

A photograph of a brown chicken in a field. The chicken is the central focus, shown in profile facing right. It has a large, bright red comb and wattle. The background is a grassy field with another chicken visible in the distance under a cloudy sky.

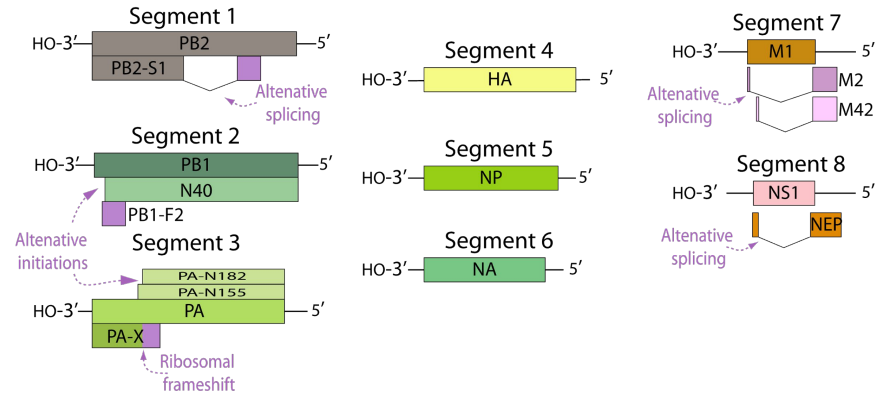
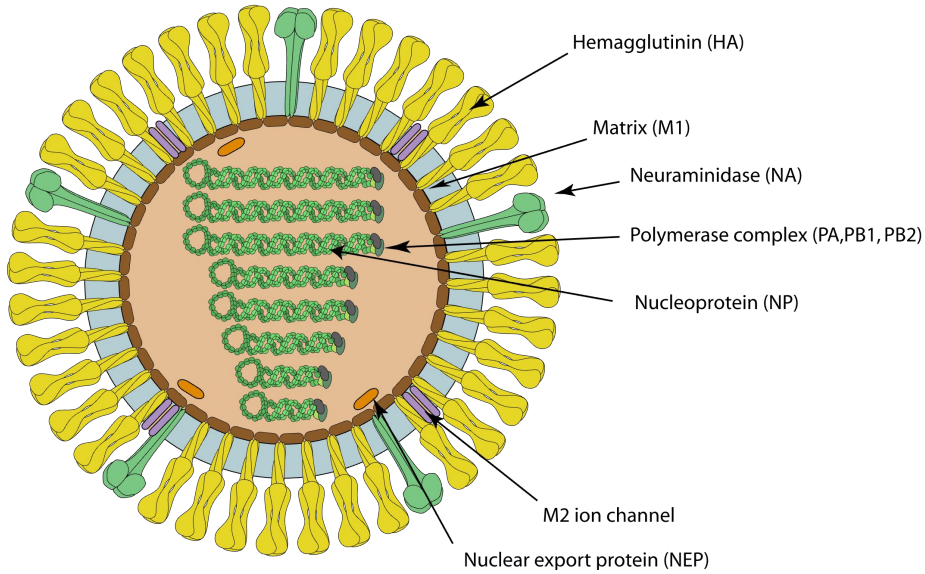
# What the Cluck?!

Brian Hooker, PhD

Children's Health Defense

January 9, 2025





# What is Bird Flu?

- Influenza A - Strain H5N1 (of current concern in US)
- Single stranded, segmented RNA virus with 8 separate segments
- Influenza A is typically stronger and Influenza B doesn't infect animals
- Reports of infection in mammals including foxes, cats, dogs, tigers, leopards, other species sporadically over the last 20 years
- Numerous US reports since 2022 in wild birds, commercial poultry and backyard flocks
- 919 herds of cattle affected in 16 states as of 1/8/25
- 66 human cases in 10 states as of 1/8/25

