The infectious growth of a Federal Government medical role.

The medical wellbeing of Americans is first and foremost the responsibility of the individual. That responsibility is part of the freedom we enjoy, to maintain ourselves in all ways. America is not responsible for the health or lively hood of any individual as might be true for a socialist of communist nation.

The United States is comprised of the citizens in 50 states employing one federal government. One role of the state is managing the public medical services for the citizens in that state. The citizens benefit from an organized medical system in their state. Through a combination of licensing the Doctors, and medical professional allowed to work in the state, licensing the facilities, hospitals, labs, clinics, and other medical facilities following the rules and oversight of that state has established. A state provides and manages the public health services including medical surveillance appropriate for medical safety and a reporting system to protect the public.

The Federal government has pushed past its Constitutional limits to provide medical related services to the country and acts as a backup to the states through agencies of the Health and Human Services department. The Food and Drug Administration (FDA), the National Institute of Health (NIH) and Center for Disease Control (CDC) all have various rolls in research and advising the state health agencies, along with also creating "recommendations" for practices and policies in medical care, like when to test.

Since the 1906 Pure food and Drugs Act, the FDA traditionally is a testing laboratory for new medical treatments, requiring tests of both the success of treatment for a drug, AND the safety of a drug. The safety testing is a relatively new requirement, being added in (about 1980?).

The American medical community is guided by the FDA tests and approvals of prescription drugs, The FDA approved list of uses for a drug may be limited BUT a Doctor MAY always use a drug "off label", that is for something not specifically previously tested by the CDC, and 25% or more of all prescription treatments are based on a Doctors choice to use it "off label". In the United States, a medial doctor is the one person who makes the decision on treatment.

In the United States, once a drug has been approved for sale for one purpose, physicians are free to <u>prescribe</u> it for any other purpose that in their professional judgment is both safe and effective, and are not limited to official, FDA-approved indications.^[19] <u>Buckman Co. v. Plaintiffs' Legal Comm.</u>, <u>531 U.S. 341</u> (U.S.S.Ct. 2001) ("the FDCA expressly states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396 (1994 ed., Supp. IV)."). – Wikipedia.

In the COVID-19 event, a significant breakdown in government provided services has greatly increased the damage done by the virus alone. This should cause a review and reorganization of the existing government agencies and employees, both state and federal.

What should have happened -

Remembering the Constitution and Bill of Rights form the supreme law of the land and applies to all Americans, it does not allow any government agency or agent to take away rights without due process. The covid-19 current "stay at home" dictates in many states violates our rights without any due process. It may be common sense for a person to limit their interaction based on a flu event but the government does not have the power to order that behavior unilaterally.

In 2017, the US Government was aware of the virus lab in Wuhan, China and internally expressed concerns with its possible safety issues. Since 2017, the virus community had received several published research papers from the Wuhan lab related to their work on the coronavirus in horseshoe bats along with the historic knowledge that the 2003 SARS virus was a coronavirus originating from China. This was an earlier event that COULD have suggested to US Medical officials there was an ongoing need to have surveillance testing methods designed to be ready to gather infection facts in the event of a future outbreak. Knowing in 2017 there was were concerns with the Level 4 Wuhan lab, who was doing very dangerous coronavirus DNA modifications, which were partly funded by the NIH through a grant to Columbia University, there was an ample warning to prepare American systems were in place to test and identify when needed.

The HHS / NIH / NIAID, Dr Fauci should have been making sure America was prepared to protect ourselves IF/When a virus, like WUHAN was developing ever got out.

-Ensuring a coordinated medical surveillance system was in place to give states and federal agencies the required level of information.

-Ensure there were testing protocols, including test equipment in all locations appropriate to the population size required.

-Ensure how a NEW TEST for a previously unknown pathogen would be created, produced and distributed to the existing nationwide network.

-Ensure that a strategic medical equipment reserve is established and maintained against a future event.

