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VACCINE SCIENCE & POLICY GROUP

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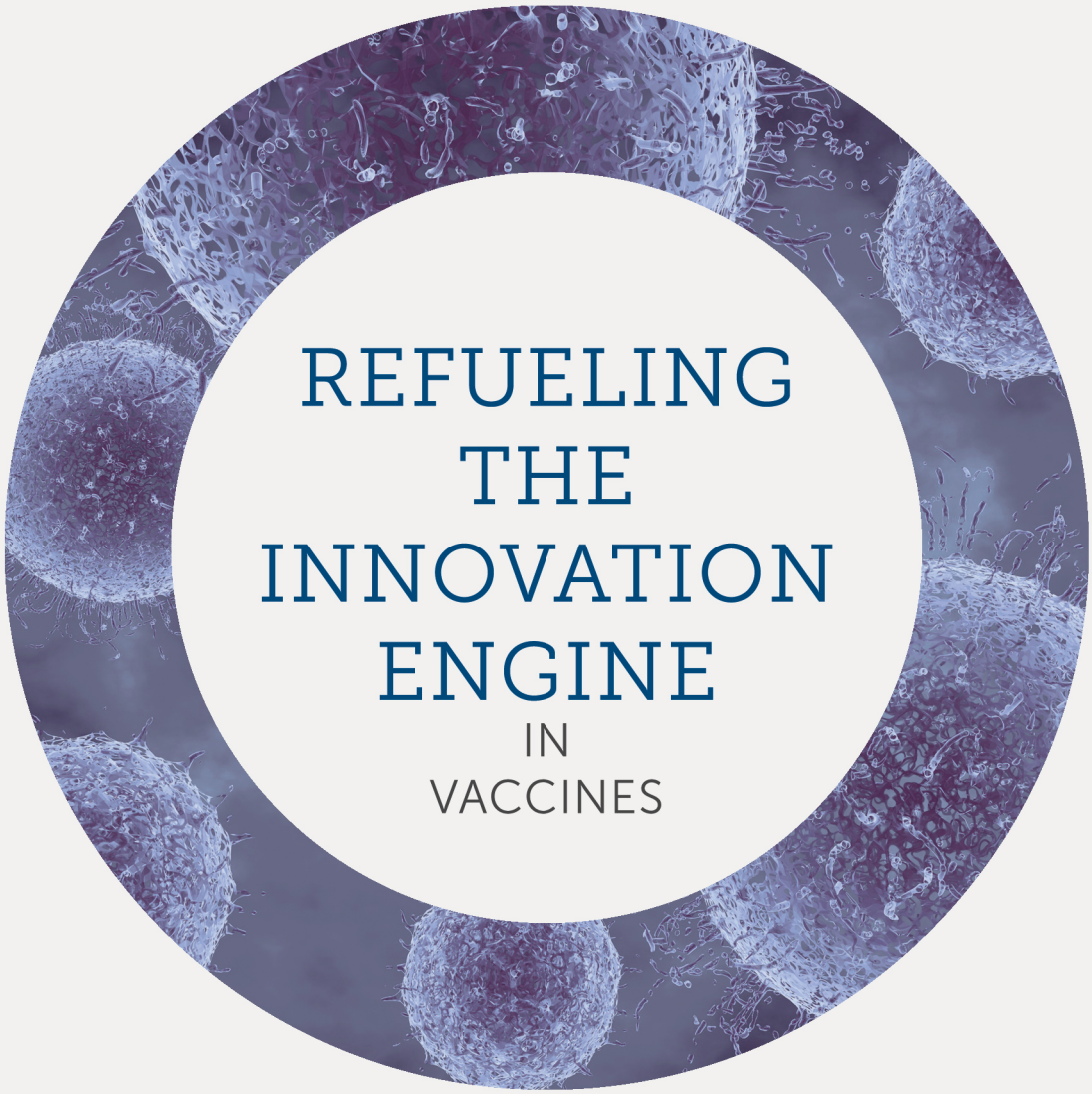

REFUELING THE INNOVATION ENGINE IN VACCINES

Michael Conway, J.D.; Adam Sabow, M.B.A.; Jennifer Heller, Ph.D.; Gila Vadnai-Tolub, M.B.A.; and Tara Azimi, M.P.P.