# What is actually happening with H5N1

- Bird flu was originally detected in the US in January 2022 (South Carolina, wigeon)
- Bird flu is infecting commercial poultry (starting in Indiana in February 2022)
- Bird flu has passed from poultry to mammals
- Bird flu is passing among mammals
- Bird flu is passing among dairy cattle (as early as December 2023)
- Bird flu is passing from bird to human (2022, 2024)
- Bird flu is passing from cow to human (starting April 1, 2024)
- Bird flu is not passing from human to human
- CDC reports two human cases with unknown exposure sources (California and Missouri)

## Bird flu in poultry (HPAI)

- First case of H5N1 in the US was in South Carolina (Wigeon) in January 2022
- Case was H5N1 subclade 2.3.4.4b genome B3.13
- Cases spread rapidly, some birds recover and some die
- Over 130 million birds (poultry) have been culled or infected
- Largest bird flu outbreak in US history
- Even without 100% mortality, the whole flock is culled to prevent spread of the virus
- On Dec. 18, 2024, Gov. Gavin Newsom declared a state of emergency in California – all cases of H5N1 influenza in California have been mild
- Price of eggs in California is now \$9/dozen

## Bird flu in dairy cattle

- Detected first in Texas on March 24, 2024
- Sixteen different states have reported dairy cattle herds with H5N1 influenza
- Mortality rate in cattle is less than 2%
- Virus particles found in raw milk made mice sick (ruffled fur and lethargy) with recoverable virus in respiratory tract (Guan et al. 2024 *NEJM*)
- This study was completed by Yoshihiro Kawaoka (U Wisc.), the king of H5N1 gain-of-function research
- Virus fragments have been found in pasteurized milk
- Pasteurization is not designed to “sterilize” milk from bird flu

# PCR testing of cattle



What is the cycle threshold for PCR testing are being performed on cattle?

Anything less than 40 cycles...

Anthony Fauci stated that a 36 or higher cycle threshold is just dead nucleotides and will create a false-positive PCR test.

## NIH RESEARCH MATTERS

June 4, 2024

# Assessing avian influenza in dairy milk

### At a Glance

- H5N1 avian flu virus survived in raw dairy milk kept under refrigerated conditions for at least five weeks.
- When mice consumed infected raw milk, they showed signs of illness, suggesting that drinking raw milk may pose a risk of transmission to people.
- Heating milk in ways similar to pasteurization significantly reduced levels of the virus.



# California Movement Restrictions and Interstate Movement Requirements for Dairy Cattle

**All dairy breed cattle originating from Highly Pathogenic Avian Influenza (H5N1) affected state(s):** Must be accompanied by a Certificate of Veterinary Inspection (CVI) and signed by an accredited veterinarian within seven (7) days of transport that includes the following statement: "All animals identified on this Certificate of Veterinary Inspection (CVI) have been inspected within seven (7) days and do not originate from a premises with a confirmed detection of Highly Pathogenic Avian Influenza (H5N1) or that is currently under investigation as a suspect premises."

1. All lactating dairy cattle moving interstate require a CVI and matrix-A negative HPAI test from a NALHN laboratory within seven (7) days of movement, in addition to any state-specific entry requirements of destination state.
2. Dairy cattle moving interstate direct to slaughter are exempt from the test requirement but do require a CVI or a [state-approved owner shipper statement](#) and Premises ID (NPIN), in addition to any state-specific entry requirements of destination state.
3. Lactating dairy cattle from herds which have tested positive for Influenza A are not eligible for interstate movement for thirty (30) days from the most recent collection of **any sample that tests positive from any individual animal in the herd**. Re-testing may occur after this 30-day period.
4. Lactating dairy cattle with clinical signs consistent with HPAI in dairy cattle are ineligible for interstate movement (including to slaughter) as per 9 C.F.R. 71.3(b).