Working with the CDC and FDA, the NIH should have

-Ensuring the FDA policies and practices worked to enhance, not delay any future emergency

-Ensured that a federal medical equipment strategy was coordinated fully with all states and their own reserves

-Ensured that States maintained the recommended levels of hospitals and staff based on their own emergency planning forecasts.

-Continued to train and develop response strategies, actively coordinating with states to get their buy in.

Each state should have been prepared for an unknown pathogen event by having an existing network of medical testing in place.

A state should NOT overreact, but have a constant reliable information site available to identify where the pathogen is found and in what number. The state should have an action plan that is based on laws in place before such an event, ensuring the Constitution is upheld in all cases, and when limitations to those rights are temporally required, clearly state why it is and when the rights will be returned. Justification must be an actual event, not a "forecast" of a possible future problem. Likely exceptions would be natural events, like tornados or hurricanes - where some established shortterm forecast, like daily or weekly will be tracking the probable path and magnitude of the weather event. In that case, we do expect government actions that may temporarily limit some of our freedom to properly help everyone stay safe. What the covid-19 shutdown of the economy have taught is that having a wildly inaccurate forecast of a medical emergency should never allow political decisions to take citizens rights, and it is clearly an abuse of political power. Medical testing and evaluation needs to be in place to provide factual, not forecast evaluation of issues. The covid-19 event had a disproportionate impact on the northeast US, the greater NY area accounting for over 60% of deaths. That should never have triggered mass shutdowns in other states.

Any review of the HHS organization should include considering what Dr.Judy Mikovits states in her book, *Plague of Corruption* with a forward by Robert F. Kennedy Jr. and discusses in the video interview. Her claims about the suppression of existing medications seems to have merit, but each reader should judge for themselves. https://kfyi.iheart.com/content/2020-05-06-coronavirus-watch-dr-anthony-faucis-ex-employee-tell-all

Sections below;

National Institute of Health

Center for Disease Control

Food and Drug Administration

Annual Flu season

Overview of the HHS, FDA, NIH, CDC

HHS

FY16 budget 1.119 Trillion, FY17 1.126 Trillion, FY18 1.112 Trillion, FY19 1.214 Trillion, FY20 1.322 Trillion

The HHS department spends in the following area; (example FY20)

Medicare
 Medicaid
 Discretionary
 Mandatory
 Children Ent.
 Children Ent.

Part of the HHS funding is to provide preparation for emergencies, which would cover an event such as the Covid-19 virus pandemic event. As we have found the states and the HHS departments had not adequately prepared and now we are trying to play catch up creating the equipment, methods and testing programs on the fly so we can get some information and get ahead of the information curve.

On May 11, 2020 it was reported "Feds spent nearly \$100 Billion on pandemic readiness, health security in decade leading up to coronavirus crisis." This obviously was wasted money we cannot get back. We should learn from it, and REDUCE the role of HHS. <u>https://www.foxnews.com/politics/pandemic-preparedness-spending</u>





News is now getting out that the Federal agencies did not properly use the funds they were given.

Jan 28, 2021 Millions of federal dollars for health emergencies were diverted to unrelated projects. Crimes from 2010 to 2019. Millions of federal dollars for health emergencies were diverted to unrelated projects, watchdog says | The Seattle Times

Regarding the Federal role in a State event.

While most states did not get seriously infected by this unique coronavirus, several northeast states did get their hospitals overrun, and their preparation was found to be wanting. Early political demands by the NY Governor that he must have 30,000 ventilators showed there was no medially guided planning at work in that state. Facts later learned was NY state had unused ventilators in a warehouse, and the total number actually required was in the 3-4 thousand range. Sadly, while several emergency hospital facilities were provided to NY, including the US Navy hospital ship, the state choose NOT to refer patients there. It was found that nursing home patients tested positive for covid-19 who could have been sent to these temporary hospital sites, were instead sent back to the nursing homes on NY State orders – resulting in the infections and death of other nursing home patients. This was NOT the fault or result of the HHS or Federal Government, Some in the media say the deaths in NY were a failure of the Federal Government, without any factual basis.

