed through [Dr. Hampshire's] web site it is actually filled by a firm named VetCentric which fills and ships the order," and that there was "no evidence of a Nexus between Dr. Hampshire … and VetCentric."[144] The letter nonetheless indicates that Dr. Hampshire's 2003, 2004, and 2005 Confidential Financial Disclosure Reports were deficient because she does not mention that AVA had an internet pharmacy component.[145] While the letter recommended consideration of potential violations, it also noted that the investigation found, "no evidence to suggest the subject committed any fraud when compiling Adverse Event Reports for ProHeart 6."[146] By letter dated February 24, 2005, the USAO declined criminal prosecution of Dr. Hampshire.[147]

c. The Administrative Case against Dr. Hampshire

OIA continued to build an administrative case against Dr. Hampshire. On February 24, the same day the United States Attorney declined prosecution, OIA Agents notified Dr. Hampshire that they needed to speak with her.[148] Dr. Hampshire advised the Committee that she met with two OIA agents that afternoon. According to Dr. Hampshire, the FDA agents informed her that there had been an ongoing inquiry into her conduct and that this was no longer a criminal matter. More importantly, Dr. Hampshire was advised that the investigation had originated from information generated by Wyeth, including attempts to see if she would dispense heartworm prescription products without a valid veterinary client relationship.[149] OIA also informed Dr. Hampshire that OIA had attempted to obtain prescription products from the AVA website, downloaded all of her emails and internet usage, and had determined that most of her clients were friends and neighbors.[150] Next, OIA agents pressed Dr. Hampshire regarding the changes she made to her outside activities form and stated that the changes raised integrity issues.[151]

The OIA agents questioned Dr. Hampshire on various topics during the February 24, 2005, interview, including details of her amendment to the OAR on February 11. One of the agents told Dr. Hampshire that he had been one of the people attempting to order heartworm medication to see if she would dispense the product without a prescription or a valid veterinary client relationship.[152] Further, according to Dr. Hampshire, the OIA agents referred to contacts she made with Congressman Van Hollen, who had asked FDA about her reassignment, and asked her if she had "called off the congressman."[153] Dr.

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[144] Referral Letter from OIA to the United Sates Attorney's Office dated Feb. 23, 2005 (Att. 2).
[145] *Id.* Ironically, Dr. Hampshire's retrieval of her 2005 Confidential Financial Disclosure Report was for the purpose of clarifying that AVA had a link to an internet pharmacy—a clarification for which she was referred for criminal prosecution.
[146] *Id.*
[147] Letter from Asst. United States Attorney Dunne to FDA Office of Internal Affairs, February 24, 2005 (Att. 43).
[148] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[149] *Id.*
[150] OIA Investigative Report, March 7, 2005, at 3 (Att. 42A).
[151] *Id.*
[152] Letter from Dr. Victoria Hampshire to Senate Finance Committee, April 11, 2005 (Att. 1).
[153] *Id*; see also OIA Investigative Report, March 7, 2005 (Att. 42A); Dr. Hampshire informed my Committee staff that the OIA Agents specifically questioned her during their interview about the confidential communications between Dr. Hampshire and a member of Congress. While it appears this line

Hampshire provided OIA a sworn statement regarding the events surrounding her OAR amendment.[154] Finally, she informed OIA that other veterinarians at CVM utilized VetCentric prescribing accounts as part of their outside activities, in addition to other third party prescription filling houses.[155]

d. Remark by a Wyeth Sales Representative about Dr. Hampshire

The investigation into Dr. Hampshire remained open into the summer of 2005. The next entry into her OIA case file indicates that, during the summer, FDA received a letter from a veterinarian who was outraged by disparaging remarks a Wyeth field representative made about Dr. Hampshire.[156] This veterinarian wrote that a Wyeth field representative told her that Dr. Hampshire**,** "had generated $70,000.00 in one year from competitor product sales."[157] Further, this veterinarian reported that the Wyeth representative said that Wyeth had Dr. Hampshire "investigated by private detectives." This Wyeth representative went on to say that information about Dr. Hampshire's financial interests "had all been verified."[158] Finally, the Wyeth representative stated that once Dr. Hampshire was "taken care of," the adverse event reports would drop off and that the product would return to the market.[159]

