

Future Federal Policy Directions: Influenza Vaccine and Vaccination

National Influenza Vaccine Summit
May 18, 2010

Bruce Gellin, MD, MPH
Director, National Vaccine Program Office
Deputy Assistant Secretary for Health



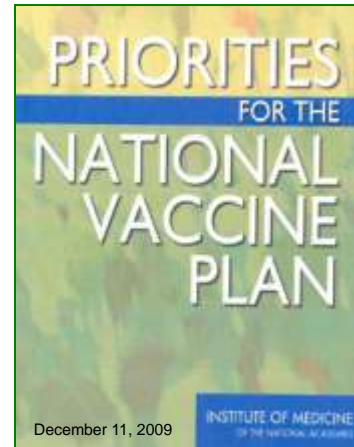
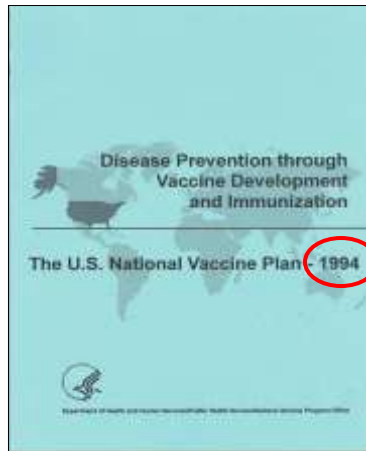
Seasonal-Pandemic-Seasonal-Pandemic-Seasonal-Pandemic-Seasonal

**Look ahead but remember
where you've been**



Pandemic-Seasonal-Pandemic-Seasonal-Pandemic-Seasonal-Pandemic-Seasonal

**Updating the National Vaccine Plan:
A roadmap for the next decade**
A National, not Federal, Plan

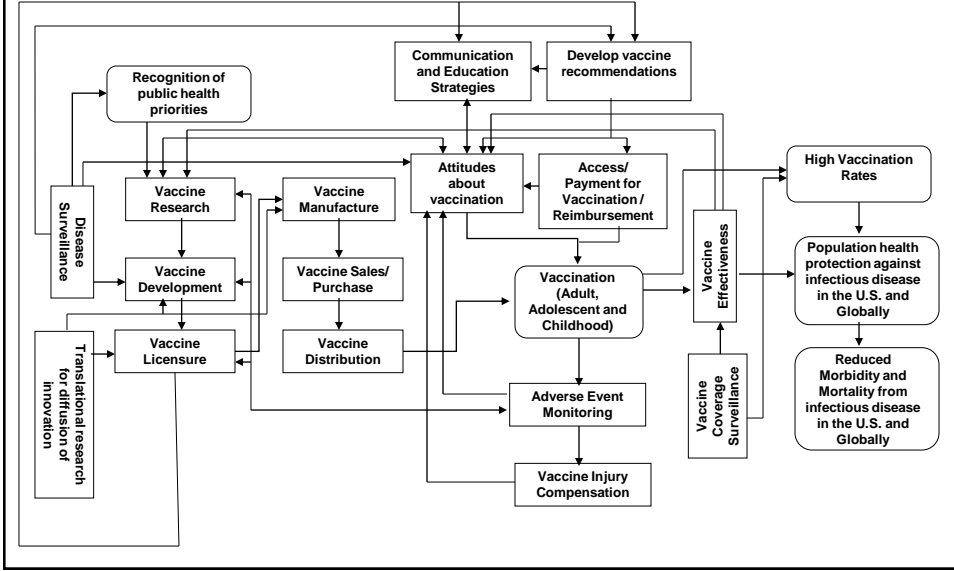


2008 Draft Strategic National Vaccine Plan

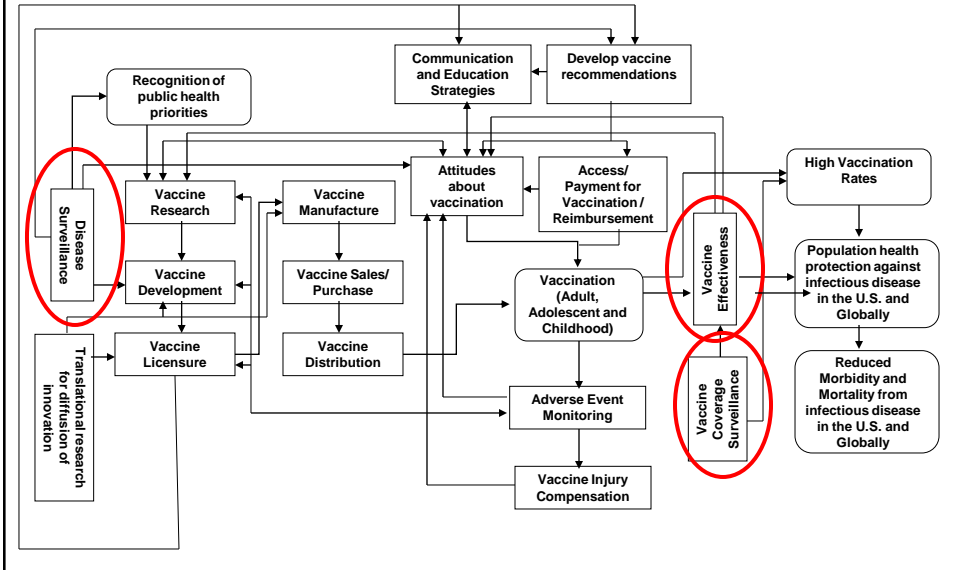
Goals

1. Develop new and improved vaccines
2. Enhance the safety of vaccines and vaccination practices
3. Support informed vaccine decision-making by the public, providers, and policy-makers
4. Ensure a stable supply of recommended vaccines and achieve better use of existing vaccines to prevent disease, disability and death in the United States
5. Increase global prevention of death and disease through safe and effective vaccination