Each year HHS spends over a Trillion dollars, and provides Congress the purposes they use to justify this funding. From the last several budget summaries, I've highlighted sections in their plans that claim they are preparing America for biodefence measures, plans and emergency equipment. It suggests that HHS departments had plans and equipment in place to ensure both the facts of an event, and emergency equipment is being stockpiled to be used. A review of the past several years show several examples of the huge funding that resulted in America almost not at all prepared, and had to rely on a impromptu White House Task Force to make the emergency plans daily. This suggests the established HHS programs for emergencies was not appropriate to address this covid-19 crisis. This also suggests any HHS programs to train and prepare the public health professionals and hospitals was lacking.

The HHS FY19 Budget summary includes this note; PRIORITIZING BIODEFENSE AND PREPAREDNESS PROGRAMS

The FY 2019 Budget will continue to improve our Nation's preparedness for, and capabilities to respond to, emerging infectious diseases and incidents involving chemical, biological, radiological, and nuclear agents. The Budget includes <u>\$512</u> <u>million for the Biomedical Advanced Research and Development Authority</u> and <u>\$510 million for Bio Shield to support the development and procurement of new medical products (medical countermeasures) that will strengthen our national preparedness and biodefense against chemical and biological threats. These resources would build on prior HHS investments, which have resulted in a robust development pipeline of more than 190 medical</u>

Putting America's Health First4countermeasure candidates and the procurement of 14 new products for the Stockpile, of which 6 have achieved Food and Drug Administration (FDA) approval. The Budget reflects to transfer the Strategic National Stockpile to the Office of the Assistant Secretary for Preparedness and Response (ASPR), and <u>provides \$575 million to maintain and replenish the</u> <u>Nation's largest supply of life-saving medical countermeasures that can be</u> <u>deployed in the event of a public health emergency</u>.

Advancing Preparedness and Response Capabilities

Some disasters require a Federal response as evidenced by the number of powerful hurricanes and historic wildfires in 2017. HHS remains ready to respond to any and all hazards when disaster strikes. The Budget provides \$2.2 billion to the HHS Office of the Assistant Secretary for Preparedness and Response(ASPR) to ensure the Department is able to continue operations in the event of a disaster and to support essential emergency exercises to refine our response in realized emergency situations. Hospital Preparedness Program resources will continue to be allocated to states and localities according to risk, ensuring communities with more risk have the necessary coordination and resources to mitigate loss in the event of disaster. The Budget <u>continues to provide \$50 million to support the National Disaster Medical System's response capability by updating patient care supplies and providing essential training to the team members each year.</u>

Global Health and Global Health Security

To protect Americans from the threat of infectious diseases, it is critical that the U.S. Government maintain effective global response capacity and ensure other countries follow through on their commitments to build their own domestic capabilities. Investing in global public health preparedness is far less expensive than mounting an international public health response to control an epidemic. To support this endeavor, the Budget provides a total of \$409 million for CDC's global health activities, which serves to strengthen CDC's international preparedness and response capabilities. This funding will help improve detection programs, response team efforts, and partner collaboration. Furthermore, substantial progress has been made toward meeting global health security goals

regarding the prevention and management of global disease threats as a result of the CDC's Ebola emergency appropriation, which expires at the end of FY 2019.

The HHS FY20 Budget summary include this note;

Prioritizing Biodefense and Preparedness

The Administration prioritizes the nation's safety, including its ability to respond to acts of bioterrorism, natural disasters, and emerging infectious diseases. HHS is at the forefront of the nation's defense against public health threats. The Budget provides approximately \$2.7 billion to the PublicHealth and Social Services Emergency Fund within the Office of the Secretary to strengthen HHS's biodefense and emergency preparedness capacity. The Budget also proposes a new transfer authority that will allow HHS to enhance its ability to respond more quickly to public health threats. Additionally, the Budget supports the government-wide implementation of the President's National Biodefense Strategy. The Budget supports advanced research and development of medical countermeasures against chemical, biological, radiological, nuclear, and infectious disease threats, including pandemic influenza. The Budget also funds late-stage development and procurement of medical countermeasures for the Strategic National Stockpile and emergency public health and medical assistance to state and local governments. These investments protect our nation against health security threats such as anthrax, botulism, Ebola, and chemical, radiological, and nuclear agents.