Upon receiving this letter and determining that the letter contained "egregious claims," OIA decided that the matter was "best handled with a formal response to Fort Dodge Animal Health [Wyeth] by FDA legal counsel."[160] No formal correspondence from FDA Legal Counsel to Wyeth regarding this referral from OIA was ever produced to my staff. Mr. Secretary and Commissioner von Eschenbach, I reiterate my official request for a copy of that correspondence, if it exists.

Ultimately, OIA reported its findings of the investigation to then-CVM Director Sundlof via the CVM Executive Officer.[161] The Executive Officer for CVM reported back to the OIA agents on July 19, 2005, that Dr. Hampshire and the colleague who tipped her to the ongoing OIA investigation were both provided "a verbal reprimand and counseling by their supervisors and a memo documenting these actions was completed and retained by their respective supervisors."[162] The OIA case against Dr. Hampshire

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of questioning was only cursory, it must be noted that retaliation by federal agencies for contacting Congress is not new and could be construed as intimidation for protected whistleblowing in violation of the Whistleblower Protection Act, among other federal statutes.

[154] Although OIA alleged to the United States Attorney's Office in its referral letter (Att. 2) that Dr. Hampshire received $774.55 from Oct. 21, 2003 through February 23, 2005, Dr. Hampshire has informed Committee staff that she only received around $200, because she accidentally threw away a check for $472.57, thinking it was junk mail. Letter from Dr. Hampshire, April 11, 2005 (Att. 1). Technically, however, the website generated $774.55 over that time period.

[155] OIA Investigative Report, March 7, 2005, at 4 (Att. 42A).

[156] Letter dated 2005 (redacted by Committee Staff) (Att. 55); OIA Investigative Report, September 2005, at 2 (Att. 42D).

[157] *Id.*

[158] *Id.*

[159] *Id.*

[160] OIA Investigative Report, Sept. 23, 2005, at 2 (Att. 42D).

[161] OIA Investigative Report, June 8, 2005, at 2 (Att. 42C).

[162] OIA Investigative Report, Sept. 23, 2005, at 2 (Att. 42D). Dr. Hampshire informed Committee staff that the OIA agent told her he was going to recommend that she be reprimanded for changing her OAR without

was closed by report dated September 23, 2005.[163] Despite the completion of the investigation and the determination by OIA that Dr. Hampshire committed no fraud in the adverse event report collection for ProHeart 6,[164] Dr. Hampshire was not provided an opportunity to return to her previous position.

III. Conclusions and Recommendations

The series of events set forth in this Letter describe the removal of the lead adverse drug coordinator on ProHeart 6 issues from her position, ostensibly at the request of an industry sponsor, without sufficient proof of wrong-doing. Although a conflict-of-interest allegation deserves serious attention, this investigation, which includes information readily available to the FDA (particularly FDA agents) at the time of the events described, has shown that the allegations presented by Wyeth in its November 19, 2004, slide presentation were misleading.

For instance, Wyeth informed FDA that Dr. Hampshire was operating an internet pharmacy.[165] The AVA website, however, was a portal from which customers could order products from VetCentric, which was an independent pharmacy. A customer ordering products had to click on a "store" button that would take the customer to the VetCentric link.[166] Wyeth was fully aware that orders for products were sent to VetCentric for processing, shipping, and invoicing, because it so informed FDA during its November 19, 2005, slide presentation.[167]

