Testimony on behalf of the

National Cattlemen's Beef Association

With regard to

Foot and Mouth Disease Preparedness

Submitted to the

United States House of Representatives – Committee on Agriculture
Subcommittee on Livestock and Foreign Agriculture

The Honorable David Rouzer, Chairman
The Honorable Jim Costa, Ranking Member

Submitted by

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BEEF USA National Cattlemen's Beef Association

Mr. Chairman, Ranking Member Costa and members of the subcommittee, my name is Dr. Dave Sjeklocha. I am a veterinarian and the Operations Manager for Animal Health and Welfare for Cattle Empire, LLC. Cattle Empire is owned by the Brown family and is located in southwest Kansas. The company consists of five feedyards, ranging in size from 18,000 head capacity to 87,000 head capacity, for a total one-time capacity of approximately 240,000. In addition, there is a farming and ranching operation associated with Cattle Empire.

I grew up on diversified farming and ranching operations in Iowa and Missouri and received my degree from Kansas State University's College of Veterinary Medicine. Before joining Cattle Empire I spent several years as a practicing veterinarian in Nebraska, Colorado, Kansas, Texas and Oklahoma with a focus on beef cattle production management and medicine. I am an active member of the American Veterinary Medical Association, the Academy of Veterinary Consultants and the American Association of Bovine Practitioners. In 2011, I was recognized as the Beef Cattle Institute's "Beef Cattle Veterinarian of the Year" from Kansas State University and in 2013 recognized as the AVC's Consultant of the Year.

NCBA is the nation's oldest and largest trade association representing America's cattle producerswith a strong and united voice in our nation's Capital. On behalf of NCBA's membership, I appreciate the opportunity to share with you more background on Foot and Mouth Disease (FMD), our concerns regarding this disease, and our ability to respond to a reintroduction of FMD into the United States.

FMD is an extremely contagious viral disease of cloven hoofed animals and some wildlife species. FMD is present in approximately two-thirds of the world and endemic in parts of Africa, Asia, Eastern Europe, the Middle East, and South America. North America and Central America are free of FMD, as is Western Europe, Australia, and New Zealand. The United States has not experienced an FMD outbreak since 1929, yet FMD is still a significant threat to American cattle producers. International travel and trade pose a substantial risk for FMD by providing pathways to enter the United States. FMD can be transmitted over long distances by animal products, people and other vectors. FMD is also considered as a potential agent for agricultural terrorism. The size, structure, efficiency, and extensive movement inherent in the United States livestock industry will present unprecedented challenges in the event of an FMD outbreak. No country with a livestock industry comparable to the U.S. has had to deal with an outbreak of FMD.

FMD presents a great economic threat to U.S. livestock producers and is viewed as the most concerning trans-boundary disease in the world. An FMD outbreak in the United States would result in the immediate closure of most, if not all, of our foreign export markets. To put this into perspective, we need to only look at the economic impact of a single case of bovine spongiform encephalopathy (BSE) found in a Canadian-born cow located in Washington state on December 23, 2003. As a result of a single case of BSE, we saw U.S. beef exports decline by two billion pounds from 2003 to 2004. It took eight years for U.S. beef exports to get back to pre-December 2003 levels. Over a decade later

we still do not have access to several critical markets, such as China, nor do we have full access to every country we were trading with prior to December 2003. It's not just the international trade impact which concerns us. In addition, we expect to see significant economic impact to U.S. beef producers due to depopulation, restrictions on cattle movements, and a potential shutdown of overall cattle trade in the affected regions. There are many variables which affect how we may see introduction of the disease and its spread. These variables include the region of the country, the type of operation, the timely reporting of the disease, and the response time. In the "Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment" conducted for the National Bio and Agro-Defense Facility, models are used to estimate the economic impact of an outbreak of FMD. In scenarios that model the economic impact of FMD on cow-calf operations, feedlots, and livestock markets, the total economic impact of a case of FMD can reach over $50 billion in losses to the U.S. beef industry. Again, we must note that this report was based on 2010 cattle prices where the average fed cattle price was $95 per hundredweight. Currently, Live Cattle futures are in the $135 per hundredweight range. Regardless of the model or scenario used, it is obvious from the information above that the reintroduction of FMD would cost our industry billions of dollars.