The HHS FY21 Budget summary includes this note;

Emergency Preparedness

HHS plays a key role in supporting domestic and international preparedness and response to ensure our nation's safety. The Budget invests <u>\$2.6 billion in the</u> Office of the Assistant Secretary for Preparedness and Response (ASPR) to expand efforts to prevent, prepare for, respond to, and recover from, the adverse health effects of public health emergencies. This amount includes \$562 million for the Biomedical Advanced Research and Development Authority to maintain a robust pipeline of innovative medical countermeasures that mitigate health effects of infectious diseases and chemical, biological, radiological, and nuclear agents. It also includes \$535 million for Project BioShield to support procurement of medical countermeasures against these threats, and \$705million for the Strategic National Stockpile to sustain and increase inventory of high-priority countermeasures such as antibiotics to treat anthrax exposure and vaccine to prevent smallpox. These investments will help HHS advance progress towards national preparedness goals. NIH supports a robust research portfolio to develop vaccines and therapeutics that enable rapid response to public health threats

including emerging microbial threats, such as extensively drug-resistant tuberculosis, emerging viral strains such as Zika, and viral hemorrhagic fevers such as Ebola. The Budget continues investments in NIH in scientific research on these new threats, and invests \$120 million in FDA to facilitate medical countermeasure development and availability to respond in the event of a microbial or other public health threat.

Health and Human Services includes many sub departments, including the CDC, FDA and NIH that are detailed further below.

NIH 41.7 Billion

NIH has a mind-bogeying list of departments to study everything, created over the years by some action of congress no doubt. One department of note is charged with <u>understanding and protecting us from infectious diseases</u>, and is headed by Dr. Fauci since 1984.

National Institute of Allergy and Infectious Diseases (NIAID) — Est. 1948 FY19 5.5 Billion \$5,523,324,000

NIAID research strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives.

The NIH invests (hands out university/ science welfare funding) about \$31.1 billion annually in research grants.

More that 80 percent of NIH's funding is awarded for extramural research, largely through almost 50,000 <u>competitive grants</u> to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions in every state.

About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the <u>NIH campus in Bethesda, Maryland</u>. (4.17 Billion / 6000 employees = \$695,000 per employee.)

In 2019, NIH distributed funds this way;

Organization Type	Number of	Total Awards	Total Funding
	Organizations		
Higher Education	479	43,655	22,286,282,774
Research Institutes	167	3,413	2,737,689,536
Independent	64	4,627	2,784,176,919
Hospitals			
Other Domestic	1,689	2,595	2,381,179,583
Nonprofits			
Foreign	211	494	238,037,521
TOTAL	2,930	56,200	31,192,343,463

Year	Total Grants
2016	25,225,846,739
2017	26,972,060,072
2018	28,975,943,278
2019	31,192,343,463
TOTAL (2016-2019)	\$112,366,193,552

CDC FY19 12 Billion

The CDC was established in 1946 to prevent malaria from spreading in America. Their charter expanded to include other communicable diseases including the Asican flu 1957 pandemic. A measles program was run in the 1960's reducing that infection. In 1971, CDC discontinued routine vaccine of smallpox due to its being eradicated. In the 1980's their focus was on AIDS, then establishing the office on smoking and health to change behaviors. A flawed study claiming guns were a medical problem drifted further away from their medical purpose. In 1999 established the <u>CDC Laboratory Response</u> <u>Network</u>, an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological threats, emerging infectious diseases, and other public health threats and emergencies. In 2004 rubella is eliminated in the US.