Wyeth also told FDA that, because Dr. Hampshire's AVA website offered access to one or more products sold by VetCentric that were competitive with Wyeth's ProHeart 6, this demonstrated a conflict of interest. VetCentric, however, also offered ProHeart 6 (tablet form) and other Wyeth products.[168] Moreover, Dr, Hampshire informed the OIA agents that it is not uncommon at CVM for veterinarians to have similar arrangements with third-party fulfillment houses such as VetCentric.[169] The only significant activity on Dr. Hampshire's AVA site was, coincidentally, created by Wyeth itself. This may have resulted in the OIA agents' mistaking this activity as evidence of a "conflict of interest."[170] It appears that FDA agents failed to conduct a thorough investigation into the Dr. Hampshire matter prior to making a referral to the USAO.

In addition, Wyeth indicated to the FDA that Dr. Hampshire had inappropriate contacts with anti-ProHeart 6 activists.[171] Although several activists did contact Dr.

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getting permission from Dr. McChesney. She said that she was supposed to receive a written reprimand from Dr. McChesney, but that she did not receive one, nor has she seen one in her personnel file.

[163] *Id*. The report synopsized the issues, but did not set forth any findings.

[164] Referral letter from FDA-OIA to USAO dated Feb. 23, 2005 (Att. 2).

[165] See Wyeth's November 19, 2005 slide presentation (Att. 8).

[166] GAI's Interim Research Report, Oct. 12, 2004, Bates GA-4-00202 (Att. 26).

[167] Wyeth's November 19, 2005 slide presentation at p. 8.

[168] Dr. Hampshire's Rebuttal to Wyeth's slide presentation (Att. 44).

[169] OIA Investigative Report, March 7, 2005, at 4 (Att. 42A).

[170] See Letter of Referral from FDA Office of Internal Affairs to Assistant United States Attorney Dunne (Att. 2).

[171] See Wyeth Nov. 19, 2004 slide presentation (Att. 8).

Hampshire, such contacts were to report adverse events and her responses to these contacts were well within her job description.[172] Finally, the two emails offered by Wyeth to demonstrate that Dr. Hampshire's peers feared that she was on a vendetta came from two veterinarians with ties to FDAH (see footnotes 43, 45). That information, however, was not revealed by Wyeth to the FDA.

The allegations regarding Dr. Hampshire's bias against ProHeart 6, as pointed out above, were eventually rejected by FDA. Significant resources, however, were devoted to investigating Dr. Hampshire.[173] These resources may have been saved had the former FDA Commissioner, former Chief Counsel, and/or Director of CVM approached Dr. Hampshire and inquired about the information presented by FDAH. Instead, resources were expended by (1) two FDA/OIA Special Agents, (2) HHS/OIG, and (3) the USAO, not to mention (4) other offices within FDA. Further, the only violation that Dr. Hampshire committed and that was proven by FDA—amending her OAR forms—apparently happened because she learned of an investigation into her outside activities and panicked. Thus, it appears that Dr. Hampshire was verbally reprimanded as a result of the investigation conducted by the OIA agents and not as a result of any proactive campaign against an industry sponsor. By mishandling an investigation and submitting material to law enforcement that was rife with error, FDA not only wasted resources, it created serious doubts about the integrity of its processes.

Based upon these findings, I offer the following recommendations to the FDA and would appreciate your comments.

A. Require Formal Disclosure and Full Documentation of All Meetings Held by FDA Staff with Regulated Sponsors

At present, FDA regulations allow and encourage the FDA to accept requests for private meetings with every person outside the Federal Government.[174] These requests can be made by industry sponsors, as was the case with former FDA Commissioner Crawford agreeing to meet with Wyeth and FDAH representatives. The regulations state "An official transcript, recording, or memorandum summarizing the substance of any meeting described in this section will be prepared by a representative of FDA when the Agency determines that such documentation will be useful."[175]

Because the standard for documenting meetings is discretionary, it could potentially allow meetings with senior FDA employees to go unrecorded. In the case of the November 19, 2004, meeting that then-FDA Commissioner Crawford and then-Chief Counsel Troy had with FDAH and Wyeth representatives, FDA officials made a