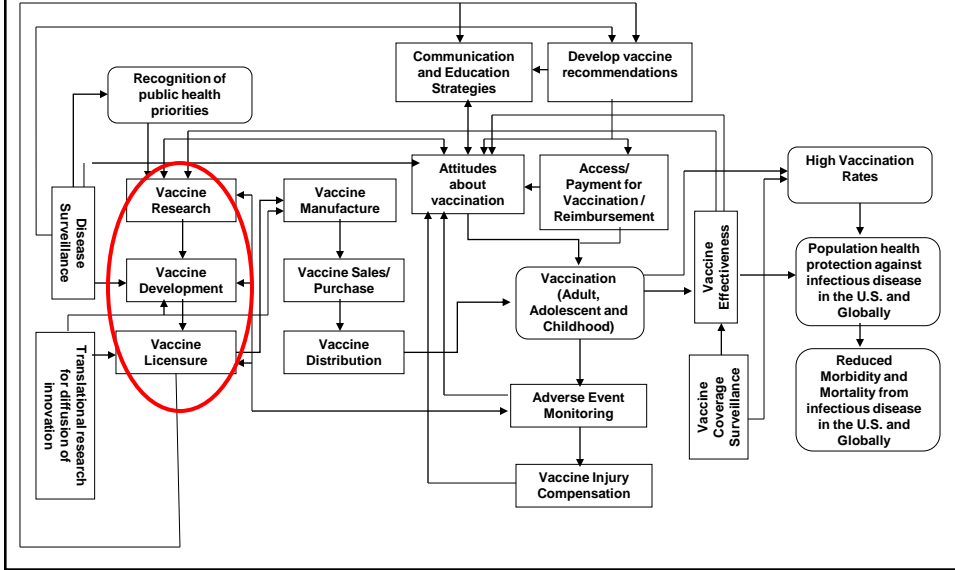
The Vaccine and Immunization Enterprise



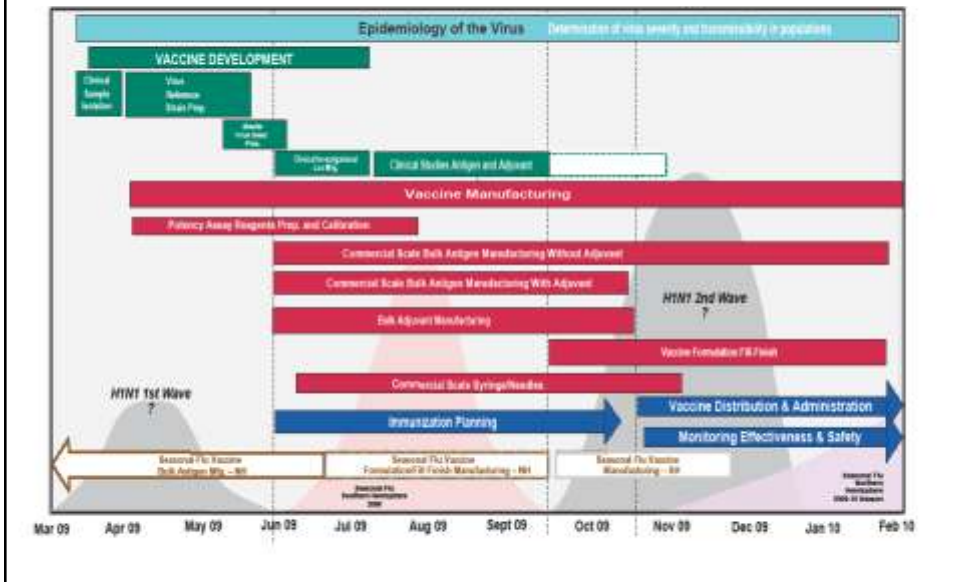
The Vaccine and Immunization Enterprise



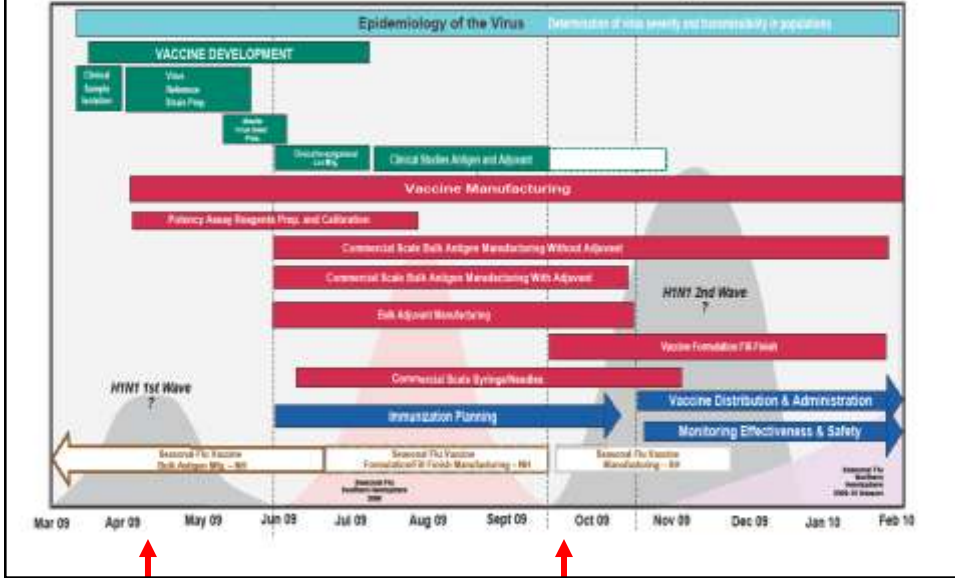
The Vaccine and Immunization Enterprise



The race between the virus and the vaccine



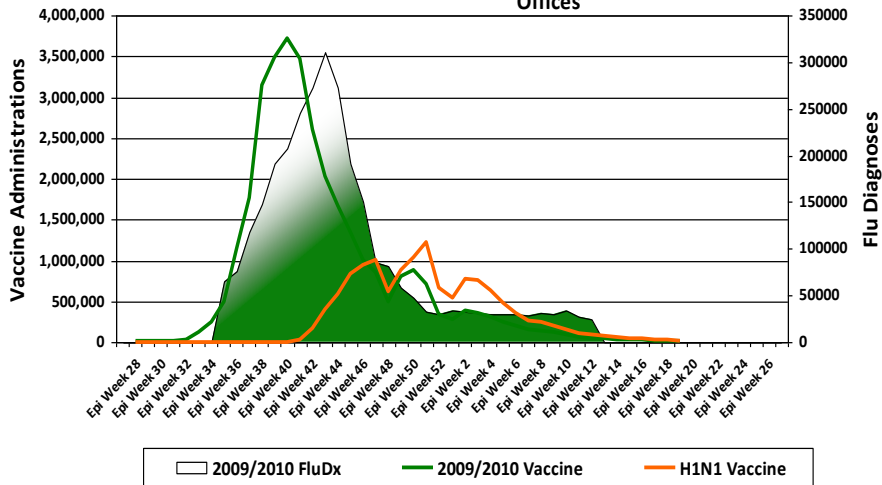
The race between the virus and the vaccine



The race between the virus and the vaccine

National Weekly uptake of vaccine and Disease Activity 2009/2010 season