CDC Justification of Estimates for Appropriation Committees, FY19

We accomplish our public health mission through putting science into action; rapidly detecting and containing diseases, outbreaks, biosecurity threats and environmental hazards; and working with state and local health departments to strengthen communities and increase public health impact.

Our fiscal year 2019 budget request includes:

•Continued emphasis on global health security capacity development primarily through the Global Health Security Agenda to protect Americans from the threat of emerging infectious diseases

•Ongoing efforts to reduce deaths due to opioid abuse, misuse and overdose

•New activities focused on infectious disease elimination in select jurisdictions, including those with high rates of opioid-related transmission

•Investments that protect mothers and babies from emerging threats and build capacity to respond to vector-borne diseases

CDC scientists and disease detectives work around the world to track diseases, research outbreaks, and respond to emergencies. We carry out research that leads to the best solutions to fight disease and protect health, and we get results through proven, lifesaving actions that defend Americans against health threats. Performance improvement is a critical aspect of our work, and we regularly measure how our programs serve the public and meet key public health goals. We are committed to maximizing the impact of every dollar entrusted to our agency.

Immunization and Respiratory Diseases	798,405,000
HIV/AIDA, Viral Hep, STI and TB	1,123,467,000
Emerging and Zoonotic Infections	<mark>620,372,000</mark>

Chronic Disease Broyentian	1 197 771 000	
Chronic Disease Prevention	1,187,771,000	
Birth Defects, Disabilities	155,560,000	
Environmental Health	209,350,000	
Injury Prevention	648,559,000	
Public Health Services	496,397,000	
Occupational Safety	336,300,000	
Global Health	488,621,000	
Public Health Preparedness and	<mark>857,893,000</mark>	
Response		
Cross Organization Activities	<mark>857,893,000</mark>	
Building and Facilities	30,000,000	
TOTAL listed -	7,339,025,000	
Other program not listed	4,767,870,000	
TOTAL FY19 CR from Congress	12,106,895,000	

These three budget categories all having to do with aspects of a pandemic, totaling \$2.4 Billion.

Year	Total Budget
2012	11,193,320,000
2013	10,258,330,000
2014	10,791,897,000
2015	8,711,537,000
2016	11,519,365,000
2017	11,868,182,000
2018	11,973,448,000
2019	12,106,895,000
2020	12,710,815,000
2021	12,550,137,000

FDA FY19 5.7 Billion - \$5,798,555,000

FDA Justification for FY19 budget to Congress -

The FY 2019 Budget provides FDA with the resources to continue to fund our current programs at consistent levels. The request will allow the agency to continue to support our core public health mission, including protecting the safety of the foods we eat. It also includes additional funding to further promote innovation and competition and advance the health and safety of American families, including:

• \$400 million in medical product innovation initiatives that will result in unproved treatment and diagnostic options for patients; increased competition and medical product efficiencies that can help lower healthcare costs; the development of new industries that will lead to U.S.based jobs; and manufacturing advances that are more re liable, lower cost and high quality;

• \$50 million for 21st Century Cures Act activities;

• \$10 million as part of an Administration opioid initiative to support development of tools to stem the misuses and abuses of opioids and development of medication assisted treatments (MATs); • \$10 million for the review of growing numbers of pioneer and generic new animal drugs; • \$22 million in proposed user fees to implement meaningful reforms to the regulation of over the-counter (OTC) monograph drug products to foster OTC innovation and expand consumer choice;

• \$21 million to ensure that FDA's offices and labs across the country are modern and efficient, to help FDA carry out its mission and respond to food safety and medical product emergencies.

Emergency Response, Recovery, and Medical Countermeasures

FDA has wide-ranging responsibilities to protect the public when the nation is faced with public health threats, whether naturally-occurring, or man-made . The devastation caused by Hurricanes Harvey, Maria, and Irma brought to light the critical work the agency does in overseeing the safety of the food and medical supply in this country. FDA worked around the clock to ensure farmers in Texas and Florida could safely handle their crops affected by flooding. FDA remains

committed to the recovery in Puerto Rico and that island's long-term success, and worked closely with drug and medical device manufacturers in Puerto Rico to take steps to address potential and apparent shortages of medical products that resulted from the devastation left by Hurricane Maria. FDA's work and commitment to hurricane victims and patients in need of critical medical products will continue into 2018.

