

**Iowa’s Harrisvaccines gets bird flu vaccine order from USDA**

October 14, 2015

Harrisvaccines will supply its vaccine to the U.S. Agriculture Department to help prevent poultry from getting the deadly bird flu virus that battered Iowa and 14 other states this year, the Iowa company said Wednesday.

The USDA’s Animal and Plant Health Inspection Service (APHIS) awarded the Ames livestock vaccine manufacturer a $6 million, two-year contract to provide 48 million doses, 25 million of them by the end of November.

France-based Ceva Corp. also was awarded a $6 million contract to manufacture its vaccine.

“We are very close to people very worried about what could happen” if the virus returns again, said Joel Harris, a vice president with Harrisvaccines. “(We’re) in a position to rapidly produce additional vaccines if the virus changes or a new strain emerges.”

Harris said the contract from USDA was “a very significant order for us and it just validates the potential value this company could have,” citing its success in developing a vaccine for the fast-moving porcine epidemic diarrhea virus.

He said the 45-employee company is looking at using its platform to develop vaccines for other species such as foot-and-mouth-disease in cattle and canine influenza in dogs. Harrisvaccines also is seeking partners overseas to help expand its business around the world. In the long term, the company could explore potential vaccines for humans.

The bird flu virus spread through 15 states this year, resulting in the death of 50 million chickens and turkeys. In Iowa alone, almost 34 million birds were lost to the disease, including about 40 percent of the state’s egg-laying hens.

State and federal regulators are closely watching to see if the virus reappears this fall as birds migrate for the winter. Researchers have said the virus spreads from the droppings of wild birds, but “lapses” in biosecurity by workers, such as failing to sanitize boots or equipment, contributed to the outbreak.

The USDA told drug companies in August it was interested in stockpiling as many as 500 million doses of one or more vaccines. The department said the companies must be able to make the vaccine quickly, with delivery within 10 days of the order, and store the doses as long as five years.

The companies are allowed to sell their vaccines only to the USDA, and cannot distribute them to poultry producers to use. But the decision to stockpile the vaccine does not mean the USDA has decided to vaccinate birds for the deadly bird flu virus.

“While APHIS has not approved the use of vaccine to respond to (highly pathogenic avian influenza), the agency is preparing to ensure that vaccine is available should the decision be made to use it during a future outbreak,” APHIS said in a statement. “Any decision to use vaccination in a future HPAI outbreak would require careful consideration of the efficacy of the vaccine, any impacts of using HPAI vaccine in the field, and the potential trade impacts.”

The USDA has said any decision to use a vaccine will be made with state and industry officials to assess the impact it would have on trade. Broiler chicken producers who depend on trade have expressed concern that some trading partners could ban U.S. poultry imports if the vaccine is used. Egg and turkey producers, who are less dependent on exports, have been more open to the vaccine.

Harrisvaccines said its vaccine can be produced in about four weeks and can be quickly altered to reflect mutations in the virus. Researchers are able to differentiate the company’s vaccine from the virus itself, meaning animals will not test positive for the bird flu simply because they were vaccinated. This could be beneficial for U.S. trade if the government decides to use a vaccine.

The company, which first started work on the vaccine in March, already has started production at its facility in Ames.



**Bird Flu Vaccine Conditionally Approved, but still can’t be sold**

September 21, 2015

A vaccine to help protect the nation’s chickens from avian influenza after more than 48 million birds died during an outbreak this year has cleared a first hurdle, with the Agriculture Department granting its maker a “conditional” license.

Harrisvaccines announced on Monday that the department had granted the license, a type issued to deal with emergencies, market limitations or other special circumstances, for a vaccine that can be easily updated as new strains of the virus appear.

But the company does not yet have government approval to sell the drug.

“U.S.D.A. has said no vaccine is to be used for highly pathenogenic avian influenza,” said Joel Harris, vice president for sales and marketing at Harrisvaccines, which was founded by his father, Dr. Hank Harris. “What this license does is that if they allow a vaccine to be used, we would immediately have a U.S.D.A.-licensed product available for producers.”

The H5N2 strain of avian influenza that did most of the damage in the spring is extremely virulent, moving from one or two birds to entire flocks within 24 to 48 hours. It is believed to have been spread by wild birds migrating north, and poultry and egg producers have been concerned that birds will bring it or another equally devastating strain back with them as they begin their migration south this winter.

Last month, the Agriculture Department announced plans to create a stockpile of vaccine for the Eurasian H5 virus strain that destroyed flocks earlier this year and asked vaccine developers to submit their proposals. Mr. Harris said the stockpile would contain 500 million doses of vaccines, most likely supplied by several companies.

A U.S.D.A. spokeswoman referred questions about the vaccine to the department’s announcement about the stockpile.

Mr. Harris said Harrisvaccines, which previously developed a vaccine used to combat a deadly pork virus, had been working to develop such a vaccine since the outbreak began, and it submitted its vaccine to the U.S.D.A.’s Southeast Poultry Research Center for evaluation.

The company’s technology creates a synthetic version of a virus’s genetic code and uses that to make a vaccine, eliminating the need to work with a live virus in making the drug.