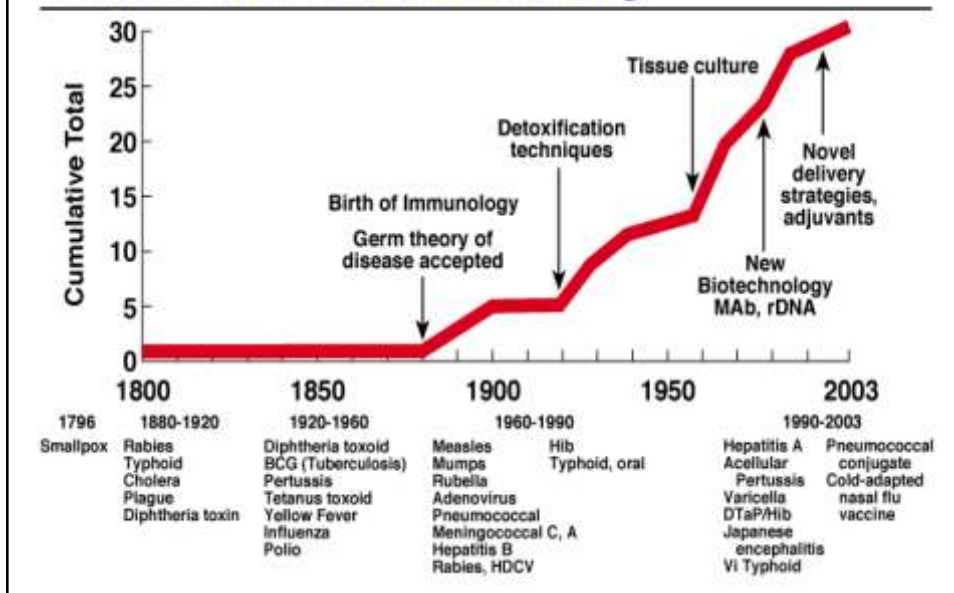
Weekly Uptake of Seasonal and H1N1 Vaccine and Disease Activity in Physician Offices



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Source: SDI

Introduction of New Vaccines, Jenner to the Present Day



Improving Influenza Vaccine Manufacturing

- Surge capacity
- Vaccine platforms that can shorten production timelines
- Dose optimization strategies
 - Adjuvants
 - Delivery systems
- A “universal” vaccine