# Scientists are testing mRNA vaccines to protect cows and people against bird flu



## Bird flu in humans

- Sixty-six cases of H5N1 influenza in humans in 10 US states since April, 2024
- Fifty-three cases are genome B3.13
- Twelve cases are genome D1.1 (Washington State and Louisiana)
- One case has an indeterminate genome designation (California)
- Genome B3.13 has transmitted to humans via birds and cattle
- Genome D1.1 has transmitted to humans via birds only
- In 65 cases, symptoms are mild – conjunctivitis
- One severe case in Louisiana has died

## Deceased Patient from Louisiana

- Women over 65 years of age with significant comorbidities
- Contracted H5N1 genome D1.1 from backyard flock of poultry which included sick and dead birds
- Virus found in her airway (oral passage only) showed mixed mutations in the hemagglutinin gene:
  - A134A/V [Alanine 88%, Valine 12%];
  - N182N/K [Asparagine 65%, Lysine 35%]; and
  - E186E/D [Glutamic acid 92%, Aspartic Acid 8%]
- These changes may result in increased virus binding to  $\alpha$ 2-6 cell receptors found in the upper respiratory tract of humans.
- These mutations were not found in the sick and dead backyard poultry

## Different strains of bird flu

- Genome B3.13 – likely emerged from the USDA ARS SEPRL facility in Athens, GA in late 2021
  - Prior to detections in South Carolina, this strain was detected in St. Johns, Newfoundland
- Genome D1.1 – may have emerged from the North American Pacific Flyway in late 2021
  - Prior to this, the genome D1.1 was found in birds in East Asia

# Bring on the fear porn!



**Rick Bright** 

@RickABright



This is exactly what I'd expect from high path avian influenza H5N1 in many mammals. It's a deadly virus. Any attempts to minimize the threat of this virus are irresponsible.

This virus can change easily, can spread swiftly, and cause great harm. There has never been such widespread of this virus among mammals. We cannot be overly confident in our current vaccine / antiviral preparedness posture. We need to do more. Now is the time to act, not when there are more cases.

April 29, 2024

## Who is Rick Bright?

- Director of Biomedical Advanced Research and Development Authority (BARDA) from 2016 to 2020
- Researcher and Manager at BARDA from 2010 to 2015
- Director of Vaccine Manufacturing, PATH from 2008 to 2010
- VP of Global Influenza Programs, Novavax from 2006 to 2008
- Bird flu researcher at CDC from 1998 to 2006
- Holds key patent on bird flu vaccine in pre-clinical studies
- Blocked hydroxychloroquine EUA for COVID-19





# Robert Redfield – Former CDC Director



“I believe the great pandemic is still in the future. And that’s going to be a bird flu pandemic from man. It’s going to have significant mortality, in the ten to fifteen percent range. It’s going to be trouble. And we should get prepared for it.” (Robert Redfield)