Harrisvaccines is continuing to test the efficacy of the vaccine, with one trial with turkeys underway and other planned for testing on adult hens and day-old chicks. Mr. Harris said the biggest drawback so far is that the vaccine must be injected, which is logistically complicated in operations involving tens and even hundreds of thousands of birds.

He said he did not know whether the company would ever sell the vaccine directly to producers or whether it would be bought for the government stockpile and distribution.

“Down the road,” Mr. Harris said, “we can use this license to register the product in foreign countries that have avian flu endemically.”



**2015 Pork Master: Hank Harris, Vaccine company entrepreneur**

June 5, 2015

It’s not the first time Harris has been featured in the magazine; in 2005 Harris was named as one of the 50 top contributors to the swine industry. “That’s the year I started this company,” Harris notes. And that’s important in his being named a 2015 Pork Master. After what was already an influential career, Harris wasn’t finished as he got Harrisvaccines started. Sitting in Hank Harris’ office in Ames, Iowa, it’s not hard to picture him lecturing to a new class of young veterinary wannabes interested in being a part of the world of animal medicine. Yet he’s speaking to National Hog Farmer at Harrisvaccines, a firm innovating the way viral diseases are treated.

As Harrisvaccines enters its 10th year, the firm is still celebrating a major win. Last year the company licensed the first vaccine for the treatment of porcine epidemic diarrhea virus, but that success came after more than a decade of work in developing a new approach to viruses. Perhaps the bigger surprise to Harris’ friends happened back when he made the switch from bacteriology to virology as his specialty.

“I began working in virology to tackle PRRSV [porcine reproductive and respiratory syndrome virus],” Harris says. “That was the direction I felt I needed to go, and that’s what led me to the technology we’re using today.”

That road wasn’t a smooth trip on fresh pavement. For Harris, who has always had an entrepreneurial spirit, creating a new way to take on PRRSV meant financing research into novel ways to tackle troublesome and difficult diseases, and blazing a path for a different approach to vaccine development.

Harrisvaccines is a pioneer in the animal vaccine business using an approach called RNA particle technology. Researchers in the firm’s lab never get near the live virus for anything they’re treating. Instead, a diagnostic lab just sends along an electronic map of a key part of the virus, and from that Harrisvaccines can start to build a vaccine. (See “[Designing a vaccine](http://nationalhogfarmer.com/health/designing-vaccine).”)

**Starting on the farm**

Harris grew up on a farm not far from Ames, working with all kinds of animals through 4-H and FFA projects. “We had them all,” he chuckles, looking back. “We were a purebred Duroc breeder; we had Angus cattle, rabbits and sheep.” Back in the 1950s, that kind of diversification was common for farms, and from that Harris gained a respect for animal health and husbandry.

Harris was always going to go to Iowa State, but back then the idea of leaving the farm for college was still novel. He recalls his father being chastised by other family members for sending Hank and his brother to college. “He was just adamant that we would go to college, didn’t have the money necessarily, but that we were going to college,” Harris recalls. “It was fantastic … there wasn’t any question.”

But it appears pigs would get most of his attention. Harris earned his doctor of veterinary medicine degree from Iowa State University, and his work as a student with Bill Switzer led him down a research path — including a research program when he graduated.

“I practiced in the field for three weeks, once,” he recalls. “A classmate asked me to cover for him for three weeks, and I helped out his practice near Mount Pleasant, Iowa. I got the practice fever out of me then.”

He laughs easily when he tells the story of his “fieldwork,” but it was his work in the lab and creating new ways to protect pigs that was more interesting; that has led to some industry-leading discoveries. In the 1970s, Harris is credited with discovering and naming the cause of swine dysentery, a debilitating herd disease that was a global problem. Harris’ research team at Iowa State discovered the root cause of the disease, *Brachyspira hyodysenteriae* — a nasty bug that causes heavy herd losses.

The ISU research coincided with work at Cambridge University that made a similar finding and validated the work at the time. Identifying the problem was the first step in finding prevention measures to help producers protect herds.

Yet Harris had an entrepreneurial bent. While research was his focus, he looked off campus to the idea of creating his own business. He was one of the founders and a CEO of NOBL Laboratories. The business grew to be a leader in the development and manufacture of novel swine vaccines. That work included the development of highly effective oral ileitis and intranasal atrophic rhinitis vaccines. The work caught the attention of another company that was growing its U.S. business — Boehringer Ingelheim Vetmedica. BIVI acquired NOBL Labs in 1997. By then Harris was already on to other things.

Harris later joined PIC — originally known as the Pig Improvement Co. He set up the company’s health program and was involved with the firm’s innovative system of swine breeding and genetics. He’s also credited with helping perfect the PIC multiple-site production system — a process that has been adopted globally.

Eventually, Harris moved up to become a vice president of PIC USA. “They actually brought weekly recordkeeping to the United States,” Harris recalls. “When they came in during the early 1970s, the idea of once a week actually doing an inventory of the deads by age group, and calculating your costs, whatever the expenses were that week and whatever the income was that week … those were not common concepts in the industry at that time.”

