mRNA Vaccines in Livestock and Companion Animals are here now.

The current (public) receipts are included in this essay, and more are on the way

Robert W Malone MD, MS
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Before we can discus mRNA vaccines for livestock, pets and wildlife, we must first address the elephant in the room. That is, how come the public is able to access human clinical trial information, but is not able to do the same for clinical trials involving animal health?

During the early days of the AIDS epidemic, the AIDS community demanded public access to clinical trials. In 1988, the U.S. Congress passed the Health Omnibus Programs Extension Act of 1988 (Public Law 100-607) which mandated the development of a database of AIDS Clinical Trials Information Services. This Congressional Act motivated other non-profit disease related groups to demand access also.

The Food and Drug Administration Modernization Act of 1997 amended the Food, Drug and Cosmetic Act and the Public Health Service Act to require that the NIH create a

and Cosmetic Act and the Public Health Service Act to require that the NIH create a publicly available clinical trials database. This eventually led to the development of the website ClinicalTrials.gov. This allowed tracking of drug efficacy studies resulting from approved Investigational New Drugs (including vaccines).

The law requires (from Wiki):

- Federally and privately funded clinical trials;
- The purpose of each experimental drug;
- Subject eligibility criteria to participate in the clinical trial;
- The location of clinical trial sites being used for a study; and
- A point of contact for patients interested in enrolling in the trial.
- The National Library of Medicine in the National Institutes of Health to host the public website/database

(BTW, one of my former clients held the federal contract to support ClinicalTrials.gov and Pubmed. I have spent time in the back rooms of the NLM and do know a fair amount about these things….)

The searchable ClinicalTrials.gov website was made available to the public via the internet on February 29, 2000.

ClinicalTrials.gov makes searching for human clinical trials easy. For instance, a quick search reveals that there are over 50 clinical trials for mRNA vaccines in progress and over 200 registered.

With animals, there is no such database. mRNA vaccines in the "animal health" or veterinary markets are difficult to track until the company or the USDA is ready to release information on that product's development or release. The USDA and/or the NIH have no mechanism for tracking potential new vaccines, drugs or biologics for the animal market.

Therefore, one must rely on press releases, the occasional peer reviewed paper, conference notes, USDA grant and contract notifications, university websites and company profiles for discovery of such new products. Not adequate, in my opinion, and most definitely not transparent. By federal law, the public should have open access to the results of this type of federally funded research.

In today's substack, the state of mRNA "vaccines" for animal "health" is discussed. Citing public sources, I will review what is known and not known about commercial liaisons and partnerships, the corporations involved, ongoing research and products in various states of development.

Bayer Partners with BioNTech to Develop mRNA Vaccines, Drugs for Animal Health

Genetic Engineering and Biotechnology News. May 10, **2016**

> **Bayer will partner with BioNTech to develop novel, first-in-class mRNA vaccines and therapeutics for animal health indications**, the companies said today, under a collaboration whose value was not disclosed.
>
> Bayer agreed to secure exclusive rights to BioNTech's mRNA technology and intellectual property for development of mRNA vaccines for animal health applications…
>
> **The companies said their partnership is the first of its kind focused on developing mRNA therapeutics specifically for animal health applications.**
>
> …
>
> **Infectious disease vaccines is the focus of one of the three therapy platforms BioNTech is building through mRNA technologies; the other two are cancer immunotherapies and protein replacement. The three platforms are designed to produce pharmacologically optimized protein coding RNA for targeted *in vivo* delivery…**

2016. This means that Bayer and BioNTech have been working on livestock and companion animal mRNA vaccines for over six years…

Logic predicts that they will soon have livestock and companion mRNA vaccine and RNA therapeutics on the market.

Bayer, BioNTech developing new mRNA vaccines

Feedstuffs.com May 16, 2016

> **Companies collaborate on cutting-edge technology to develop new solutions to protect companion and farm animal health.**

Again, note the date…2016. This means that Bayer and BioNTech have been working on livestock and companion animal mRNA vaccines for over six years…

There are three therapy platforms that BioNTech has been building through mRNA technologies to be used in livestock and companion animals.

- **Infectious disease vaccines**
- **Cancer immunotherapies and**
- **Protein replacement.**

Bayer to manufacture mRNA vaccine in Germany

Bayer Website, February 1, 2021

> "Following discussions with the German government it has become clear that current manufacturing capacities for vaccines need to be increased, particularly for potential variants of the SARS-CoV-2 virus.
>
> This includes the need to expand production capacity as well as related manufacturing expertise in Germany.
>
> We at Bayer will contribute even further by making more vaccine available to help fight the pandemic.

So, Bayer lent their mRNA manufacturing vaccine facilities for use for the making of COVID-19 mRNA vaccines. Given the above 2016 press releases, that Bayer and BioNtech were collaborating to make mRNA vaccines for the animal markets, it would make sense that these facilities were actually built for the production of veterinary vaccines.