## Clayton Baker on Gain-of-Function Research

*“One doesn’t create Godzilla in order to save Tokyo”*



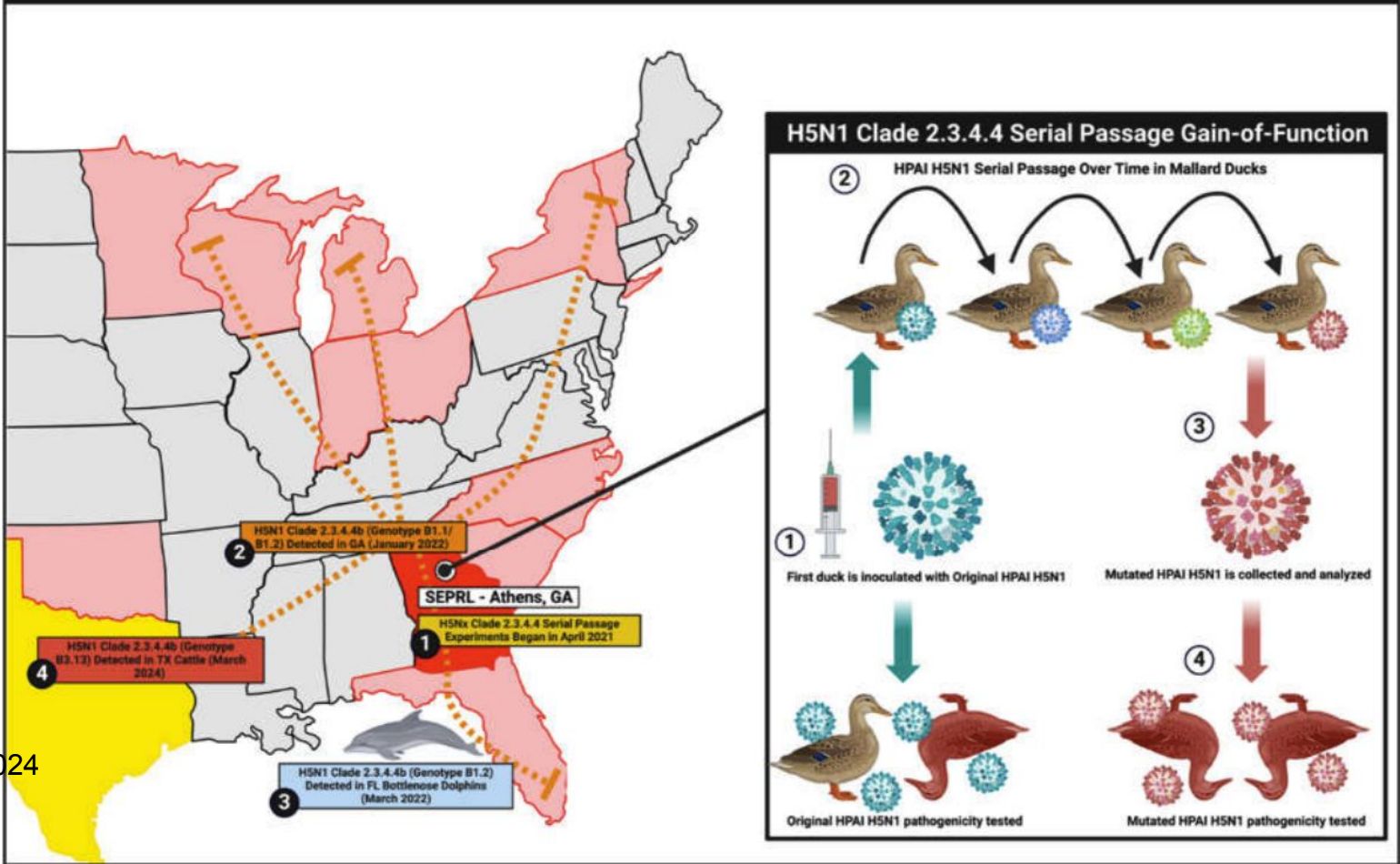
## Gain of Function Research on Bird Flu – United States

- **Influenza Division, NCIRD, CDC (US and Vietnam), NIH**
  - Dr. Jessica Belser - Has introduced current subclade of H5N1 (2.3.4.4b) into human lung fibroblasts
  - Has created transmissible version in ferrets where transmission occurs via respiratory droplets
- **BARDA, Administration for Strategic Preparedness and Response (ASPR), Department of Health and Human Services (HHS)**
  - Hold numerous patents on bird flu vaccines for humans (Dr. Rick A. Bright)
- **University of Wisconsin**
  - Dr. Yoshihiro Kawaoka – responsible for four earlier safety incidents in his lab and has an extensive patent portfolio
  - Have adapted a strain of bird flu to be human transmissible (killed ferrets and replicated in human lung cells)
- **St. Jude Hospital (NIAID)**
  - Researchers are studying human vaccines and therapeutics against humanized bird flu
- **APHIS, USDA**
  - Researchers work in collaboration with CDC to evaluate the threat against humans

