Pennsylvania Animal Diagnostic Laboratory System

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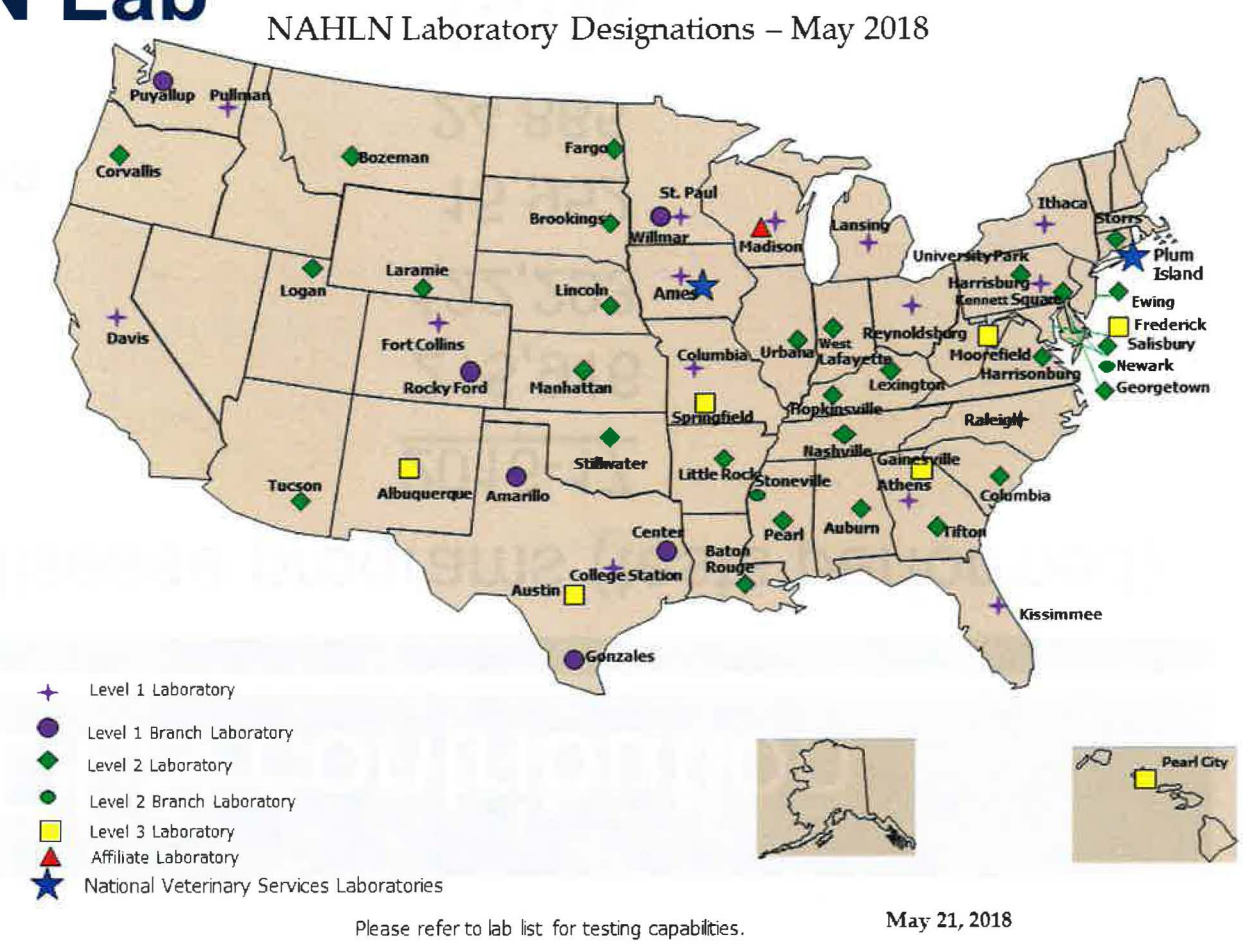
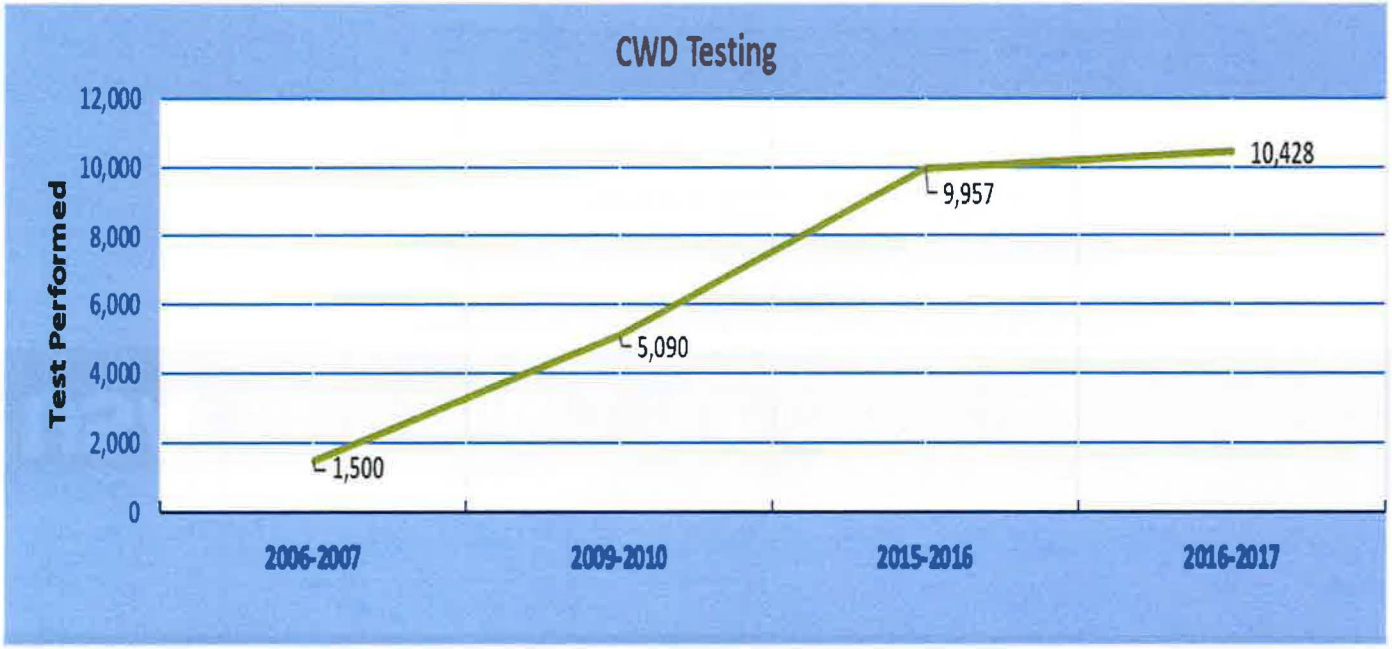
PADLS LABS