In addition, over the past two years, FDA mobilized more than 500 staff members to respond to the Zika virus outbreak, including deployments to Zika-affected Puerto Rico. As part of the U.S. Government response efforts, FDA has worked to:

•protect the nation's blood and tissue supply

facilitate the development and availability of diagnostics, including authorizing 20 diagnostics for emergency use
support development of vaccines and therapies.

Year	Total Budget
2015	4,530,175,000
2016	4,745,287,000
2017	5,104,580,000
2018	5,135,610,000
2019	5,661,889,000
2020	5,939,575,000
2021	6,204,936,000

Major influenza pandemics

Year and Event	Worldwide deaths
1889 Flu	1,000,000
1918 Spanish Flu	17,000,000
1957 Asian Flu	1,500,000 (70,000 in
	USA)
1968 Hong Kong Flu	1,000,000 (34,000 in
	USA)
2009 H1N1 Flu	151,700 (12,469 in USA)
Typical annual flu	300,000
season	

The ANNUAL FLU Season in America

The average deaths from the annual flu season between 1976 and 2007 was 23,607. From a low of 3,349 in 1986 to a high of 48,614 in 2003.

The first year of a universal seasonal influenza vaccination was the 2010-11 season distributing 163,000,000 doses. The CDC document does not address if the vaccination had any impact on protecting against getting the flu, only speaks to how many are getting it. CDC rates the effectiveness of the custom annual vaccine by what percentage of those who got the vaccine were not hospitalized, verses those without the vaccine who were hospitalized. The effectiveness Is not did it keep you from getting influenza, but did it moderate the effect and not require you to be hospitalized.

https://www.hhs.gov/sites/default/files/nvpo/nvac/meetings/pastmeetings/2013/nvac_universal_flu.pdf

Year	CDC Hospitalization estimates	Influenza/Pneumonia Deaths*	CDC Vaccine Effectiveness
2010	290,000	50,097	60%
2011	140,000	53,826	47%
2012	570,000	50,636	49%
2013	350,000	56,979	52%
2014	590,000	55,227	19%
2015	280,000	57,062	48%
2016	500,000	51,537	40%
2017	810,000	61.099	38%
2018	490,561	80,000	29%
2019	490,600	34,200	29%
2020	400,000	22,000	39%

https://www.cdc.gov/flu/about/burden/2018-2019.html

• CDC Wonder system statistics for deaths to 2016.

The CDC website offers glowing reasons about vaccination benefits;

https://www.cdc.gov/flu/prevent/vaccine-benefits.htm

-Flu vaccination can keep you from getting sick with flu.

-Flu vaccine prevents millions of illnesses and flu-related doctor's visits each year. For example, during 2017-2018, flu vaccination prevented an estimated 6.2 million influenza illnesses, 3.2 million influenza-associated medical visits, 91,000 influenza-associated hospitalizations, and 5,700 influenza-associated deaths.

-During seasons when the flu vaccine viruses are similar to circulating flu viruses, flu vaccine has been shown to reduce the risk of having to go to the doctor with flu by <u>40 percent to 60</u> <u>percent</u>.