[172] Dr. Hampshire's Rebuttal to Wyeth's slide presentation (Att. 44).
[173] GAI, the firm that investigated Dr. Hampshire, estimated that its investigation cost about $20,000. Letter from Pamela Stuart, Attorney for Lea Ann Germinder, to Sen. Grassley, May 16, 2006 (Att. 15). We have no estimates from FDA regarding its expenditure of investigative man-hours, duplication of resources required to get Dr. Hampshire's replacement for the VMAC meeting up to speed, and time spent by supervisors and others on this matter.
[174] 21 C.F.R. § 10.65(c) (2006).
[175] 21 C.F.R. § 10.65 (e) (2006) (emphasis provided).

determination that documentation of the meeting was necessary.[176] The documentation of the meeting on November 19th is sparse and unhelpful, however.

Regarding Dr. Hampshire, the memorandum notes that, "Wyeth representatives conveyed their concerns with the FDA assessment of adverse reaction data, and a potential conflict of interest issue."[177] This is the only statement about the conflict of interest issue. This one sentence does not begin to describe Wyeth's production and delivery to the FDA of more than 25 slides of information challenging Dr. Hampshire's credibility. Further, the memorandum does not mention that this information was to be referred to the CVM Director for appropriate action. The bare-bones memorandum, which does not fully describe the events that transpired or the follow-up action that was recommended, thus effectively failed to disclose the real substance of the meeting. This is the sort of double standard that highlights the problem with transparency at the FDA: the transparency is there; you just can't see it.

My Committee staff received no further documentation from the FDA regarding any of the other contacts or meetings that then-FDA Commissioner Crawford or other FDA officials had with Wyeth/FDAH. However, OIA agents informed Committee staff about numerous contacts between them and FDAH's Chief Counsel.[178] The flow of information between OIA agents and FDAH's Chief Counsel is of great interest to me. It appears that all the industry sponsor's Chief Counsel had to do was to pick up the phone in order to contact an OIA agent. In order for me to converse with OIA, I have had to resort to obtaining a subpoena.

In addition, notes provided by Wyeth regarding a conversation between Dr. Corcoran of FDAH and Dr. Sundlof of the FDA, provide evidence of FDA's release of pre-decisional information to the company. Clearly, documentation of these meetings and discussions would provide much-needed insight into the interactions between the FDA and industry sponsors, and whether such interactions are appropriate. Accordingly, I recommend that new policies and procedures be put in place that require formal disclosure and full documentation of all meetings held by FDA staff with regulated sponsors.

FDA's failure to document has been brought to the FDA's attention on numerous occasions. I am now seeking your assurance, Mr. Secretary and Commissioner von Eschenbach, that this issue will be promptly resolved.

B. Improved Management of Internal Investigations

This case represents, among other things, a breakdown in FDA's internal investigation processes. Regarding the initial inquiry into Dr. Hampshire, then-CVM Director Sundlof chose not to discuss Wyeth's allegations with Dr. Hampshire and instead referred the matter to OIA Special Agents. This led to a poorly handled investigation involving significant resources and created an environment of fear that

[176] See, Memorandum of Meeting between Wyeth and FDA Officials, November 19, 2004 (Att. 38).
[177] *Id*.
[178] See, FTDO 001654 (Att. 11).

apparently encouraged Dr. Hampshire to engage in the activity for which she was ultimately reprimanded—altering her ethics form.