- **Tier 1 NAHLN Lab**



CWD Workload



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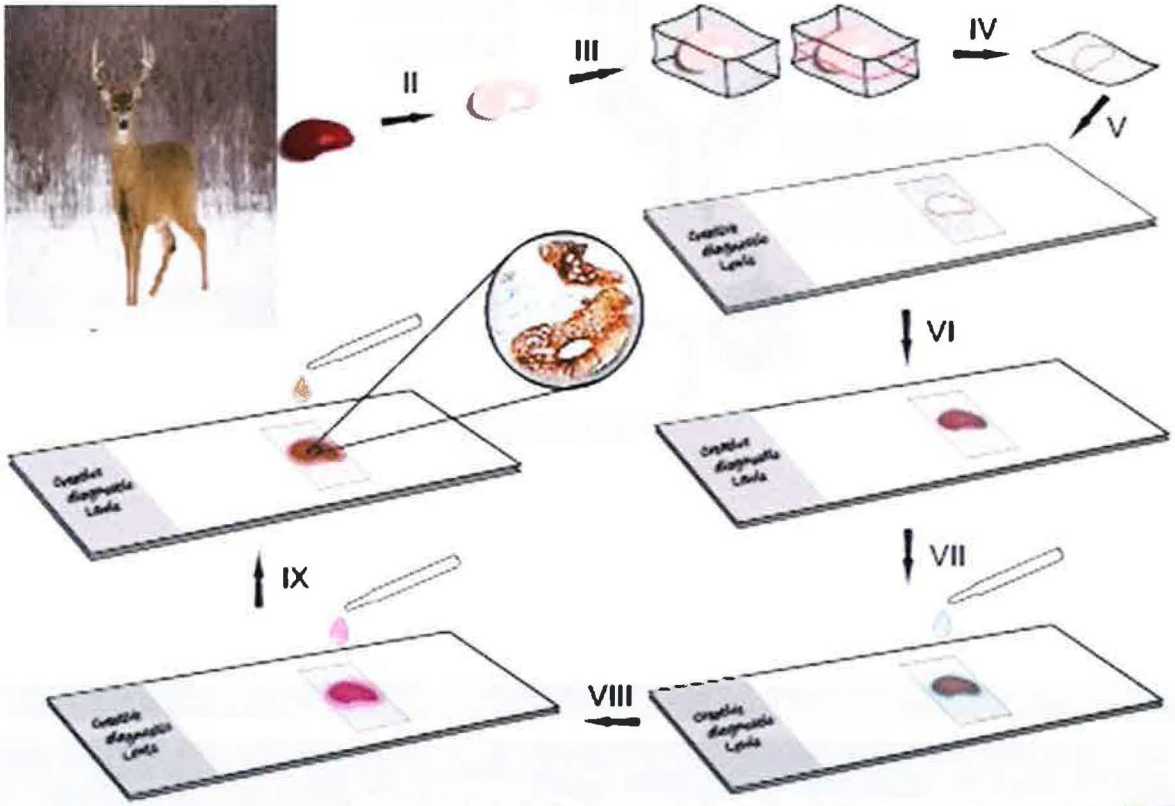
CWD Detection-Immunohistochemistry



Gold standard

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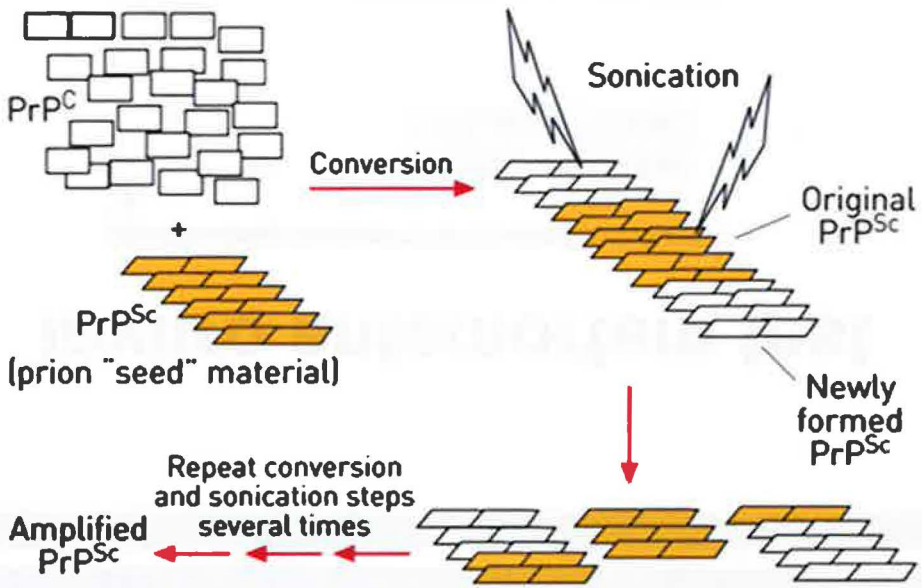
Detection- Protein Misfolding Cyclic Amplification