Looking at the referenced studies they state support this claim has mixed results, and none reviewed claimed to prevent illness as the CDC page claims, which are only CDC projections. None of the studies suggested that taking the vaccine would eliminate you from getting influenza.

https://www.ncbi.nlm.nih.gov/pubmed/28525597

This study was not based on actual vaccination patients, but guessed by using "used propensity score matching to account for the probability of vaccination within age strata (18-49, 50-64, and ≥65 years)"

https://www.ncbi.nlm.nih.gov/pubmed/9580647

This study was of safety in treating children "A live attenuated, cold-adapted influenzavirus vaccine was safe, immunogenic, and effective against influenza A(H3N2) and B in healthy children"

Comments about the flu shot program -

A CDC review of this "annual flu shot" recommendation four years later found little evidence that annual vaccination of seniors and others thought to be at high risk for influenza had any appreciable impact on influenza-related mortality rates. A 1968 double-blind randomized study conducted by CDC officials and published by the World Health Organization (WHO) came to similar conclusions and even suggested that *"attention should be redirected towards finding a more efficacious means of protection."*¹¹ Yet, despite studies demonstrating that the influenza vaccine was ineffective, government vaccine policy recommendations for annual flu shots continued. <u>https://www.nvic.org/vaccines-and-diseases/Influenza/vaccine-history.aspx</u>

"Flu is unpredictable, but you can predict that the single-best thing you can do to protect yourself is to get a flu vaccine," CDC Director Dr. Tom Frieden said at a news conference last month.

The market's been growing along with a public health push for vaccination; rates in the U.S. have been steadily rising, and five years ago the CDC expanded its recommendation for the flu shot to everyone in the U.S. older than 6 months.

That's even as the vaccine proves to be just about 50 to 60 percent effective most years; still, public health experts emphasize flu can be a serious illness, and the vaccine cuts down on infections and complications. Each year, millions of people get flu, more than 200,000 Americans are hospitalized with complications, and the virus kills thousands of people. <u>https://www.cnbc.com/2015/10/19/the-16-billion-business-of-flu.html</u>

Inactivated vaccines can reduce the proportion of healthy adults (including pregnant women) who have influenza and ILI, but their impact is modest. We are uncertain about the effects of inactivated vaccines on working days lost or serious complications of influenza during influenza season.

https://www.cochrane.org/CD001269/ARI_vaccines-prevent-influenza-healthy-adults

Older adults receiving the influenza vaccine may have a lower risk of influenza (from 6% to 2.4%), and probably have a lower risk of ILI compared with those who do not receive a vaccination over the course of a single influenza season (from 6% to 3.5%). We are uncertain how big a difference these vaccines will make across different seasons. Very few deaths occurred, and no data on hospitalisation were reported. No cases of pneumonia occurred in one study that reported this outcome. We do not have enough information to assess harms relating to fever and nausea in this population. The impact of influenza vaccines in older people is modest, irrespective of setting, outcome, population, and study design. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004876.pub4/abstract

The <u>WHO Global Influenza Programme</u>(GIP) with its backbone <u>Global Influenza</u> <u>Surveillance and Response System</u>(GISRS) is a complex network of 143 national reference centres and specialist laboratories in 113 states carrying out surveillance of circulating influenza viruses. GISRS was devised and developed to guide annual

influenza vaccine production, and the emphasis is mainly on influenza viruses, their variants, and emerging strains.

However there is no reliable system to monitor and quantify the epidemiology and impact of ILI, the syndrome that presents clinically. Few states produce reliable data on the number of physician contacts or hospitalised cases due to ILI, and none tie these data to the proportion of ILI caused by influenza. We do not know for certain what the impact of ILI is, nor the impact of the proportion of ILI caused by influenza. Prospective studies apportioning positivity to the scores of viruses probably causing ILI are rare, as interest is focused on influenza. The standard quoted figure of 36,000 yearly deaths in the US is based on the "respiratory and circulatory deaths" category including all types of pneumonia, including secondary to meconium ingestion or bacterial causes. More recently, the US Centers for Disease Control and Prevention (CDC) have proposed estimates of impact ranging between 3,000 and 49,000 yearly deaths. When actual death certificates are tallied, influenza deaths on average are little more than 1,000 yearly. So, the actual threat is unknown (but likely to be small) and so is the estimation of the impact of vaccination.

https://community.cochrane.org/news/why-have-three-long-running-cochrane-reviewsinfluenza-vaccines-been-stabilised