Advances in influenza and influenza vaccine: Science and Opportunity



New Strategies for Influenza Vaccines



DNA-based vaccines



Recombinant subunit vaccines



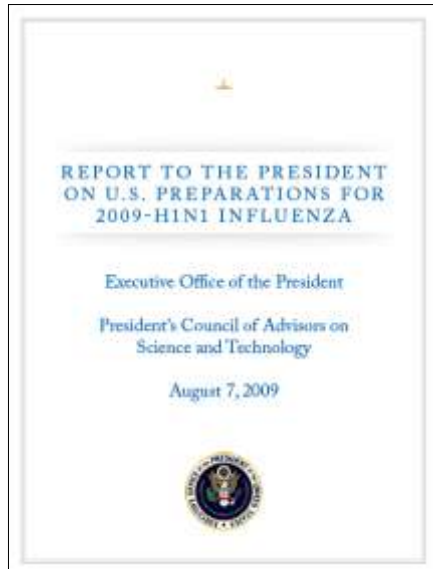
Microbial vector vaccines



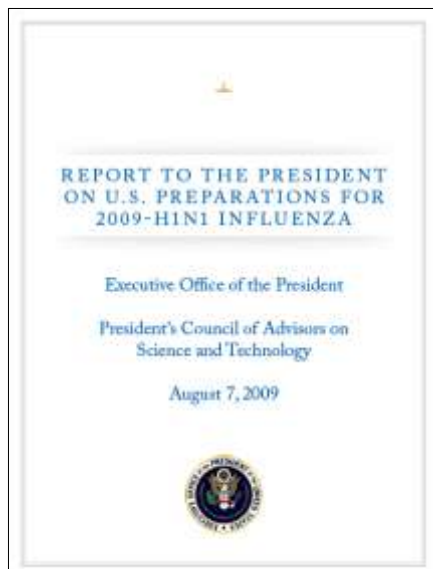
Virus-like particles



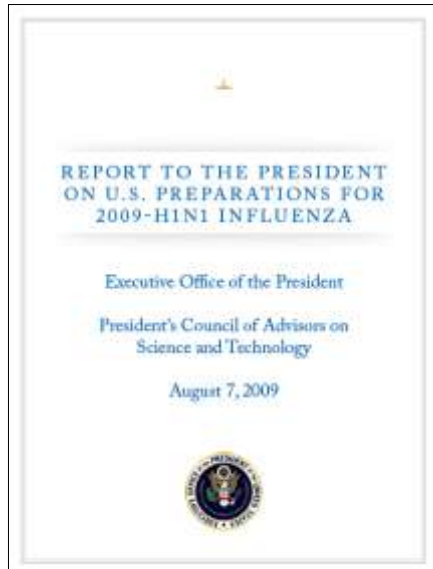
Synthetic peptide vaccines



- Coordination
- Scenarios
- Surveillance
- Response
- Barriers
- Communications
- Future Preparedness



- Coordination
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- Communications
- Future Preparedness



- **Future Preparedness**

- Accelerate speed and increase yield and effectiveness of vaccine production
- Facilitate development of additional antiviral drugs
- Improve medical surveillance
- Enhance animal surveillance measures



The White House
Office of the Press Secretary
For Immediate Release
January 27, 2010

Remarks by the President in State of the Union Address

We have gone from a bystander to a leader in the fight against climate change. We're helping developing countries to feed themselves, and continuing the fight against HIV/AIDS. ***And we are launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease — a plan that will counter threats at home and strengthen public health abroad.***



President's Council of Advisors on Science and Technology (PCAST)

Workshop on Influenza Vaccinology

- Prospects for and barriers to improved production of influenza vaccines
- Next generation influenza vaccines in development
- Financial and regulatory incentives/disincentives
- Implications for other biological threats



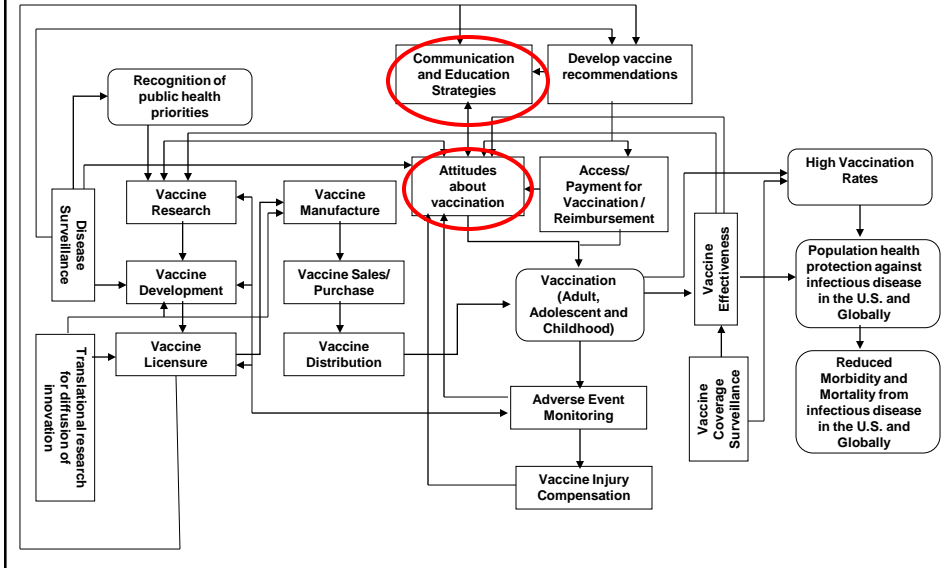
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

**The Public Health Emergency Medical Countermeasures
Enterprise: Innovative Strategies to Enhance Products from
Discovery Through Approval**
February 23-24, 2010

- Translation of early phase investments in basic science towards potential public health interventions.
- Partnerships: federal programs, the innovator and the commercial marketplace
- Market forces: incentives and disincentives
- Regulatory issues and regulatory science
- Application of innovative approaches being used to advance drug development for orphan products (e.g., rare, neglected, tropical diseases) or any other area of difficult commercial market development (e.g. oncology therapeutics)