Invitro antemortem test



- Amplification

- Normal
+ Abnormal prion

- Detectable level of prion

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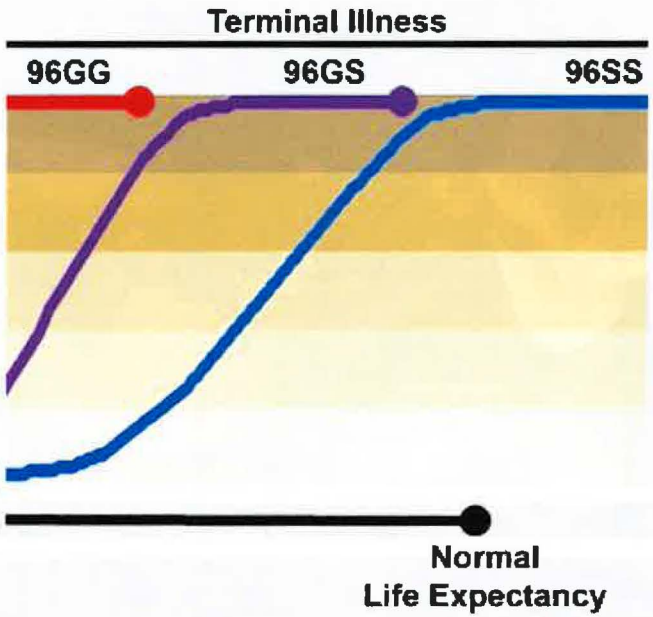
Genetic Resistance in Deer

Codon 96 and disease Courtesy N Haley



- Survival advantage in white tail deer with

Codon 96S, 95H

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PADLS Services Supporting Agriculture

Acknowledgements: PVL, PADLS & Bureau Staff

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House Game and Fisheries Committee
June 14, 2018
Hearing on Chronic Wasting Disease
Testimony of
Kevin Brightbill, DVM
Assistant Director
Pennsylvania Department of Agriculture
Bureau of Animal Health and Diagnostic Services
and
Deepanker Tewari, BVSc, PhD, DACVM
Resident Director
Pennsylvania Veterinary Laboratory

Good morning Chairman Gillespie, Chairman Barbin and Members of the House Game and Fisheries Committee. Thank you for calling this hearing today to discuss Chronic Wasting Disease (CWD) and to provide the Department of Agriculture with the opportunity to share with you our direct and shared role and the scientific methods the department is utilizing to manage this challenging disease. The department recognizes there are profound implications to Pennsylvania's economic health and the environment with CWD, including and beyond a sustainable healthy deer herd. Collaboration between agencies and other partners has been effective in addressing animal disease, whether it originates domestically or in the wild. Collaborative efforts to address CWD in Pennsylvania has led to the development of a response plan that includes both short-term and long-term strategies and allows for modification in the event that new science or technology is developed to support our efforts.

Outbreaks of any type are devastating to animal agriculture. These events can close borders, shut down agricultural operations and related businesses, and drive up the cost of food for consumers. The Pennsylvania Department of Agriculture's Bureau of Animal Health and Diagnostic Services (BAHDS) is responsible for regulatory animal disease programs within the commonwealth and is specifically charged with monitoring, detecting, preventing, responding to, and removing agents that threaten the health and safety of Pennsylvania's livestock resources. This authority is provided by the Domestic Animal Law at 3 Pa.C.S. Chapter 23. This work, performed by a network of 12 veterinarians and 18 animal health inspectors throughout the state, relies on the testing capabilities of the Pennsylvania Animal Diagnostic Laboratory System, or PADLS.

In addition to its standard regulatory work, the bureau plays an active role in the commonwealth's emergency preparedness network. This is an important connection, as it brings together state and local public health, emergency response and agriculture officials on topics such as the Avian Influenza Response Plan, the Pennsylvania State Animal Response Team, and other groups that would have first-responder roles in an agricultural emergency.