SEQUIVITY: Custom Swine Vaccines, using RNA vaccines.

Merck Website, Accessed Jan 2023

> Combat current and future swine diseases with SEQUIVITY from Merck Animal Health. A revolutionary swine vaccine platform, SEQUIVITY harnesses **RNA particle technology** to create customized prescription vaccines against strains of influenza A virus in swine, porcine circovirus (PCV), rotavirus and beyond. It's supported by a sophisticated dashboard filled with comprehensive data and insights, all to help you stay on top.

Important to know. Merck is already selling mRNA vaccines for swine. For whatever reason, they are selling these products as "**customized prescription vaccines** against strains of influenza A virus in swine, porcine circovirus (PCV), rotavirus and beyond." This is an interesting market segment. Merck's reason to limit the production of mRNA vaccines in the "**customized prescription**" **market is unclear.** Production facility size and scaleability of the RNA product could be factors.

Acquisition Expands and Complements Merck Animal Health's Strong Vaccine Portfolio

Merck Press Release, November 12, 2015 5:00 pm ET

> MADISON, N.J., November 12, 2015 – Merck Animal Health (known as MSD Animal Health outside the United States and Canada) and Harrisvaccines, Inc., today announced the companies have entered into an agreement under which Merck Animal Health will acquire Harrisvaccines, a privately-held company that develops, manufactures and sells vaccines for food production and companion animals.
>
> "As a leader in biologics, Merck Animal Health has built a robust portfolio of vaccines across all animal species," stated Rick DeLuca, president, Merck Animal Health. "Combining Harrisvaccines' R&D and portfolio of products with our strong capabilities and global reach will enable us to address even more devastating diseases that are impacting production animals and reinforce our commitment to the science of healthier animals."

> Harrisvaccines offers innovative technology and an **important portfolio of vaccines, with a focus on production animals**, an increasingly important segment as consumer demand for protein continues to grow worldwide. **The company has a unique RNA Particle technology which represents a breakthrough in vaccine development. It also has a highly versatile production platform able to target a wide range of viruses and bacteria. Pathogens are collected from a farm and specific genes are sequenced and inserted into RNA particles, making safe, potent vaccines able to provide herd-specific protection.**
>
> **This pioneering system is rapidly adaptable to new disease challenges and was instrumental in producing the first conditionally licensed vaccine to help control Porcine Epidemic Diarrhea Virus (PEDv), a deadly virus that has killed more than eight million piglets since suddenly emerging in the U.S. in 2013.**

Read that last paragraph again. Slowly.

Sometime before 2015, the USDA issued a conditional license for a mRNA vaccine for use in pigs for **Porcine Epidemic Diarrhea Virus (PEDv), information about this product can be found at drugs.com.**

Basically something akin to an emergency use authorization was issued around 2014 or 2015. Just like with the mRNA COVID-19 vaccine, full licensure was not granted but the conditional license remains in place. Is this a strategy to circumvent the USDA vaccine licensing and/or authorization process?

To conclude:

Like with the BioNtech's veterinary mRNA vaccine development, Merck's development of an mRNA vaccine product started years ago. For Merck, it may have begun in earnest in 2015 with the acquisition of Harris Vaccine.

Some ongoing research:

NOVEL MRNA VACCINE TECHNOLOGY FOR PREVENTION OF BOVINE RESPIRATORY SYNCYTIAL VIRUS

IOWA STATE UNIVERSITY (grant summary page)

Non Technical Summary

Bovine respiratory syncytial virus (RSV) is a significant viral pathogens of young cows that is a key component of the respiratory disease complex and often leads to secondary bacterial pneumonia. Prefusion F has recently shown to be highly efficacious in barrier housed RSV challenged cows. However, the difficulty in generating prefusion F along with the cost of its production are a hurdle for adoption to the farm. RSV immunity also tends to wane quickly and given the complications of field or pen raised cattle and their stressors and other circulating diseases, and a protein vaccine may not prove highly efficacious in the real world. Here, we will test a novel mRNA vaccine system we have developed that substantially lowers the price point for production animals and may lead to more thermal stable transcripts compatible with vaccinating on the farm. The use of an alternative delivery system rather than lipid nanoparticles will also lower the vaccine costs. We expect to demonstrate efficacy of the vaccine platform using mice at first as proof of principle before switching to a full cow vaccination and challenge system in year 2. Our overall goal is to test a novel mRNA system for inducing immunological protection from bovine RSV infection. We hypothesize that a prefusion F mRNA delivered continuously by vaccine implant will lead to prolonged and robust cellular and antibody immunity. Here, we will optimize our vaccine further and then test for potential correlates of protection to examine for in eventually challenged cows.

Research into mRNA vaccine livestock vaccines in New Zealand and Australia continues with governmental fast-track approval.