The goals of USDA's Animal and Plant Health Inspection Service (APHIS) in managing an FMD outbreak in the United States are to detect, control, and contain the outbreak in order to eradicate FMD from the country as quickly as possible. As a result of changes in livestock demographics and larger herd sizes, the FMD control paradigm at USDA-APHIS has shifted from "stamping out" or total depopulation, to the use of vaccination to achieve control for type 3 outbreaks or larger. In September 2014, NCBA joined other animal agricultural stakeholders attending a meeting called by USDA-APHIS to develop concrete strategies to improve alignment between USDA's response strategies for FMD and our current vaccine capabilities. The stakeholders in attendance were informed that gaps existed in vaccine preparedness for a type 3, (large regional), or greater FMD outbreak. An immediate need was identified at this meeting to begin modernization of the current U.S. FMD vaccine response capabilities. Budgetary shortfalls at USDA for acquiring sufficient supplies of FMD vaccine present a major hurdle to achieving modernization of the FMD vaccine capabilities in response to an FMD outbreak.

There are critical reasons for considering vaccination strategies in an FMD outbreak. In anything beyond a small, focal FMD outbreak, stamping out or rapid depopulation is not viable or sustainable. There is a lack of capability and capacity to rapidly depopulate and dispose of the large number of carcasses which would be found in feedyards that can easily feed 50,000 to 100,000 head of cattle. Even the smaller feedyards would pose a challenge for "stamping out," both logistically and economically. During the 2007 Palo Duro FMD exercise in the Texas Panhandle, rapidly depopulating 50,000 to 75,000 head of cattle was deemed a logistical challenge that would not be possible within 72 hours for depopulation and within 96 hours for disposal. Since the Texas Panhandle is a livestock dense region, 75,000 animals constitute only a small portion of the region's total susceptible livestock population (over 3.5 million animals in a 100 mile radius). If FMD spread rapidly prior to detection, it is clear that a stamping-out strategy would not be feasible or appropriate.

Key objectives have been identified by APHIS Veterinary Services in regard to FMD vaccine and vaccination policy, and there is definite recognition that additional response capabilities will be required. There is an immediate need to increase the guaranteed access to FMD vaccine. The requirements to achieve response goals include: identifying the type of vaccine needed (topotypes and strains); establishing multiple sources or manufacturers; establishing which vaccines will be used in specified livestock populations; establishing a desired quantity of vaccine and determining the necessary time to deliver the vaccine.

Vaccination of cattle against FMD has been practiced with relatively positive immunity results. Cattle are considered to be the highest priority for emergency FMD vaccine use. If the disease is under control in cattle, it should not persist in other species. For example, in the 2001 FMD outbreak in Uruguay, the outbreak was brought under control by the rapid vaccination of all the cattle in the country. To effectively induce immunity in the cattle population, all cattle in the affected region should receive two doses of normal potency FMD vaccine one month apart, or a single dose of high potency FMD vaccine as soon as possible. Certain limitations of vaccination, however, do exist. Vaccines provide only serotype specific protection. There are seven immunologically distinct serotypes of the FMD virus and more than 65 strains. There is a substantial amount of genetic variability in FMD viruses, and new strains can occasionally develop spontaneously. Also, vaccination against one serotype may fail to protect fully or at all against other strains within the serotype. Immunity is not immediate. Inactivated FMD vaccines may decrease viral shedding and clinical signs in cattle as early as 4 days with protection improving over the next 2 to 3 weeks. No currently available vaccine provides "sterilizing immunity" which will prevent subsequent infection. It is possible that individual vaccinated cattle which are infected with FMD virus could become asymptomatic virus carriers. Differentiating field infected animals from vaccinated animals, known as DIVA strategy, is critical to emergency vaccination in an FMD outbreak. DIVA diagnostic techniques typically use tests for antibodies against viral non-structural proteins (NSPs) to differentiate animals that are infected with FMD naturally from those animals vaccinated with FMD vaccine. The diagnostic DIVA capability of a vaccine is important for an effective vaccine campaign, business continuity processes, and FMD surveillance. All FMD vaccines should be DIVA compatible unless the animals are intended for slaughter.