PADLS provides rapid and accurate diagnostic services to protect animal health and consequently has an important impact not only on animal health but also on human health, food safety, and the economic well-being of Pennsylvania residents. Pennsylvania Veterinary Lab (PVL), one of the PADLS tripartite system partners, located in Harrisburg, is a Tier 1 National Animal Health Lab network laboratory and has the authority and ability to respond to disease threats arising from foreign animal diseases (FAD) like foot and mouth disease (FMD), a devastating disease of cattle and swine; highly pathogenic avian influenza (HPAI), a disease of very high concern for the poultry industry; or classical swine fever (CSF) causing high mortality and losses in pigs. The laboratory has primary responsibility for testing diseases of high concerns that are important to agriculture stakeholders. These important diseases are called dangerous transmissible diseases (DTD) and include rabies; equine infectious anemia (EIA) in horses; Pullorum and avian influenza in poultry; Brucellosis, leucosis, mad-cow disease and bovine viral diarrhea in cattle; and Chronic Wasting Disease in deer. The laboratory system yearly tests more than a half million samples and supports most of Pennsylvania's livestock industries.

The PVL, a Tier 1 National Animal Health Lab is one of only 25 national labs that offer CWD testing. PADLS is very robust in providing testing support for animal disease diagnosis and in supporting trade and export of animals nationally and internationally.

PADLS-PVL is accredited by the American Association of Veterinary Diagnosticians (AAVLD). It is a network partner lab for the Food and Drug Administration (FDA), Food Emergency Response Network (FERN), offering additional testing capacity to protect the food supply, and it participates in disease investigations as a Veterinary Laboratory Investigation Response Network (FDA Vet-LIRN) partner.

Chronic Wasting Disease

The PVL laboratory helped diagnose the first case of CWD in Pennsylvania's deer population in 2012, although surveillance for the disease, carried out by both PDA and the Pennsylvania Game Commission in Pennsylvania, has been ongoing since 1998. Since this first detection, due to continuous testing and rigorous surveillance measures, CWD infections have continued to be detected with increasing frequency in recent years.

Chronic Wasting Disease is caused by a misfolded protein called a prion. All mammals produce normal prions that are used by cells, then degraded and eliminated, or recycled, within the body. When disease-associated prions contact normal prions, they cause them to refold into an abnormal shape. These disease-associated prions are then deposited in tissues and cause damage and disease. CWD is one of a group of diseases called Transmissible Spongiform Encephalopathies (TSEs), or prion diseases. CWD is closely related to, but different than, other TSEs, including Scrapie in sheep, Bovine Spongiform Encephalopathy in cattle, and Creutzfeldt - Jakob disease and variant Creutzfeldt - Jakob disease in humans. The prion, is found in greatest concentrations in nervous and lymphatic tissues and can accumulate in brain tissue giving it a sponge-like appearance. There is scientific evidence that CWD is spread through body fluids, feces, and contaminated environments.

Laboratory diagnosis and detection of this slow infection rely on techniques that detect the abnormal form of protein, testing mostly infected tissues collected post-mortem. As endemic areas have expanded, so has the need for rapid, sensitive, and cost-effective diagnostic tests—especially those which take advantage of samples collected antemortem. Over the past two decades, strategies have evolved from the recognition of microscopic spongiform pathology and

associated immune-histochemical (IHC) staining of the misfolded prion protein to enzyme-linked immunoassays (ELISA), capable of detecting the abnormal prion protein in post-mortem samples. The PVL laboratory offers both IHC and ELISA and is one of the very few laboratories among the 25 USDA-approved laboratories that conduct both of these effective and invaluable CWD tests.

It is important to note, there have been no reported cases of CWD infection in humans. Animal studies suggest CWD poses a risk to some types of non-human primates, like monkeys, that eat prion-spiked samples of meat to simulate CWD-infected animals or come in contact with brain or body fluids from infected deer or elk. The department supports the World Health Organization's recommendation to keep the agents of all known prion diseases from entering the human food chain. Translation, use common sense and never eat any meat from an animal that does not appear to be healthy.

CWD susceptible species include black tailed deer; elk, moose, mule deer, red deer, sika deer, reindeer, white-tailed deer; and hybrids of these species.