NSW fast tracks mRNA FMD and Lumpy Skin Disease vaccines (in cattle)

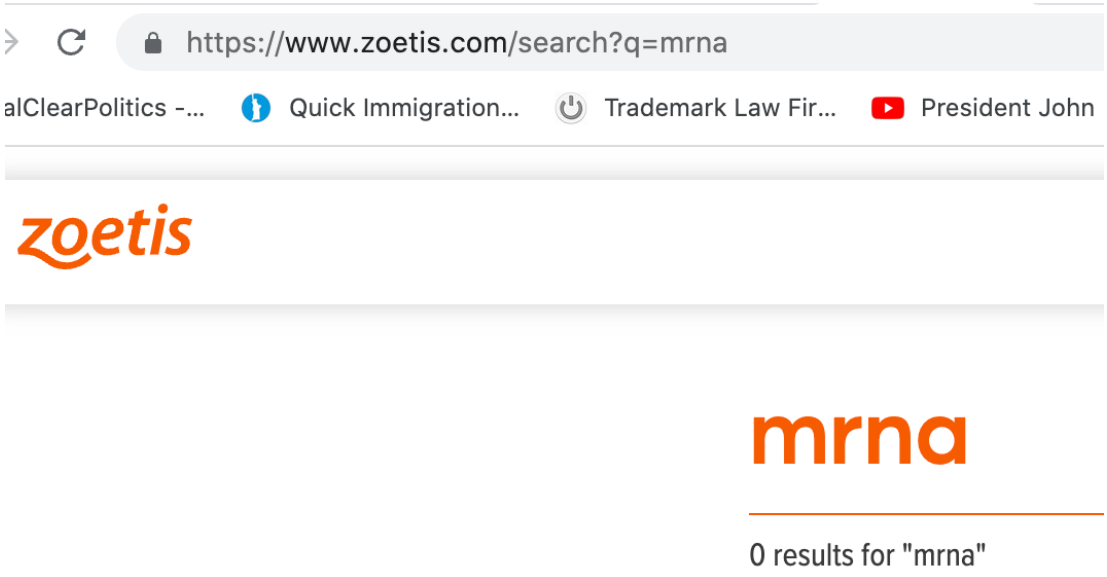
The NSW Government has taken another step towards fast tracking the world first mRNA vaccines for Foot and Mouth Disease (FMD) and Lumpy Skin Disease, inking a deal with US biotechnology company Tiba Biotech

A Foot and Mouth Disease mRNA Vaccine Deal Has Been Signed Between the NSW Government and US Company Tiba Biotech

Finally, inquiring minds want to know… what is Pfizer up to?

Pfizer animal health goes by the name Zoetis.

Zoetis clearly does not make its animal vaccine developmental stages known to the public. Internet searches do not reveal much inside the workings of Zoetis, in terms of mRNA vaccines. However, we can safely assume that development of mRNA vaccines and therapeutics for “animal health” are underway - so stay tuned.



Finally, there are mRNA vaccines for COVID-19 for wildlife that have been developed and authorized for distribution by the USDA.

Black-footed ferret COVID-19 vaccination seems to be working

The Wildlife Society, Feb 18, 2021

> After finding similar species can be infected, researchers quickly began to increase safety protocols at zoos and the U.S. Fish and Wildlife Service’s National Black-footed Ferret Conservation Center in Colorado, the main source of the captive-breeding and release program for the federally endangered species.
>
> “They have done a magnificent job in keeping those animals safe,” said Tonie Rocke, a research scientist with the USGS National Wildlife Health Center who works with

> ferrets.
>
> But U.S. Geological Survey researchers who also study black-footed ferrets had learned about recent studies in mice and hamsters, demonstrating safety and efficacy of vaccination against COVID-19 using purified viral protein. They decided to try something similar on a handful of ferrets this past May and June.
>
> **The vaccine used in ferrets is different — it's a simplified version of the Moderna or Pfizer vaccinations now being used for humans** — and it's based on a similar protein, said Rocke.
>
> Under the authority of the USFWS, the scientists could test the solution on a handful of ferrets in a process that is much quicker than the extensive approvals needed for commercial vaccination for humans like the Pfizer or Moderna inoculations.
>
> The isolated ferrets that had received this trial vaccination produced antibodies against the coronavirus.

Unfortunately, I could find no updates to this program and whether it was expanded into other wildlife populations.

Again, something akin to an emergency use authorization was issued for this experimental vaccine. Just like with the mRNA COVID-19 vaccine and the RNA porcine vaccine above, full licensure was not granted but it appears that the conditional license remains in place. I raise the question again, is this a USDA and/or corporate strategy to circumvent the USDA vaccine licensing and/or authorization process?

The issue being of course, that there is no mechanism for "right to know" of animal health vaccine development.

There were news stories in 2020 that mRNA vaccine(s) were being developed for COVID/SARS-CoV-2 for administration to livestock and companion animals. However, the lack of updates suggest that these plans may have been scrapped with the new, less virulent variants.