

Access to Vaccines & the Economic Landscape

Arizona VFAAC Meeting, 9-19-14

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Introduction

- Vaccines have had a dramatic impact on the health of Americans.
 - One of the few forms of clinical primary prevention.
 - Considered one of the best public health interventions of the 20th c.
- Collaboration among government, public and private healthcare providers, and vaccine companies has made this success possible.
- Vaccine companies are committed to public health and their partnership with immunization stakeholders.
- The Vaccines for Children (VFC) Program is a clear illustration.
 - VFC is one of our nation's most successful public-private partnerships.
 - Congress intended the VFC program to provide free vaccines to vulnerable children while not disrupting the private marketplace.
 - VFC celebrated its 20th anniversary this year.

Vaccines for Children

20 years of protecting America's children

The Vaccines for Children program was established in 1994 to make vaccines available to uninsured children. VFC has helped prevent disease and save lives...big time!



CDC estimates that vaccination of children born between 1994 and 2013 will:

prevent **322 million** illnesses


more than the current population of the entire U.S.A.

help avoid **732,000** deaths


greater than the population of Boston, MA.

save nearly **\$1.4 trillion** in total societal costs
(that includes \$295 billion in direct costs)


or \$4,473 for each American



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

MMWR. Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994–2013. [MMWR 2014](#) | 64.20.2014

www.cdc.gov/features/vfcprogram



Introduction Cont.

- Companies are investing in a broad range of novel and improved vaccines to protect people of all ages from disease.
- To continue this progress, there must be a balanced vaccine ecosystem with a viable vaccination environment.

Manufacturers Serve a Key Role in the Battle against Infectious Diseases

Manufacturers are best positioned to develop and produce vaccines

Extensive expertise

State-of-the-art facilities

Capital independent of government grants

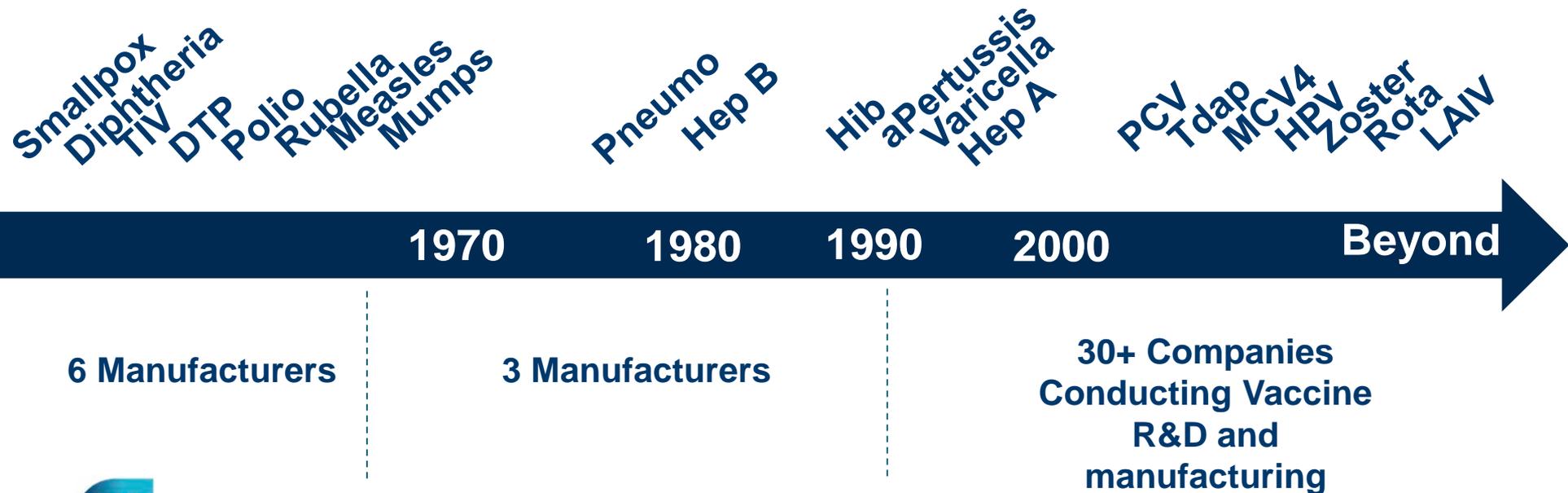
Future innovation, however, is dependent on an adequate return on investment.