As with other diseases, CWD testing methods have seen major advancements with the advent of new technology. Currently, CWD is receiving much attention from researchers, and newer methodologies are being developed. With the development of these more sensitive and semi-quantitative approaches has come a greater understanding of the pathogenesis and epidemiology of this disease. These newer techniques have not yet been deployed in control programs due to pitfalls these methods have during routine testing and scalability problems they present. However, the problems these newer technologies present are being addressed and these methods are set to change CWD diagnostics in the very near future. The two such most studied new techniques for CWD detection are Protein Misfolding Cyclic Amplification (PMCA) and Real-Time Quaking-Induced Conversion (RT-QuIC). Both of these techniques have yet to receive USDA approval, but PADLS has already begun investigating their usefulness and accuracy. Currently, under the newly-unveiled USDA National CWD program plan, only the National Veterinary Services Lab in Iowa will be approved to perform ante-mortem testing on Rectal Mucosal Lymphoid Tissue (RMALT) and investigate genetic variability within the codon 96 of the Prion protein gene in at-risk white tail deer. This gene is said to afford resistance to the CWD disease progression. The department is ready to deploy these new options when and if they are approved.

Managing Chronic Wasting Disease in Pennsylvania

Pennsylvania has the second largest domestic cervid (a cervid is any animal in the deer family) industry in the country. There are currently 896 domestic cervid breeding farms, hobby farms, and hunting preserves in the Commonwealth.

Today, 205 cervid breeding farms are enrolled in the CWD Herd Certification Program, a federally guided, state-administered voluntary program of surveillance and related actions designed to determine the CWD status of farmed or captive deer and elk herds. Herds that have completed five years of complaint participation in the program with no evidence of CWD are designated "Certified." Participation in this program allows for interstate movement of cervids.

The remaining herds are enrolled in the CWD Herd Monitored Program, a mandatory program of surveillance and related actions designed to monitor farmed or captive deer and elk herds for CWD. This program restricts movement of cervids to within Pennsylvania.

Chronic Wasting Disease was listed as a dangerous transmissible disease in July of 2000 by the Pennsylvania Department of Agriculture due to its potential negative impact on cervid herd health. By designating Chronic Wasting Disease as a dangerous transmissible disease, any cervid owner, veterinarian, or diagnostic laboratory suspecting a case of CWD is obligated to report it to the department immediately. Suspect animals include all cervids exhibiting signs of staggering, drooling, wasting, or other unusual behavior. It is important to note that clinical signs are not predictable and may only be seen in the end stages of the disease.

The department's BAHDS currently enforces a 2014 Quarantine Order, CWD Program Requirements for Herd Certification Program and Herd Monitoring Program, and the USDA Chronic Wasting Disease Program Standards. These regulatory documents strictly delineate: 1) annual herd inventory reporting requirements; 2) fencing requirements; 3) identification and testing requirements and 4) provide guidelines on how infected herds and herds that may have sold into them or purchased from them must be quarantined to mitigate disease threat. These requirements are designed to detect the status of CWD within a herd and to promote healthy cervids (both farmed and wild populations) with a reduced risk of CWD.

Since the inception of testing in 1998 by PVL, more than 33,500 captive deer have been tested for CWD and 49 have been confirmed positive. Nine positive premise have been identified and all but four have been depopulated. The four remaining farms remain under quarantine with mandatory monthly facility inspections, strict requirement to test 100% of all cervids 9-months and older for CWD that die for any reason and movement is restricted onto and off a farm for all cervids and potentially contaminated equipment. Any time a positive is detected on a quarantined facility the 5-year quarantined period is reset to count down an additional 5 years.

Building a strategic plan to manage CWD

In 2011, Pennsylvania established an inter-agency CWD Task Force to implement its CWD Response Plan. The task force is currently comprised of PDA, PGC, the Pennsylvania Department of Health, the Pennsylvania Department of Environmental Protection, and USDA's APHIS Veterinary Services and Wildlife Services. Recently, the Pennsylvania Department of Conservation and Natural Resources has also become a valuable partner in managing CWD and has joined the task force. This partnership is vital in continuing to manage this disease as they bring to the table their Bureau of Forestry's mission of ensuring the long-term health, viability, and productivity of the commonwealth's forests and the conservation native wild plants. The management of the "collective herd" (i.e. all the wilds and captives alike) is critical to the preservation of our valuable Penn's woods.