<http://www.iom.edu/Activities/PublicHealth/MedPrep/2010-FEB-22.aspx>

The Vaccine and Immunization Enterprise



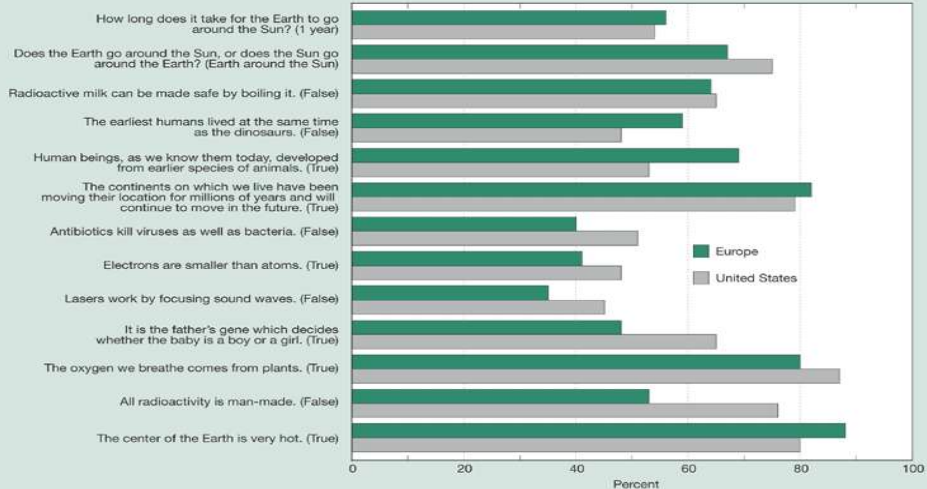
The Critical Role of Communications





Public Understanding of Science

Figure 7-6
Public understanding of scientific terms and concepts: 2001

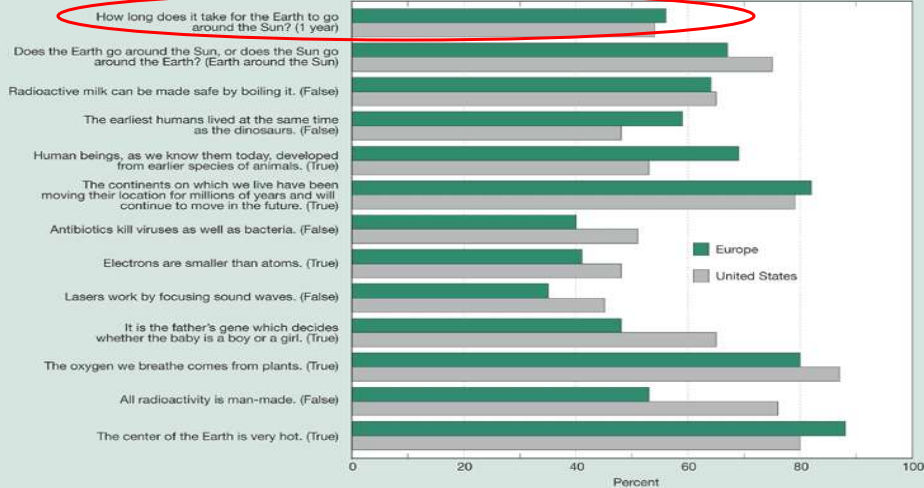


SOURCES: National Science Foundation, Division of Science Resources Statistics, Survey of Public Attitudes Toward and Understanding of Science and Technology, 2001; and European Commission, Eurobarometer 55.2 survey and standard report, *Europeans, Science and Technology*, December 2001.
Science & Engineering Indicators - 2004

Public Understanding of Science

How long does it take the Earth to go around the Sun?

Figure 7-6
Public understanding of scientific terms and concepts: 2001

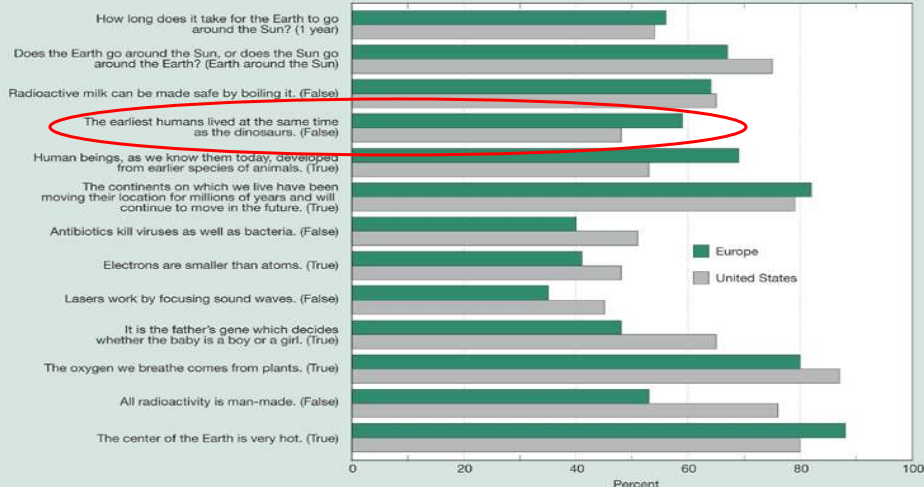


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Science & Engineering Indicators - 2004

Public Understanding of Science

The earliest humans lived at the same time as the dinosaurs

Figure 7-6
Public understanding of scientific terms and concepts: 2001

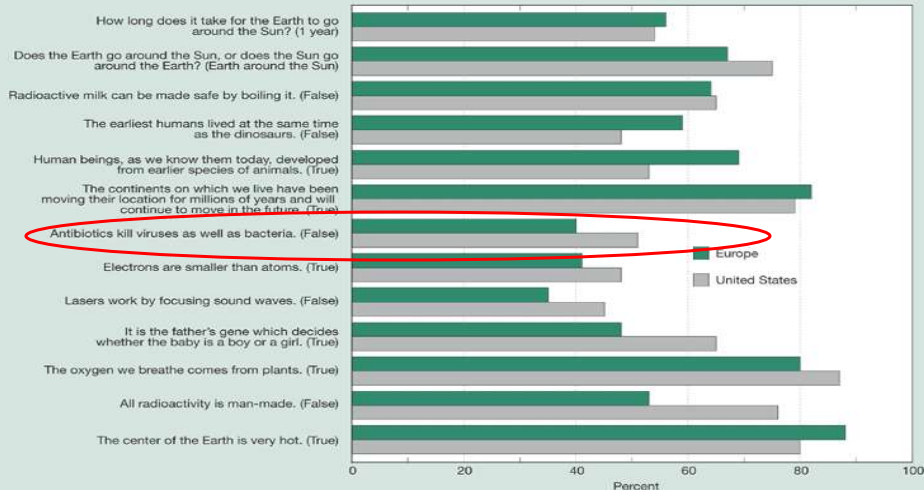


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Science & Engineering Indicators - 2004

Public Understanding of Science

Antibiotics kill viruses as well as bacteria

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Public understanding of scientific terms and concepts: 2001



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Science & Engineering Indicators – 2004

ACIP Recommendations for H1N1 Vaccine: Implications for Implementation of Universal Recommendations