Past Concern over Number of Vaccine Manufacturers Led to Policy Changes

- In the 1970s and 1980s, litigation against vaccine manufacturers had forced all but one manufacturer of DTP out of the market. The U.S. government became concerned that the country's vaccine supply was at risk.
- To prevent such shortages, Congress enacted unique legislation in 1986 creating a program to govern liability and preserve a viable vaccine industry, known as the National Vaccine Injury Compensation Program (VICP).
- VICP protects patients, providers and manufacturers.

These Changes Helped Stimulate New Entrants into a Growing Market

- Over the last 2 decades, more than a dozen new vaccines have been introduced and the number of companies developing products has increased.
- Companies can increase investment in vaccines because new vaccines can now demonstrate comparable Returns on Investment (ROI) relative to new biologicals and pharmaceuticals.
- Large and small companies, as well as investors, are continually assessing these ROI's and making decisions on resource allocation priorities.



More Companies Are Now Contributing to Greater Innovation

Targets for vaccine development include traditional viruses and bacteria, and also non-communicable diseases. Vaccines may become a key part of anti-microbial stewardship programs.

Over the next decade, we may see:

New Vaccines for Global Health

Malaria
Dengue
Ebola
Tuberculosis
Chikungunya

New Adult or Pediatric Vaccines

Universal influenza
Meningococcal A,C, Y, W-135
Meningococcal B
CMV
RSV
Streptococcus vaccines
Norovirus
New combinations of existing pediatric vaccines

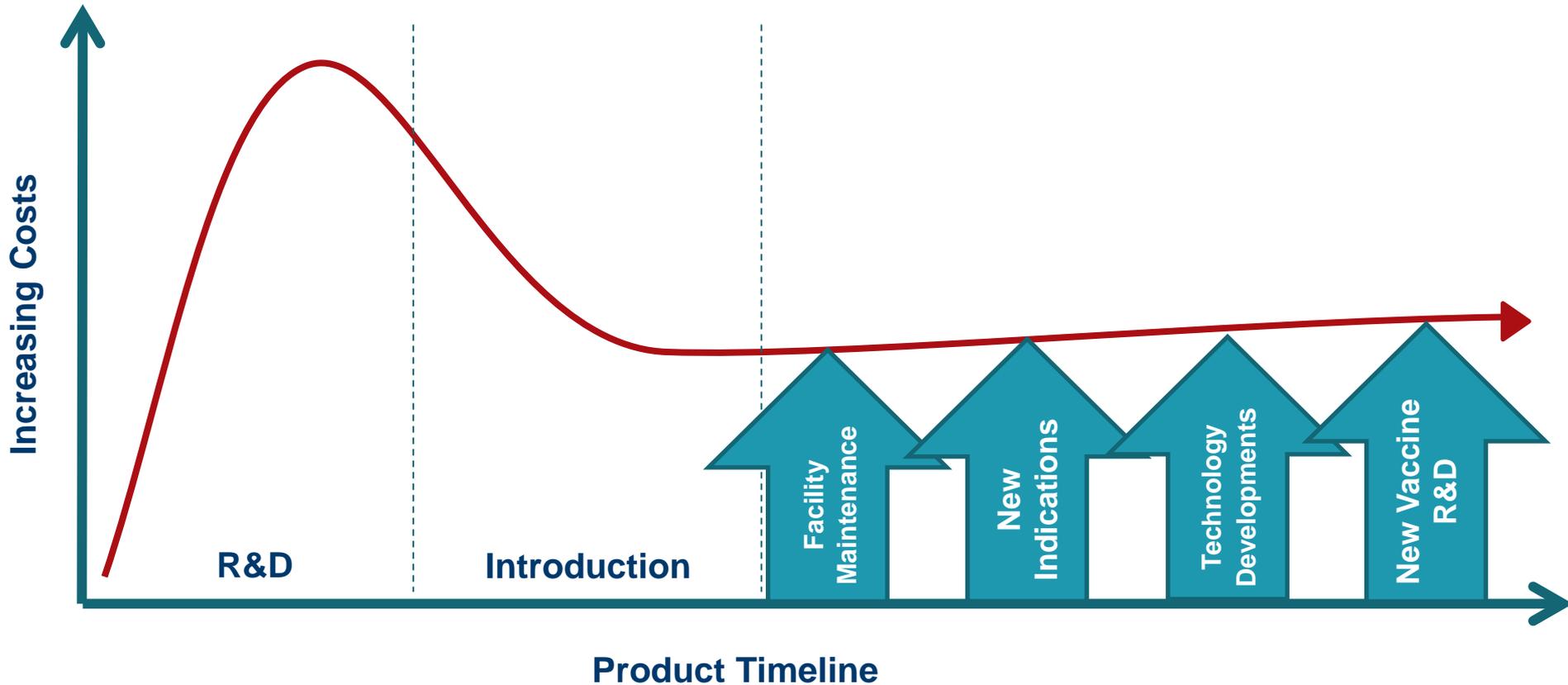
New Healthcare-acquired Infection Vaccines