Currently, FMD virus is listed by USDA as a "select agent" on the Select Agent Program registration list. This means that it is currently illegal to have FMD virus on the U.S. mainland, even for FMD vaccine production purposes. As such, there is no conventional, killed virus FMD production (which requires live FMD virus) in the United States. The U.S. must rely on the overseas production of FMD vaccine in the event of an FMD outbreak.

Novel FMD vaccine technologies are currently under development using subunit and recombinant DNA. These vaccines do not utilize live FMD virus and can be safely produced in the U.S. mainland. USDA's Agricultural Research Service (ARS) scientists

at Plum Island, New York, have developed a leaderless FMD vaccine (FMD-LL3B3D) that will allow safe production of FMD vaccine on the U.S. mainland and protect livestock against clinical disease as well as prevent virus shedding and virus transmission. Although work has started for commercialization of the leaderless FMD vaccine, the cost and timeline for vaccine production remains highly uncertain. NCBA actively supports the development of novel FMD vaccine technologies, such as the USDA-ARS leaderless FMD vaccine technology, for use in meeting future FMD vaccine needs. In addition, NCBA requests immediate steps be taken to update the current FMD vaccine supply made up of conventional vaccine technology in order to meet surge capacity for emergency use and to safeguard the health of the U.S. cattle herd.

The structure of modern agriculture in the United States, including large herd sizes and extensive intra- and interstate movement of cattle and cattle products will make it nearly impossible to control an FMD outbreak in livestock dense areas without the rapid use of tens of millions of doses of FMD vaccine. It is estimated that over 400,000 head of cattle are in transit daily in the United States. Established in 1982, the North American FMD Vaccine Bank currently holds vaccine antigen concentrate for use by Mexico, Canada, and/or the United States. The amount of antigen in the North American FMD Vaccine Bank is far below what would be needed to provide vaccine for a single livestock dense state in the United States. The funding that USDA has for the supply of FMD vaccine in the National Veterinary Stockpile is insufficient to provide adequate FMD vaccine supplies. An outbreak of FMD occurring in a livestock dense area, such as Iowa, and which was not contained rapidly with "stamping out", could easily exhaust the world's supply of emergency FMD vaccine. A FMD outbreak in South Korea depleted the banks of FMD vaccines from around the world in order to vaccinate a population roughly half the size of the livestock population in Iowa. For an outbreak in Iowa with over 20 million hogs and approximately 4 million cattle, the amount of vaccine needed could easily exceed 50 million doses in a very short time. Insufficient vaccination capacity limits the ability of a strategic response to FMD by USDA. The need for additional supplies of FMD vaccine, as well as new vaccine approaches and technologies, to help meet this need has been recognized by USDA and Department of Homeland Security (DHS) officials. USDA has funded the development of the Secure Food Supply Plans that incorporate the use of FMD vaccines as an important tool. Currently, the beef industry is involved in a collaborative effort with USDA, state animal health officials, and academic partners to develop a Secure Beef Supply Plan to manage movements of non-infected cattle in the event of an FMD outbreak; provide business continuity for producers, transporters, and processors; and to maintain a continuous supply of safe and wholesome beef for consumers.

