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March 15, 2007

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Ms. Mary Bender
The Department of Agriculture
Bureau of Dog Law Enforcement
2301 North Cameron Street
Harrisburg, PA 17110-9408

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2007 MAR 30 PM 3:06
INDEPENDENT REGULATORY
REVIEW COMMISSION

Re: Proposed Amendments to Title 7 of the Pennsylvania Code, Chapters 21, 23, 25 and 27 (7 Pa.Code §§ 21.1.-27.14), ("Dog Law").

Dear Ms. Bender:

Wyeth Pharmaceuticals, a division of Wyeth, appreciates this opportunity to submit comments on the proposed rule to amend Title 7 of the Pennsylvania Code, Chapters 21, 23, 25 and 27 (7 Pa.Code §§ 21.1.-27.14), ("Dog Law"), as published in the Pennsylvania Bulletin on December 16, 2006 (Volume 36, Number 50). The proposed rule would amend the Pennsylvania Dog Law to impose new rules and is intended to address deplorable and cruel living conditions for dogs in "puppy mills."

Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. Wyeth is also a leading employer in Pennsylvania and the headquarters for our Pharmaceuticals Division is located in Collegeville, Pennsylvania. In addition to providing well-paying jobs to Pennsylvania residents, Wyeth and its 5,000 employees contribute to the strong life sciences industry presence in the state.

Wyeth commends Governor Rendell and the Department of Agriculture's efforts to crack down on the "puppy mills" by implementing reforms that will improve living conditions for dogs located in the state. Wyeth shares this commitment to the proper treatment for all animals and adheres to all state and federal regulations to assure appropriate care is maintained.

However, Wyeth has significant concerns that many of the reforms in the proposed amendments go beyond their intended purpose and would impose hardships on research facilities in the state with no incremental benefit to the dogs it seeks to protect. Wyeth is already regulated by federal law that assures the appropriate treatment of research animals. As a result, the amendments put forth by the state would provide no additional benefit or protection to dogs housed at Wyeth facilities.

Wyeth

In the preamble to the proposed amendments to the Dog Law, the state estimates the financial impact to the private sector of \$5,000 to \$20,000 per facility. This is a substantial underestimate. While the basis for the state's estimate to the private sector is unclear, it appears that the potential impact on research facilities in the state were not included. To meet the new requirements, Wyeth would need to build new infrastructure and retrofit existing facilities. The estimated costs of such renovations would exceed \$10 million dollars. Additional costs would also be incurred in having to hire new personnel and retrain existing personnel on the new obligations set forth by the Commonwealth.

Because of these unintended consequences for research facilities located in Pennsylvania, Wyeth respectfully recommends that the state adopt **any of the following options:**

- Exempt Research Facilities from the Requirements of the Dog Law.
- Adopt Federal Standards as Provided in CFR, Title 9, Chapter 1, Subchapter A, Parts 1-3.
- Redraft Regulations After Consulting with Pennsylvania Society for Biomedical Research.

I. Exempt Research Facilities from the Requirements of the Dog Law

Wyeth requests that Pennsylvania provide an exemption from the proposed amendments of the Dog Law for research facilities that are regulated by the federal Animal Welfare Act (AWA).

Under the federal Animal Welfare Act (AWA)¹, any institution using live animals for research, testing, teaching or experimentation are required to register with the U.S. Department of Agriculture (USDA) as research facilities. The AWA requires that research facilities provide their animals with adequate care and treatment in the areas of housing, handling, sanitation, nutrition, water, veterinary care, and protection from extreme weather and temperatures.

Research facilities governed by the AWA must ensure that animals located at their facilities receive appropriate veterinary care. This includes:

- Assuring the necessary facilities, personnel, equipment, and services to provide adequate veterinary care are available.
- Using appropriate methods to prevent, control, diagnose, and treat diseases and injuries.
- Guaranteeing the availability of emergency, weekend, and holiday care for animals.
- Making a daily observation of all animals by employees to assess the animals' health and well-being.

¹ See 7 U.S.C. §§ 2131 et. seq. Regulations provided in CFR, Title 9, Chapter 1, Subchapter A, Parts 1-3.

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In addition, research facilities must establish an Institutional Animal Care and Use Committee to oversee the use of animals in experiments. This committee is responsible for ensuring that the facility remains in compliance with the AWA. The committee must be composed of at least three members, including one veterinarian and one person who is not affiliated with the facility in any way.

The USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for administering the standards of the AWA. To ensure that licensed research facilities are compliant with the AWA, inspectors from APHIS make annual unannounced inspections. If an inspection reveals deficiencies in meeting the requirements of the AWA, the inspector will provide the facility with a specific timeline in which to remedy such deficiencies. If the research facility fails to take appropriate action, APHIS will document the research facility's deficiencies and consider possible legal action.