## Gain of Function Research - Netherlands

- Dr. Ron Fouchier of Erasmus University
- Controls the GISAID influenza sequence database including access to researchers
- Passaged H5N1 in duck and chicken epithelial cells (2022)
- Modified H5N1 for respiratory transmission in ferrets (2011)
- Proposed transatlantic spread of H5N1 to the US (2022)

# The Proximal Origin of Highly Pathogenic Avian Influenza H5N1 Clade 2.3.4.4b



Hulscher et al. 2024  
(McCullough)

## Alternative Explanation

- H5N1 avian influenza migrated from Northern Europe through Greenland to Canada
- Appeared in Newfoundland (St. John) December 9, 2021 in layers, geese, ducks, silkie hens, peafowl, turkeys
- Newfoundland H5N1 sequences are not publicly available
- Identified in an American wigeon in South Carolina, December 30, 2021
- Identified in a Bottlenose Dolphin in Florida, March 30, 2022
- Identified in poultry (chickens) in Indiana, April 23, 2022
- SEPRL gain-of-function sequence information is not publicly available (FOIA pending)

## Development of a nucleoside-modified mRNA vaccine against clade 2.3.4.4b H5 highly pathogenic avian influenza virus (May 23, 2024)

### **Collaborators:**

- University of Pennsylvania (Scott Hensley and Drew Weissman)
- St. Jude
- Acuitas Therapeutics

### **Funding:**

- NIAID/NIH
- Commonwealth of Pennsylvania
- Wellcome
- Penn Institute for Infectious and Zoonotic Diseases

# FDA approved H5N1 vaccine - Audenz



- Audenz, by CSL Sequiris – based on hemagglutinin (spike) protein of H5N1
- Protein subunit vaccine with adjuvant
- Adjuvant is MF59 which is predominantly squalene
- MF59 contains squalene which was at the heart of the anthrax vaccine/GWI debacle
- Multidose vial version of Audenz contains 25 mg mercury per dose
- In the clinical trial, 1 out of 200 Audenz patients died compared to 1 out of 1000 control patients

# “Cashing In” on the Pandemic



(12) **United States Patent**  
**Kawaoka et al.**

(10) **Patent No.:** **US 11,802,273 B2**

(45) **Date of Patent:** **\*Oct. 31, 2023**

(54) **MUTATIONS THAT CONFER GENETIC STABILITY TO ADDITIONAL GENES IN INFLUENZA VIRUSES** 5,786,199 A 7/1998 Palese  
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(71) Applicant: **Wisconsin Alumni Research Foundation (WARF)**, Madison, WI (US) 5,948,410 A 9/1999 Van Scharrenburg et al.  
5,994,526 A 11/1999 Meulewaeter et al.  
6,001,634 A 12/1999 Palese et al.  
6,033,886 A 3/2000 Conzelmann

(72) Inventors: **Yoshihiro Kawaoka**, Middleton, WI (US); **Satoshi Fukuyama**, Kanagawa (JP); **Shinji Watanabe**, Tokyo (JP) 6,037,348 A 3/2000 Colacino et al.  
6,146,642 A 11/2000 Garcia-Sastre et al.  
6,169,175 B1 1/2001 Frace et al.  
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(73) Assignee: **Wisconsin Alumni Research Foundation (WARF)**, Madison, WI (US) 6,270,958 B1 8/2001 Olivo et al.  
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6,544,785 B1 4/2003 Palese et al.

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days. 6,656,720 B2 12/2003 Groner et al.  
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6,951,754 B2 10/2005 Hortmann  
6,974,695 B2 12/2005 Vogels et al.