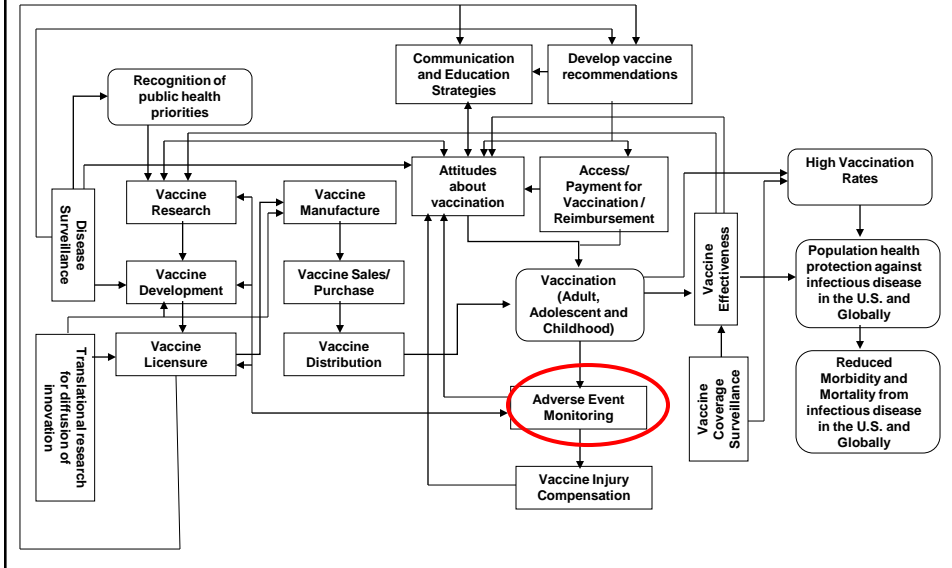
When supply adequate:

- Pregnant women,
- People who live with or care for children younger than 6 months of age,
- Health care and emergency services personnel,
- Persons between the ages of 6 months through 24 years of age, and
- People from ages 25 through 64 years who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems.

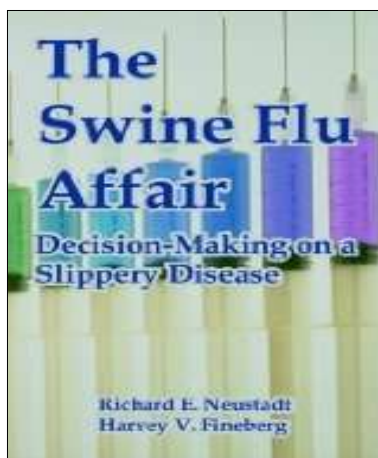
When supply limited:

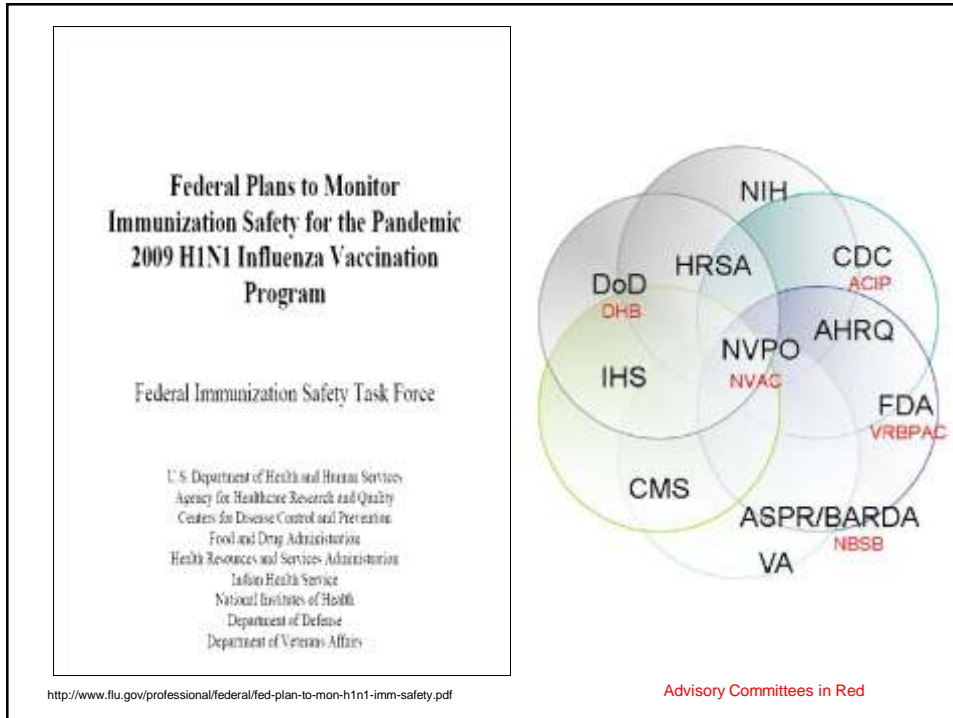
- Pregnant women,
- People who live with or care for children younger than 6 months of age,
- Health care and emergency services personnel with direct patient contact,
- Children 6 months through 4 years of age, and
- Children 5 through 18 years of age who have chronic medical conditions.