NCBA supported the preparation of a white paper by Dr. James Roth, distinguished professor and veterinary specialist at the Center for Food Security and Public Health at Iowa State University's College of Veterinary Medicine entitled: "FMD Vaccine Surge Capacity for Emergency Use in the United States." The objectives of the white paper involved securing and providing information concerning FMD vaccine that could be used to seek consensus among the stakeholders, federal officials, and state officials on the best mechanisms to ensure vaccine availability to minimize the economic, environmental,

animal welfare, and food security impacts of a large FMD outbreak in the United States. In the white paper, Dr. Roth concluded that the funds necessary to enable the surge capacity need for FMD vaccine for emergency use in the United States would be estimated at $150 million per year for five years to help to protect a $100 billion dollar a year (cash receipts) animal industry. In September of 2013, the World Reference Laboratory for FMD at the Pirbright Institute in Pirbright, United Kingdom, recommended that national antigen banks for FMD maintain 23 strains of FMD virus as live master seeds and inactivated antigen concentrates.

Subsequent to the agriculture stakeholder meeting held in September 2014 with USDA-APHIS to discuss the U.S. FMD vaccination policy for response to an outbreak and existing gaps, USDA- APHIS agreed to develop a Request for Information or "RFI" to companies regularly engaged in FMD vaccine production so that an estimated cost to update the current FMD vaccine bank for the United States could be determined.

Homeland Security Presidential Directive 9 (HSPD-9, January 30, 2004) provides for the "Defense of United States Agriculture and Food." This directive establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. HSPD 9 directs the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, and in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, to work with state and local governments and the private sector to develop a National Veterinary Stockpile (NVS) containing sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy and that will be capable of deployment within 24 hours of an outbreak. It is urgent to develop a plan to ensure that adequate supplies of multiple strains of FMD vaccine are readily available in the event of an accidental or intentional introduction of FMD virus into the United States. This action is mandated in Homeland Security Presidential Directive 9.

We encourage USDA to consider convening a stakeholder community working group of experts capable of evaluating existing and new technology FMD vaccines under development to determine the technologies which can best meet future as well as immediate needs for emergency response FMD vaccination in the United States. Furthermore, the Federal government must conduct research into alternative delivery methods for FMD vaccines which have been shown in cattle and in swine to significantly reduce the antigenic mass required for each dose of vaccine, thus enabling existing and future vaccine antigen concentrate to be formulated into significantly more doses of vaccine.

The current FMD vaccine bank has several problems. Currently, the United States does not have access to enough FMD vaccine to handle an outbreak beyond a very small, localized disease event. APHIS manages the vaccine bank at Plum Island, New York, where vaccine antigen concentrate for a limited number of FMD strains is stored. In the event of an FMD outbreak, the antigen would need to be shipped to Pirbright, United Kingdom, or Lyon, France, to be turned into finished vaccine and then shipped back to

the United States for use. This bank is currently funded at $1.9 million annually. The turnaround time from the onset of an outbreak until finished vaccine product can be delivered to the field would be weeks for a small FMD event and months for a larger FMD outbreak. Of equal concern is the limited number of FMD vaccine antigen strains currently maintained at Plum Island and the limited shelf life of the vaccine antigen concentrate that would affect the potency of the finished vaccine, should the expiring vaccine antigen stock not be rotated out of storage. Additionally, worldwide FMD vaccine production is limited and there is no surge capacity currently available to produce the millions of doses needed in the event of a large-scale FMD outbreak in the United States. Manufacturers with contracts in place are producing at maximum capacity for their contracted customers and will not abandon these established customers to produce vaccine for the United States. Furthermore, the FMD vaccine bank is scheduled to move in the future to the NBAF facility in Kansas and the storage capacity may be limited for FMD vaccine. For these reasons, we recommend consideration for establishing a contract for a vendor-managed, offshore FMD bank that has the capability to produce vaccine antigen concentrate for all FMD strains currently circulating in the world. A contracted offshore FMD bank would provide a vendor-managed-inventory of vaccine with replacement of outdated product, facilitated vaccine finishing, and ultimately increased efficiency in FMD vaccine delivery for use in an FMD outbreak.

Finally, we request that the Committee work with USDA and encourage them to budget the funds needed for the update and modernization of the National Veterinary Stockpile of FMD vaccine.

Thank you for the opportunity to be here today, and we look forward to working with you to ensure that the United States is prepared for an outbreak of FMD.