(21) Appl. No.: **17/352,845**

(22) Filed: **Jun. 21, 2021**

(65) **Prior Publication Data**

US 2022/0025339 A1 Jan. 27, 2022

AU 2012204138 B2 5/2014  
AU 2014202470 11/2016

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Recently granted Kawaoka  
Patent



# “Cashing In” on the Pandemic



(12) **United States Patent**  
**Sambhara et al.**

(10) **Patent No.:** US 8,163,545 B2  
(45) **Date of Patent:** Apr. 24, 2012

(54) **VACCINE AGAINST PANDEMIC STRAINS OF INFLUENZA VIRUSES**

(75) Inventors: **Suryaprakash Sambhara**, Atlanta, GA (US); **Jacqueline Katz**, Atlanta, GA (US); **Mary Hoelscher**, Atlanta, GA (US); **Suresh K. Mittal**, West Lafayette, IN (US); **Dinesh S. Bangari**, West Lafayette, IN (US)

(73) Assignees: **United States of America as represented by the Secretary of the Department of Health and Human Services, Centers for Disease Control and Prevention**, Washington, DC (US); **Purdue Research Foundation**, West Lafayette, IN (US)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **12/646,078**

(22) Filed: **Dec. 23, 2009**

(65) **Prior Publication Data**  
US 2010/0158939 A1 Jun. 24, 2010

**Related U.S. Application Data**

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## CDC Bird Flu Vaccine Patent

# “Cashing In” on the Pandemic



(12) **United States Patent**  
**Smith et al.**

(10) **Patent No.:** US 10,729,760 B2  
 (45) **Date of Patent:** \*Aug. 4, 2020

(54) **FUNCTIONAL INFLUENZA VIRUS LIKE PARTICLES (VLPs)**

2039/55561 (2013.01); A61K 2039/58 (2013.01); A61K 2039/70 (2013.01); C12N 2710/14143 (2013.01); C12N 2760/16022 (2013.01); C12N 2760/16023 (2013.01); C12N 2760/16034 (2013.01); C12N 2760/16122 (2013.01); C12N 2760/16123 (2013.01); C12N 2760/16134 (2013.01)

(71) Applicant: **Novavax, Inc.**, Gaithersburg, MD (US)

(72) Inventors: **Gale Smith**, Germantown, MD (US);  
**Rick Bright**, Washington, DC (US);  
**Peter M. Pushko**, Frederick, MD (US);  
**Jinyou Zhang**, Plainsboro, NJ (US);  
**Kutub Mahmood**, Cupertino, CA (US)

(58) **Field of Classification Search**

None  
 See application file for complete search history.

(73) Assignee: **Novavax, Inc.**, Gaithersburg, MD (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **16/210,501**

(22) Filed: **Dec. 5, 2018**

(65) **Prior Publication Data**

US 2019/0314484 A1 Oct. 17, 2019

**Related U.S. Application Data**

(60) Continuation of application No. 15/608,532, filed on May 30, 2017, now Pat. No. 10,188,723, which is a

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BARDA/Novavax Bird Flu  
 Vaccine Patent

# “Cashing in on the Pandemic”

## HHS awards Moderna \$176 million to develop mRNA H5 avian flu vaccine

*Lisa Schnirring, July 2, 2024*

Topics: [\*Avian Influenza \(Bird Flu\)\*](#)



The US Department of Health and Human Services (HHS), through its Biomedical Advanced Research and Development Authority (BARDA), today announced that it has awarded Moderna \$176 million to develop a prepandemic vaccine against H5 avian influenza.

In its **announcement**, HHS said the award helps bolster the nation's pandemic flu vaccine capacity, which currently relies on an older traditional vaccine platform. Moderna will leverage its domestic large-scale commercial mRNA vaccine manufacturing platforms and ongoing development of mRNA-based seasonal flu vaccines.



## Does a human transmissible variant of H5N1 exist?

- Kawaoka (U. Wisc.) and Fouchier (Erasmus) labs both developed ferret transmissible strains back in 2011
- Belser (CDC) lab developed ferret transmissible strains in 2022
- “Dozens” of research laboratories across the US are working with HPAI including H5N1 (Claude.ai)
- Genome D1.1 starts in Washington State (Oct. 20, 2024), moves to British Columbia (early November 2024), and ends up in Louisiana (early December 2024)
- Genome B1.1 starts in Newfoundland (December 9, 2021) and moves to South Carolina (December 30, 2021)



