



BIRD FLU

Brian Hooker, PhD

Children's Health Defense

Sept. 6, 2024



What is Bird Flu?



- Influenza A - Strain H5N1 (of current concern in US)
- Single stranded RNA virus
- 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
- 100,713,651 poultry affected in 48 states as of 8/22/24
- 192 herds of cattle affected in 13 states as of 8/28/24
- 13 human cases in 3 states in 2024

What is actually happening with H5N1

- Bird flu is infecting poultry (starting in US in January 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, Spring 2024)
- Bird flu is passing from cow to human (April 1, 2024)
- Bird flu is not passing from human to human

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 90 million birds (poultry) have been culled
- Largest bird flu outbreak in US history
- Even without 100% mortality, the whole flock is culled to prevent spread of the virus
- On July 5, Gov. Jared Polis declared a state of emergency in Colorado that extended to Sept. 1
- Price of eggs increased by 13.1% in the month of July

HPAI Cases by County : Sheet1

Colorado Highly Pathogenic Avian Influenza Cases by County 2022-2024

last updated 8/27/2024 3:00pm

NVSL Confirmation Date	County	Species (count)	Domestic/Wild/Mammal	Prem Identifier	Prem Type	Control Area Released
7/19/2024	Weld	Chickens (300,000)	Domestic	Weld13	Commercial (poultry)	8/27/2024
7/16/2024	Weld	Chickens (1,313,800)	Domestic	Weld12	Commercial (poultry)	8/13/2024
7/8/2024	Weld	Chickens (1,780,000)	Domestic	Weld11	Commercial (poultry)	8/27/2024
6/27/2024	Morgan	Mixed species (40)	Domestic	Morgan02	Backyard (non-poultry)	NA
6/26/2024	Larimer	Mixed species (10)	Domestic	Larimer04	Backyard (non-poultry)	NA
2/8/2024	Delta	Chickens (67,200)	Domestic	Delta01	Commercial (poultry)	3/5/2024
1/8/2024	Arapahoe	Chickens(23)	Domestic	Arapahoe02	Backyard (non-poultry)	5/11/2024
12/20/2023	Boulder	Canada goose (1)	Wild			
12/20/2023	Weld	Great horned owl (1)				
12/13/2023	Weld	Chickens (24)	Domestic	Weld10	Backyard (non-poultry)	NA
12/6/2023	Morgan	Canada goose (1)	Wild			
12/6/2023	Larimer	Canada goose (1)	Wild			
12/4/2023	Logan	Snow goose (1)	Wild			
12/4/2023	Boulder	Common raven (1)	Wild			
12/4/2023	Larimer	Canada goose (1)	Wild			
12/4/2023	Larimer	Cackling goose (1)	Wild			

Bird flu in dairy cattle

- Detected first in Texas on March 24, 2024
- States affected: Colorado, Idaho, Michigan, Texas, Iowa, Minnesota, New Mexico, South Dakota, Kansas, Oklahoma, North Carolina, Ohio, and Wyoming
- Currently in only 4 states (California, Colorado, Idaho, Michigan) with 17 diagnoses in the past 30 days
- 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

PCR testing of cattle



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

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

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



Sound the alarm!



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



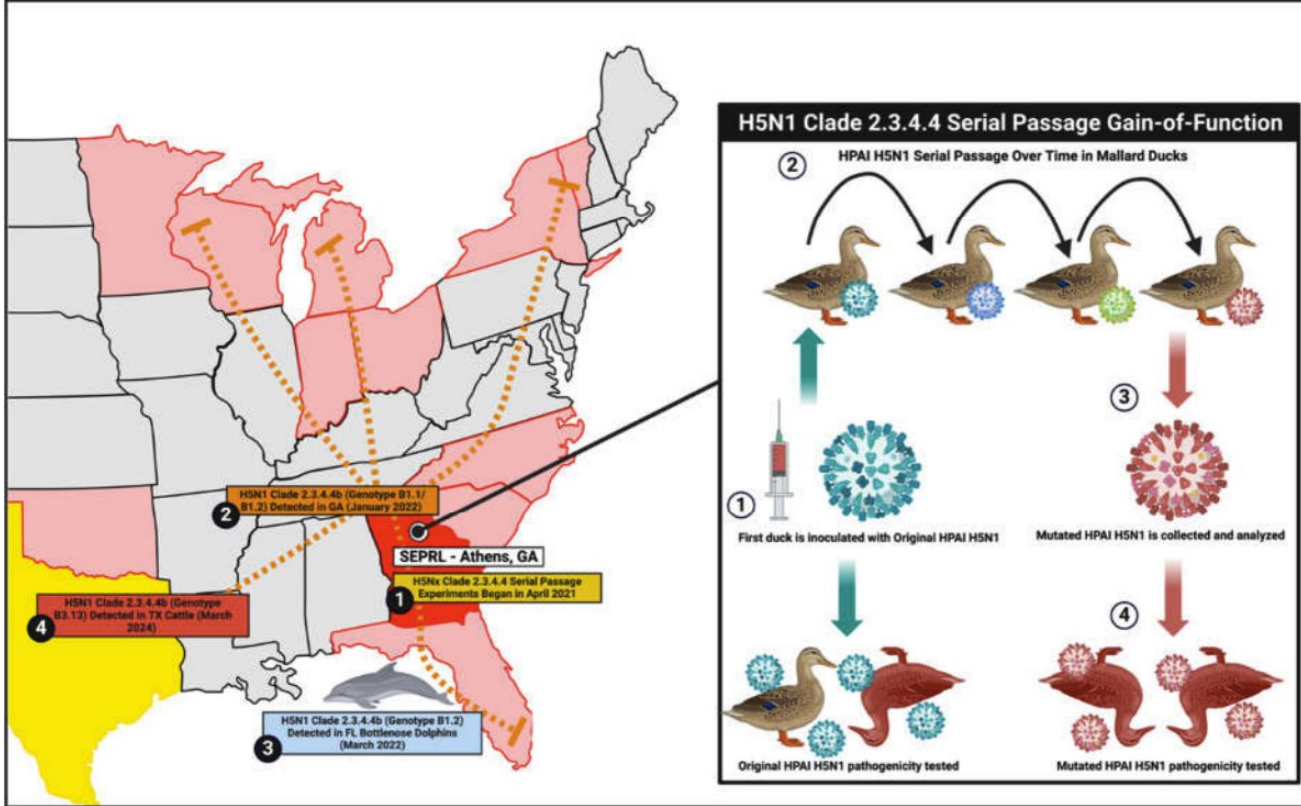
“I believe the great pandemic is still in the future. And that’s going to be a bird flu pandemic from man. It’s going to have significant mortality, in the ten to fifteen percent range. It’s going to be trouble. And we should get prepared for it.” (Robert Redfield)



Gain of Function Research on Bird Flu – United States

- Influenza Division, NCIRD, CDC (US and Vietnam), NIH
 - Have introduced current subclade of H5N1 (2.3.4.4b) into human lung fibroblasts
- 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 two earlier safety incidents in his lab and has an extensive patent portfolio
- 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

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



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
- St. Jude
- Acuitas Therapeutics

Funding:

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

“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

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(71) Applicant: **Wisconsin Alumni Research Foundation (WARF)**, Madison, WI (US) 5,948,410 A 9/1999 Van Scharrenburg et al.
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(72) Inventors: **Yoshihiro Kawaoka**, Middleton, WI (US); **Satoshi Fukuyama**, Kanagawa (JP); **Shinji Watanabe**, Tokyo (JP) 6,037,348 A 3/2000 Colacino et al.
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(*) 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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(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 Bird Flu Vaccine Patent