The Vaccine and Immunization Enterprise



1976 and 2009





National Vaccine Advisory Committee

H1N1 Vaccine Safety Risk Assessment Working Group

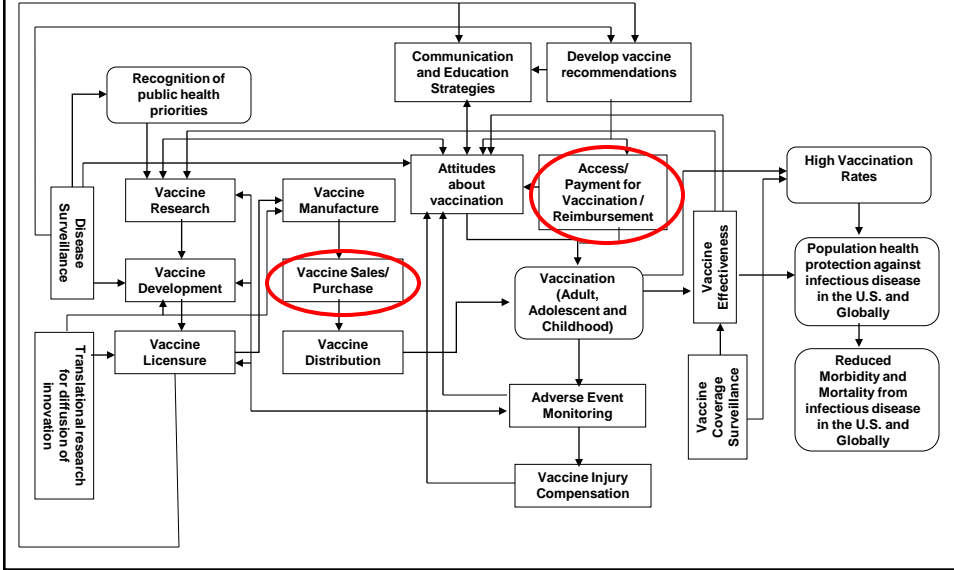
- **Conduct rapid reviews of 2009 H1N1 vaccine safety data**
- **Provide ongoing updates of their findings to the National Vaccine Advisory Committee (NVAC).**
- **They will meet regularly to review and assess data for six months after the conclusion of the 2009 H1N1 influenza vaccination program.**
- **The VSRAWG will make monthly reports to the NVAC on public conference calls.**

The working group's primary objectives are to:

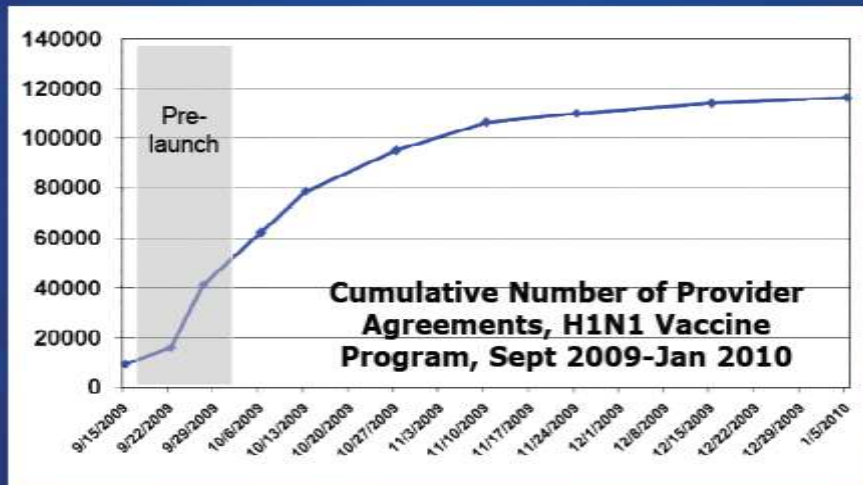
- Serve as a sounding board for the federal government to independently assess possible adverse events of interest
- Objectively and rapidly review potential vaccine-associated adverse events
- Identify and establish priorities for additional studies that will inform their assessment of an association between a vaccine and a health event
- Assess the likelihood of a causal relationship between a vaccination and a health event
- Identify any special populations who may be at increased risk
- Provide information needed for action by the health officials through the National Vaccine Advisory Committee in a timely manner

<http://www.hhs.gov/nvpo/nvac/subgroups/h1n1risk.html>

The Vaccine and Immunization Enterprise



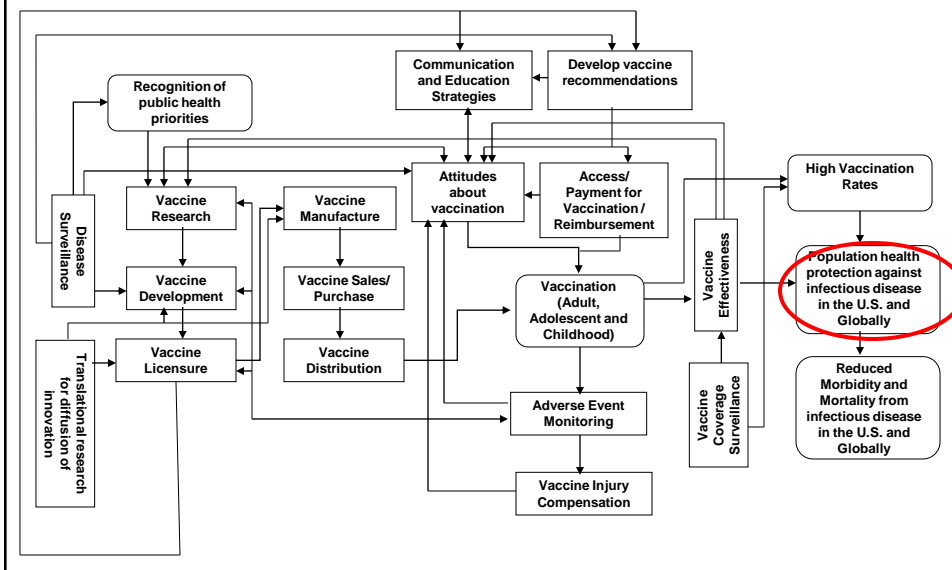
Tripled number of providers receiving vaccine through public health system



Patient Protection and Affordable Care Act and Immunization: Selected Highlights

- Expands health insurance access
- All ACIP-recommended vaccines shall be included/paid for in new private insurance plans without cost-sharing
 - Medicaid: Incentive eligible for 1% Federal Medical Assistance Percentage (FMAP) for states that cover United States Preventive Services Task Force A and B and ACIP services with no cost sharing for adults (Effective 2013)
- Comptroller General to study Medicare part D regarding any barriers to vaccines; report to Congress by 06/01/2011
- HHS may develop contracts for states to purchase (additional) vaccines for adults

The Vaccine and Immunization Enterprise





Swine flu, a false pandemic: Council of Europe

January 2010

The Council of Europe has alleged that pharmaceutical companies have forced the World Health Organization to declare swine flu as a pandemic, seeking more profits.