I am not suggesting that all internal investigations of FDA employees be brought to the employees' attention. This case required a more thorough analysis of the facts and issues by the FDA to determine if the circumstances presented were merely a misunderstanding, or something else that required further action by law enforcement. In this instance, which may have been a unique situation, one question to Dr. Hampshire could have quickly resolved the matter. Asking Dr. Hampshire about her AVA website would, in all likelihood, not have compromised the investigation, nor would it have been anything other than a question that should—and could—be asked in a normal business setting.[179] Moreover, FDA should have independently examined the information Wyeth presented at the November 19, 2004 meeting.[180]

Yet another example of questionable management involves the letter sent to the FDA from a veterinarian who was outraged by a Wyeth field representative's disparaging remarks regarding Dr. Hampshire.[181] OIA apparently forwarded the letter to FDA Legal Counsel for appropriate action.[182] No evidence of any follow-up by FDA, however, was provided to my staff. If there was any follow-up by FDA, I request that I be informed immediately.

Regarding the February 23, 2005, referral letter sent by OIA to the United States Attorney's Office for the District of Maryland, I request that both the HHS and FDA describe in detail any policies and procedures that will be put into place to ensure that future referrals to the USAO will not be riddled with inaccuracies. I would also like to know (1) whether the referral to the USAO was reviewed by FDA/HHS counsel and, if so, who reviewed it; (2) whether the referral was reviewed by any individual(s) other than

[179] Apparently, the practice of CVM veterinarians of using independent pharmacies, which Dr. Hampshire informed us was widely used at CVM, was not understood by FDA management or the OIA. After Dr. Hampshire explained the practice to management, CVM Ethics instated a clarification regarding the "Private Practice of Veterinarians," effective July 20, 2005, which states that "writing valid prescriptions to be filled by an independent pharmacy is entirely within the scope of veterinary practice" and "clearly acceptable as an outside activity for CVM employed veterinarians." See, "Outside Activity Process-Private Practice of Veterinarians." (Att. 54).

[180] One additional example of mismanagement occurred after the Committee's investigation was made public. On November 18, 2005, FDA spokesperson Susan Bro, who has since left the FDA, notified *Reuters* news service that the investigation into Dr. Hampshire was done with "Dr. Hampshire's knowledge." Letter from Senator Charles Grassley to Dr. Andrew von Eschenbach, Acting Commissioner, FDA, Nov. 30, 2005 (Att. 46). Further, Ms. Bro stated that the FDA investigation of Dr. Hampshire was not criminal, in direct contravention of the facts (*i.e.*, that a criminal referral had been made by OIA agents earlier that year in February 2005). Whether or not this was an intentional misstatement is unknown. However, it is difficult to understand why Ms. Bro made these statements, in light of the fact that Dr. Hampshire's attorney pointed out these inaccuracies to Ms. Bro's staff prior to the release of the statement. *Id*. This inaccurate statement to *Reuters* represents an instance where effective internal communication could have resulted in a correct response to the media. Further, despite un-contradicted evidence of this inaccuracy made to the press, FDA failed to set the record straight and correct the inaccurate statements made by Ms. Bro.

[181] Letter dated summer, 2005 (redacted) (Att. 55).

[182] OIA Investigative Report, Sept. 2005 (Att. 42D).

the signatory and, if so, who were the individual(s); and (3) who will be held accountable for this misleading letter.

C. New Procedures for Suspension of Advisory Panels when Sponsor Raises Allegations against FDA Employees

The FDA has guidance regarding conflicts of interest and advisory panel members, and conflict-of-interest reporting by FDA employees.[183] The case involving Dr. Hampshire raises questions, however, about yet another type of conflict of interest: a potential for targeted removal of FDA employees or panel participants who may not fully support the sponsor's views.

As part of this investigation, my Committee staff requested a list of all known OIA investigations since 1996 that were based on the complaints of industry sponsors.[184] There were several identifiable instances of such investigations. Although various reasons motivated these investigations, one common thread exists among all of the industry-initiated complaints to the FDA: there are no procedures at FDA to postpone advisory committee meetings when industry sponsors raise serious allegations against a panel participant and/or an FDA presenter. This potential loophole could allow industry sponsors to attempt to affect the votes of an advisory committee by removing individuals who possess information contrary to the sponsor's position. Therefore, I recommend that HHS and FDA create a list of requirements for those situations where industry sponsors seek to exclude an FDA employee from participating in an advisory committee meeting. The FDA should have the ability to potentially delay the proceeding until the allegations are substantiated or some other reasonable action is taken (a person with similar skills, qualifications, and understanding of the topic of the advisory committee meeting is up to speed with the presentation.) Although allegations of misconduct should always be taken seriously, they should not be acted upon without first conducting due diligence.