As noted above, dogs utilized in research facilities regulated by the AWA are afforded significant protections to assure their proper care and comfort. Many of the concerns that the state seeks to address through the proposed amendments to the Dog Law are already outlined in the AWA. Also, the federal agencies responsible for administering the AWA have at their disposal significant enforcement authority to assure compliance.

In addition to the federal oversight, research facilities must maintain appropriate conditions and provide sufficient care for dogs so as not to compromise their research studies. Good science requires that the dogs utilized in medical research be kept in an environment that would not jeopardize the results of their important scientific endeavors. By exempting facilities regulated by the AWA from the proposed amendments to the Dog Law, Wyeth believes the state would meet its goal of reforming the "puppy mill" business while allowing important medical research in the state to continue.

II. Adopt Federal Standards as Provided in the Animal Welfare Act (AWA).

Alternatively, Wyeth requests that Pennsylvania rescind the proposed Dog Law amendments and issue new amendments that adopt existing federal standards as provided in CFR, Title 9, Chapter 1, Subchapter A, Parts 1-3 to dog kennels and puppy mills.

In drafting the proposed amendments to the Dog Law, the state is seeking to address the deplorable conditions that occur in dog kennels that are used primarily for breeding and boarding. However, since the Dog Law also regulates research facilities in the state, they are also implicated by the proposed amendments. Wyeth believes that by adopting existing federal standards provided for in the AWA (CFR, Title 9, Chapter 1,

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Subchapter A, Parts 1-3) and extending them to puppy mills, the state can better regulate these facilities while allowing important medical research to continue unimpeded.

Pennsylvania's research facilities must adhere to the guidelines established by the Animal Welfare Act. This Act was first passed in 1966 and has been amended in 1970, 1976, 1985, and 1990. These amendments were made to assure the Act continues to maintain the appropriate standards for the care and treatment of animals. Many interested parties who are concerned with maintaining the well being of dogs and other animals used in research have helped shape this law. And these federal standards are working. The statutory provisions provide enough flexibility to allow important medical research to flourish without compromising the humane treatment of dogs. Adopting the federal standards will allow the Commonwealth to leverage the knowledge and experience of those regulated by the AWA while also addressing their ultimate objective of reforming the state's 'puppy mill' business.

III. Redraft Regulations After Consulting with Pennsylvania Society for Biomedical Research (PSBR)

As a final option, Wyeth requests that the Department of Agriculture withdraw the proposed amendments and work with the Pennsylvania Society for Biomedical Research (PSBR) to develop more appropriate standards that achieve the state's objective.

Wyeth believes that Pennsylvania can achieve its goal of regulating 'puppy mills' without imposing significant hardships on the many research facilities that are located within the state. The Pennsylvania Society for Biomedical Research (PSBR) was established by medical schools, pharmaceutical companies, universities, and professional societies in the Commonwealth to promote a better public understanding and increase an appreciation of the value of biomedical research, including the humane care and use of research animals. In this regard, the PSBR member companies and their employees share many of the same objectives as the Commonwealth in assuring the proper care and treatment of dogs.

PSBR companies employee veterinarians and others who, on a daily basis, are required to handle and provide care for dogs at their facilities. They have developed an appreciation for the conditions most suitable for these dogs and can share their experiences with the state. In addition, these employees have been responsible for providing care to dogs in accordance with federal regulations. PSBR employees could work with state officials to guide them as to the most appropriate standards in the treatment of dogs. By partnering with the PSBR and its member companies, Wyeth believes the Commonwealth would achieve its ultimate goal of assuring the proper treatment of dogs in the state.

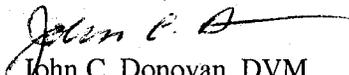
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Conclusion

Wyeth appreciates the opportunity to provide comments on the proposed amendments to the Pennsylvania Dog Law. Wyeth helps to improve the lives of millions of people with new and innovative medicines and is exploring more than 60 new therapies for medical conditions such as diabetes, breast cancer, multiple sclerosis, HIV, Alzheimer's disease and schizophrenia. An important part of these R&D efforts is the responsible use of animals that allow for the discovery of medicines for the prevention and treatment of human and animal disease.

As detailed above, Wyeth recommends that the Department adopt any of our identified options to accomplish the objective of addressing deplorable living conditions for dogs in puppy mills. We share the Governor and Department's goal of affording humane treatment and care for dogs in the state. However, we ask that the Department consider our recommendations to balance the unique needs of research facilities while achieving the ultimate goal of addressing the 'puppy mill' problem. If you have any questions about Wyeth's comments, please do not hesitate to contact me.

Regards,


John C. Donovan, DVM
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