It is of the view that they have misled governments to stockpile vaccines...and have bought billions of dollars worth of medicines.

Some of the agreements do not allow governments to get out of buying vaccines.

Now, the governments are saddled with excess vaccines, and they are planning to sell them to other countries. Excess supply over demand will push down the prices as well.

The Council is likely to probe the pharmaceutical companies based on some evidence. It is in the process of gathering arguments along with the legal standards organization.



THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

September 17, 2009

President Announces Plan to Expand Fight Against Global H1N1 Pandemic

Today, President Obama announced the United States will continue to act aggressively to stop the global spread of the pandemic 2009-H1N1 influenza virus and is prepared to make 10 percent of its H1N1 vaccine supply available to other countries through the World Health Organization (WHO).

In recognition that diseases know no borders and that the health of the American people is inseparable from the health of people around the world, the United States is taking this action in concert with Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, and the United Kingdom.

The United States will make the H1N1 vaccine available to the WHO on a rolling basis as vaccine supplies become available, in order to assist countries that will not otherwise have direct access to the vaccine.



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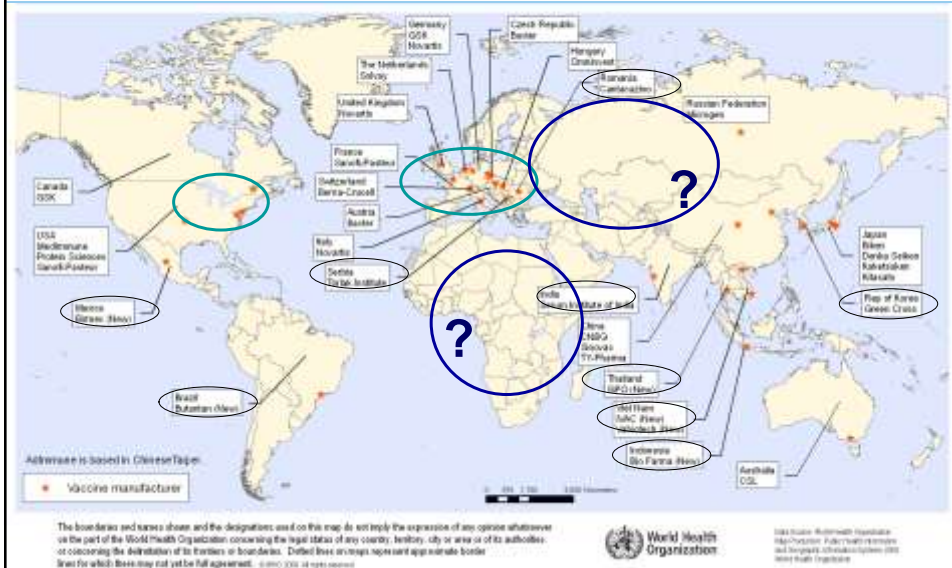


World Health
Organization

WHO Pandemic Vaccine Deployment May 3, 2010

Completed Vaccine Deliveries (01 January - 03 May)					
Country	# of Doses	Arrival	Country	# of Doses	Arrival
Afghanistan	500,000	22 Feb.	Mongolia	270,000 ^a	29 Mar.
Lao	600,600	25 Feb.	Guyana	75,000	29 Mar.
PII Guinea	700,000	26 Feb.	Guatemala	260,000	30 Mar.
Togo	132,000	27 Feb.	Philippines	1,900,000	30 Mar.
Nauru	1,000	27 Feb.	Tuvalu	1,000	30 Mar.
Maldives	31,200	02 Mar.	Azerbaijan	344,000 ^b	01 Apr.
Fiji	88,200	03 Mar.	Bolivia	900,000	02 Apr.
Nicaragua	110,000	03 Mar.	Myanmar	972,000	04 Apr.
Tonga	10,000	03 Mar.	Suriname	50,000	15 Apr.
Vanuatu	25,000	03 Mar.	Seychelles	9,000	21 Apr.
Kiribati	10,000	04 Mar.	Timor-Leste	117,000	21 Apr.
Solomon Is.	55,000	04 Mar.	Liberia	78,000	23 Apr.
Kosovo	100,000	09 Mar.	Niue	1,700 ^c	23 Apr.
Cuba	1,124,000	17 Mar.	Bangladesh	3,000,000	27 Apr.
Honduras	140,000	18 Mar.	Sudan	700,000	29 Apr.
Kenya	730,000	24 Mar.	El Salvador	2,276,000 ^d	30 Apr.
Cook Is.	2,000	24 Mar.	Georgia	100,000	01 May
Samoa	18,000	24 Mar.	Paraguay	600,000	02 May
Tokelau	200	24 Mar.	Cambodia	1,800,000 ^d	03 May
Pakistan	3,100,000	29 Mar.			
Total			39 Countries / 20,930,900 doses		

Map of current and new influenza vaccine manufacturers





**Protecting
Every
Adult and
Child
Immunization**

CDC's 2010 National Immunization Conference

- Adolescent Immunization
- Adult Immunization
- Assessment
- Barriers to Vaccination
- Community Partnerships
- Childhood Immunization
- Cultural Diversity
- Global Immunization
- Health Communications
- Health Education
- Policy and Legislation
- New Vaccines and Vaccine Development
- Vaccine-Preventable Diseases
- Vaccine Safety
- Vaccine Supply
- Immunization Registries
- Surveillance



National Influenza Vaccine Summit

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