Clostridium difficile
Staphylococcus aureus
Tuberculosis
Pseudomonas aeruginosa
Candida

Vaccines Present a Unique Need for Continuous Investment

- Higher costs for vaccines may reflect:
 - Constant maintenance and FDA-required upgrades of facilities
 - Processes and ongoing programs to improve current vaccines
 - New clinical development programs
 - Large clinical trial sizes
 - Post-marketing requirements for safety
- Over time, costs (and therefore prices) may actually increase due to the labor-intensive nature of manufacturing vaccines and to increasing regulatory requirements.

Vaccines Present a Unique Need for Continuous Investment



Novavax Initiates Phase 2 Clinical Trial of RSV F-Protein Nanoparticle Vaccine Candidate in Healthy Third-Trimester Pregnant Women

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September 16, 2014 16:05 ET | Source: Novavax, Inc.

GAITHERSBURG, Md., Sept. 16, 2014 (GLOBE NEWSWIRE)-- Novavax, Inc. (Nasdaq:NVAX), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants, today announced that enrollment has begun in a Phase 2 clinical trial of its respiratory syncytial virus F-protein nanoparticle vaccine candidate (RSV F Vaccine), in healthy women in the third trimester of pregnancy.

The purpose of this study is to evaluate the safety and immunogenicity of the RSV F Vaccine, in women in their third trimester of pregnancy. The trial will also assess the impact of maternal immunization on infant safety and RSV-specific antibody levels through one year and six months of life, respectively.

"Initiation of this trial represents a watershed event for Novavax and the entire vaccine industry," said Stan Erck, President and CEO of Novavax. "Our ability to deliver, on our timeline, the initiation of this landmark clinical trial is a measure of the credibility of our technology, the potential of our vaccine and most importantly, the commitment and

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CONTACT DATA

Sanofi faces make-or-break verdict on big dengue vaccine bet

Tue Mar 25, 2014 9:28am EDT

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1 OF 3. A view shows the logo of Sanofi Pasteur on a building at the French drugmaker's vaccine unit Sanofi Pasteur plant in Neuville-sur-Saone, near Lyon, March 14, 2014.
CREDIT: REUTERS/SROBERT PRATTA

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Ebola epidemic

Quarantines and isolation units imposed to stop the spread of the worst Ebola

(Reuters) - Sanofi expects final clinical results for its vaccine against dengue by late September, the French drugmaker's project leader has told Reuters, and has already gambled on starting production despite some disappointing early trials data.

Sanofi has invested more than one billion euros in the project and is hoping to become the first drugmaker to sell such a shot next year after two decades of research on the world's fastest-growing tropical disease, for which there is no preventative treatment.



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Glaxo's Ebola Vaccine to Be Tested for Safety in Humans

By Anna Edney · Aug 28, 2014 11:14 AM ET · 4 Comments [Email](#) [Print](#)

U.S. scientists will begin enrolling patients next week in safety trials of **GlaxoSmithKline Plc's** experimental Ebola vaccine as the death toll from the disease rises in West Africa.

The National Institutes of Health's Vaccine Research Center got approval from the Food and Drug Administration to start the Phase 1 trial, Michael Kurilla, director of the Office of Biodefense, Research Resources and Translational Research, said yesterday in a telephone interview. A Phase 1 trial is the first test of a therapy in humans to assess safety and whether it works similarly to how it does in animals.