The Department of Agriculture continues to work closely with the Pennsylvania Game Commission (PGC) to monitor this disease and to help educate deer farmer and hunter alike about how to recognize the signs of CWD, where to report it, and how to have deer tested. PDA is responsible for oversight of domestic deer while monitoring for CWD cases outside of farms is the responsibility of PGC. Our two agencies are partners in the challenging fight against CWD. Our two agencies work cooperatively as our jurisdiction intersects at the junction between the captive and the wild deer against a disease that knows no bounds recognizing that this is an issue both inside and outside of the fence.

Moving forward

The department recognizes that our efforts to address CWD must be both proactive and responsive and may be subject to the cooperative efforts of others. Uniform mitigation standards must be implemented across the collective herd and cooperatively across all Commonwealth agencies to lessen the odds of disease spread.

Planning is underway to implement the following steps:

- Continue to educate the public about CWD;
- Institute a High-risk parts ban;
- Uniform Harvest Tag Identification (HIT) requirements for all CWD susceptible species;
- Joint enforcement of taxidermy regulations to ensure compliance with high-risk parts ban;
- Further collaboration with academia and industry to research potential CWD-resistant genotypes and environmental factors that may contribute to disease incidence.

It is mission critical to educate cervid farmers, hunters and wildlife enthusiast alike not to transport high- risk parts out of endemic areas to prevent disease spread. In addition, educating the public about the downside of feeding the wilds since it congregates deer and makes prion spread more likely is important. We need to consider density management and age management of the "collective herd" as tools that can help control disease spread.

High-risk parts coming out of the Deer Management Assistance Program (DMAP), regardless of the source puts the "collective herd" at risk. The PGC high-risk parts ban was recently imposed on OH, NY, WV, MD in addition to existing DMAP restrictions. The department is in the process of modeling a high-risk parts ban after the PGC ban for all captive deer that are harvested in a DMAP.

Currently, language is being drafted to amend the department's CWD Order of General Quarantine to require HIT tags on every CWD-susceptible deer harvested in captivity. HIT tags from DMAPs will be color-coded and have a unique premise ID and sequenced number. The result of this initiative will be to provide quick means to identifying high-risk parts taken out of a DMAP.

Finally, the department is responsible for licensing the more than 1,500 taxidermists in this state. Taxidermists are only required to maintain records of the type of species mounted and the location where the specimen was harvested. The department has no authority to investigate or prosecute any instance where whole carcasses may have been illegally imported from a DMAP or from out of state and brought to a licensed PA taxidermist. Joint enforcement of taxidermy regulations by PGC and PDA is critical to ensure compliance with high-risk parts ban and to ensure proper carcass disposal.

Conclusion:

In closing, Chronic Wasting Disease is a clearly documented and pernicious disease that is expanding in Pennsylvania and will continue to expand if unchecked. The approach to addressing CWD must be comprehensive, and inclusive, and must use the best available science; both short-term and long-term solutions will be required.

Thank you and I look forward to your questions.

"Defenders of the short-sighted men who in their greed and selfishness will, if permitted, rob our country of half its charm by their reckless extermination of all useful and beautiful wild things sometimes seek to champion them by saying that "the game belongs to the people." So it does; and not merely to the people now alive, but to the unborn people. The "greatest good for the greatest number" applies to the number within the womb of time, compared to which those now alive form but an insignificant fraction. Our duty to the whole, including the unborn generations, bids us to restrain an unprincipled present-day minority from wasting the heritage of these unborn generations. The movement for the conservation of wildlife and the larger movement for the conservation of all our natural resources are essentially democratic in spirit, purpose, and method."

Theodor Roosevelt (1916)