I look forward to hearing from both of you on how HHS and FDA intend to deal with these issues.

IV. Closing

Throughout my investigation, internal FDA sources revealed concerns and disagreements held by and between CVM scientists who are involved in the ongoing scientific review of ProHeart 6. In particular, my Committee staff has received

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[183] The FDA has new draft guidance procedures for removing and recusing members from FDA advisory committees, such as the VMAC, when there are conflicts of interest posed by participation of certain members. *See* http://www.fda.gov/oc/guidance/advisorycommittee.html. The FDA code of conduct requires that employees disclose potential conflicts of interest, such as the form 450 OAR that Dr. Hampshire filed in this case. The code of conduct also requires these individuals to recuse themselves from any advisory committee should they have a real or apparent conflict of interest. Further, any FDA employees who are Commissioned Officers in the Public Health Service are bound by a similar code of conduct and ethics as part of their oath to the PHS. Therefore, supervisors should be aware of the need to recuse and police FDA employees accordingly.

[184] *See* Letter from David Boyer, then-Assistant Commissioner for Legislation, FDA, to Senator Charles Grassley, June 7, 2006, Documents at Tab E (Att. 45).

information which suggests that internal disagreement exists over whether or not old and new studies substantively address all historically reported major adverse events associated with ProHeart 6 use in dogs. By this Letter I am advising both of you that I am concerned that the scientific process is being compromised internally. In light of the findings presented in this Letter and the fact that FDA sources to this day continue to bring concerns about ProHeart 6 to my attention, I believe that involvement by FDA management at the highest levels may be necessary to ensure the integrity of FDA's processes. However, if it is decided that this matter does not need to be elevated to the highest levels, please advise me of that decision immediately.

While the details of this Letter are aimed at reforms at the FDA and the missteps made in investigating Dr. Hampshire both criminally and administratively, culpability does not lie with the FDA alone. It is uncontroverted that industry representatives ought to have a good working relationship with the FDA, but under no conditions should the scientific process be compromised by industry pressure.[185]

Moreover, I would appreciate a personal assurance from both of you that no retaliation will be taken against any person who contributed, either directly or indirectly, regarding this Letter, or who may contribute to any future investigation of ProHeart 6 that I might undertake.

In closing, please provide a response to the concerns, findings and recommendations contained in this Letter by no later than February 25, 2008. Should you have any questions please feel free to contact Angela Choy or Elizabeth Rinaldo of my staff at (202) 224-4515. All formal correspondence should be sent via electronic transmission in PDF format or via facsimile to (202) 228-2131 and original by U.S. mail.

Sincerely,

Charles E. Grassley
Ranking Member

Attachments

[185] Additionally, the actions of Lea Ann Germinder were also problematic. Ms. Germinder's recollection of the events appears to be supported by the extensive documentation provided by GAI, including a contract with a private investigator. It appears that once the Committee inquiry into Wyeth's involvement in investigating Dr. Hampshire began, however, Ms. Germinder attempted to reduce her involvement, telling Committee Investigators that she did not understand why Wyeth had her do this investigation and that in hindsight it made her uneasy. These post-hoc sentiments aside, Ms. Germinder acted as the intermediary and coordinator for the private inquiry into Dr. Hampshire that led to the internal FDA investigation. While it was only one piece in the equation, her assistance to Wyeth, including hiring the private investigator, cannot be denied. Nonetheless, we appreciate Ms. Germinder's help and cooperation with our investigation.