The current outbreak has killed 1,552 people in four countries and may soon claim more deaths than all previous Ebola outbreaks combined. The NIH and London-based Glaxo are jointly developing the **experimental vaccine**, which doesn't contain any infectious Ebola virus.

It's unclear when the vaccine will be available for at-risk people, Anthony Fauci, director of the NIH's National Institute of Allergy and Infectious Diseases, said on a call with reporters today.

Aug. 28 (Bloomberg) — Bloomberg's Scarlet Fu reports on Ebola cases may rise to twenty thousand in course of outbreak according to the World Health Organization. She speaks with Tom Koene on "Bloomberg Surveillance." (Source: Bloomberg)

Major Ebola Outbreaks

Confirmed cases and years (as of Aug. 25, 2014).

Current outbreaks
 in Guinea, Liberia, Sierra Leone, Nigeria, Democratic Republic of Congo

Sudan, South Sudan (2004, 1976, 1976)

Difficult Climate for Many Stakeholders

- As vaccine companies face higher cost pressures, healthcare providers are grappling with higher transactional costs.
 - Some public health clinics and small volume private providers may find these more difficult to manage.
- ACA is a major step forward but not necessarily a fix-all.
 - ACA helped the consumer, not the clinician.
 - ACA may cause some insurers to reevaluate provider payments as they implement the ACA requirements for coverage.
 - In 2013, 36% of covered workers were enrolled in grandfathered health plans nationwide.
 - In AZ, many are covered by self-insured plans not yet subject to the ACA immunization coverage standard.
- Options are available to help providers access vaccines in the private sector.

Vaccine Manufacturers Have Many Options to Help Providers Directly

- For example: Provider offices set up an account directly with specific manufacturers.
- Method often used by pediatric offices and some large FP offices
- Flexible Contract Terms and Conditions:
 - Extend time for payment
 - On-invoice discounts
 - Incremental discounts based on specified criteria
 - Return policies
 - Etc.

Vaccine Manufacturers Participate in Organizational Initiatives

■ Provider Purchasing Organizations

- Networks of providers who contract directly with manufacturers on behalf of members
- Contracts may include flexible terms e.g. on-invoice discounts and rebates to the organization / members
- Delivery of doses for these contracts is often direct from the manufacturer
- Example: In Ohio, the AAP manages a purchasing organization for its members.

■ Group Purchasing Organizations (GPOs)

- Networks of institutions (e.g. hospital systems) who contract with manufacturers on behalf of members
- Contracts may include flexible terms e.g. on-invoice discounts and rebates to the organization / members
- Delivery of doses for these contracts is often through wholesalers on behalf of the manufacturer

Vaccine Manufacturers Participate in Organizational Initiatives Cont.

■ Third Party Procurement & Billing (e.g. VaxCare)

- VaxCare handles vaccine procurement & management, claims processing, and patient billing.
- Physicians must only:
 - Order vaccine and supplies through VaxCare portal at no cost
 - Vaccinate their patients and register their information in the VaxCare system.
 - Collect any out-of-pocket payments.
- VaxCare offers different solutions for private physicians & health departments.

Distributors Often Work with Providers and Hospitals Directly

- There are two primary types of distributors:
 - Physician distributors: Distributors of health care products and services to office-based practitioners / clinics
 - Wholesalers: Distributors of health care products and equipment to a broader array of health care settings (clinics, hospitals, nursing homes)
- Distributors offer access to a large variety of provider/ clinic office supplies, including vaccines.
 - Most often used by non-pediatrician, primary care offices and large hospital systems
- Providers can therefore access vaccines from various manufacturers from one place.
- Distributors may offer deals across a wide array of products.
- Some manufacturers direct providers to distributors.



Other Resources for Manufacturers to Help Providers

- Manufacturers have various communication links with providers.
 - In-office representatives
 - Phone representatives
 - Distributor representatives
- In some instances, companies may be able to assist with:
 - Contracts and purchasing options
 - Inventory management
 - Order placement
 - Staff training
 - Patient educational materials
- Access to organizations that specialize in helping providers with reimbursement problems for vaccines
- Office tool kits to help the office establish immunization infrastructure



Valuable Resources from Other Key Sources

- Immunization tool kits

- AMA
- AAP
- ACOG
- ACP

- CME programs for physicians and nurses on coding and billing

- AMA
- ACOG
- AAFP



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