He notes that England, back in the 1970s, was already ahead of the U.S. in numbers like pigs per sow per year and management approaches. When he joined, PIC was growing, and Harris was part of that as the firm expanded in the 1980s.

By the turn of the century, Harris had an impressive resume. Looking back, he says that perhaps what has worked for him is that he gained the mindset of the entrepreneur. “An entrepreneur is a person who is always seeking solutions, you know, finding an interesting problem and doing whatever it takes to find the solution,” Harris says. “I’m not inhibited by not knowing something about a technology or an area of interest. Just dive in and do it.”

That problem-solving attitude even brought on a significant course change in his career in the early 2000s. “I switched to shrimp in 2002 and switched to viruses in 2003. And [up until then] I’d spent my whole career as a microbiologist working on bacteria,” he says. “That may not translate well, but that’s actually … my virology friends couldn’t believe it.”

And why the change? “It was PRRSV; that’s the best explanation,” he says.

The road to virology started a decade earlier when Harris returned to the ISU faculty, and he had to refresh his knowledge of molecular biology — a fast-growing science that has led to significant genetic discoveries. “I guess the more I learned about molecular aspects and thought about PRRSV, it just drove me” toward virology, he says.

Part of that move also involves the simplicity of viruses. Bacteria are complex organisms, but viruses are actually quite simple, Harris says. And that’s true of the cornerstone of the vaccine work he’s involved in now.

“Even the technology we use now to make vaccines, the virus we use that it’s derived from is a very simple virus molecularly speaking. That’s why it’s so easy to work with,” Harris says. “It’s why we’re able to make a new vaccine so quickly.”

A simple alphavirus is the base of what Harrisvaccines does today. The simple virus allows researchers to drop out one RNA for another and then replicate it for later creation as a vaccine. It’s the RNA that creates the immune, and cellular, response in the animal to fight off the disease. The key is to identify the right strand of RNA to prevent/treat the disease. And there’s the rub.

“We still haven’t found the solution for PRRSV,” Harris laments. “I think that’s really amazing that you start a company specifically to solve the major problem in the industry, and we’re still working on it, and yet the company has been successful, because we took technology that we thought would work for PRRSV and we were able to find that it was very useful for other diseases.”

As for PEDV? That was actually easier. “We identified the strain from China and identified the right RNA to treat for the disease,” Harris says. “PEDV is a highly conserved virus, which means that the part we chose is conserved across different strains of the virus.”

That “conservation” means that the Harris’ product doesn’t have to be customized to treat the disease in a specific herd. The PEDV vaccine works no matter the origin of the PEDV strain in a specific herd.

**Herd specificity and new technology**

It’s that herd specificity that first helped Harrisvaccines get through some regulatory hurdles when it started out. The idea of creating vaccines using particle RNA, which provides the ability to develop a vaccine in as little as four to six weeks, was a new idea to regulators. Normally, a vaccine has to go through a wide array of regulatory hurdles to get to market.

Harris notes that visitors to the facility are surprised by its size. While it has expanded space recently, the preconceived image of the company differs from what you see when you get to the Ames plant. “We use one technology to create a variety of vaccines.”

Regulators were also not up to speed on the new concept, which for a fledgling company can be a challenge, but the firm started generating income by selling its products under rules associated with autogenous vaccines (those mixed by the local veterinarian for a herd-specific problem). Using those rules with the USDA built the ground work.

Harris chronicles the process of working with regulators, lobbying the USDA and keeping up pressure. In 2012, Harrisvaccines became the first company to get full USDA approval for its H3N2 swine influenza vaccine, RNA. This was a proof of the concept that the vaccine platform was safe and efficacious. At the same time, researchers were applying the technology to new diseases. The arrival of PEDV showed that this new RNA technology could make a difference. Today, the Harrisvaccines’ PEDV vaccine is conditionally licensed by the USDA.

The company is also developing a wide range of other vaccines for use in the equine, cattle, poultry, canine and even shrimp markets. Harris got interested in shrimp — commercial shrimp have a range of potential diseases — as part of his move to viruses, too. “Shrimp are fascinating,” he notes.

**Looking ahead**

Harris, now 71, is looking to the future. “I’m looking toward retirement,” he says. “I want the company to go on, and I think we’re set up for that.” He acknowledges that the firm will need more investment if it is to grow, a constant challenge for a startup.

His sons are involved in the firm, which is a source of pride for Harris. And he feels his young team of researchers is well on its way to working out solutions to a wide range of problems, including foot-and-mouth disease and other herd issues.

Hank Harris is a pork industry leader because he’s always looking for a solution to the next problem. That lays the groundwork for a solid future for Harrisvaccines, and perhaps an eventual solution for PRRSV. It has also poised Harrisvaccines to take on newer emerging diseases in other species. Avian and canine influenza are plastered in the headlines as of late, and Harrisvaccines has already begun working on candidate vaccines for both the poultry and companion animal industries.

“This is just what our production model is meant for, to rapidly respond to new diseases faster than anyone else,” Harris notes.