An excerpt from
Accelerating the Development of a Universal Influenza Vaccine

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FOREWORD

Vaccines are among the greatest global health achievements of all time. The World Health Organization estimates that immunizing children against diphtheria, tetanus, pertussis, and measles saves 2 million to 3 million lives every year. In the United States alone, these vaccines have prevented more than 21 million hospitalizations and 732,000 deaths among children born in the last 20 years, according to the Centers for Disease Control and Prevention.

One of our most urgent needs is a vaccine that will protect the world's people against influenza — a vaccine that is safe and highly effective, a vaccine that works in the young and the old and everyone between, a vaccine that is protective against any viral strain that might arise, and a vaccine that confers lifelong immunity. The launch of the Sabin-Aspen Vaccine Science & Policy Group (the Group) in 2018 coincided with the 100th anniversary of the worldwide Spanish influenza epidemic, which infected an estimated 500 million people and led to as many as 50 million deaths. In a more typical year, when the impact of the circulating strain of influenza is not so extraordinary, the virus still causes an estimated 290,000 to 650,000 deaths worldwide, mostly in adults age 65 or older.

As co-chairs of the Group, we are convinced that the goal of attaining a universal influenza vaccine is a highly worthy pursuit. The bold, actionable recommendations we put forward in this inaugural report are designed to communicate the urgent need, invigorate the necessary research, and overcome admittedly daunting scientific and operational obstacles.

The Group was formed to advance innovative ideas for harnessing the life-saving power of vaccines in the U.S. and around the globe. Collectively, the leaders, thinkers, and practitioners among this membership bring in-depth knowledge of vaccine-related scientific, medical, and political challenges. To encourage cross-disciplinary dialogue, these experts are joined by trailblazers in public health, regulatory science, philanthropy, venture capital, biotechnology, genetics, ecology, ethics, and journalism. We owe them our deepest thanks.

In October 2018, members convened for the first time at the Aspen Institute campus in Aspen, Colorado, to participate in two and a half days of thought-provoking conversation about how best to speed the quest toward a universal influenza vaccine. Their deliberations were informed by the four commissioned white papers included in this compendium, written by some of the most knowledgeable people in the field.

The bold, actionable recommendations we put forward in this inaugural report are designed to communicate the urgent need, invigorate the necessary research, and overcome admittedly daunting scientific and operational obstacles.

Armed with those and other rich resources, members looked for transformative Big Ideas. The package of ideas contained in this report is the result of that process. We expect to disseminate the report widely through the networks of the members of the Group as well as those of both Aspen and Sabin.

The Sabin-Aspen partnership behind this initiative is powerful and synergistic. Sabin is committed to advancing vaccine research and extending the full benefits of vaccines to all people, regardless of who they are or where they live. Sabin carries on the legacy of Dr. Albert B. Sabin, best known for creating the oral polio vaccine, which contributed to dramatic reductions in the burden of polio. The Health, Medicine and Society Program has a stellar reputation as a trusted, non-partisan player in the field of health care and health policy, and the Aspen Institute, where it is housed, is widely known for its capacity to convene people from many disciplines and perspectives.

In addition to the Group's members and the authors who participated in our inaugural meeting, we are most grateful to Flu Lab — the Launch Funder of the Group — which provided support for this report and the research and other meetings that informed it. This important work simply would not have been possible without Flu Lab's strong commitment to efforts designed to accelerate the development of a universal influenza vaccine through new innovative ideas and cross-sector collaborations, in addition to and including this prestigious Group.

We also want to acknowledge the many contributions of staff from the Sabin and Aspen organizations. Bruce Gellin, Stacey Knobler, and Jamie Minchin from Sabin and Ruth Katz and Katya Wanzer from Aspen all worked tirelessly together to help develop and manage this new initiative and our inaugural meeting. Finally, we want to recognize Margaret K. Saunders, deputy editor with Health Affairs, for her editorial work on the four commissioned papers and this final report.

It is tremendously rewarding for us to work with all of those so dedicated to driving vaccine development forward, and we eagerly anticipate our continued progress.

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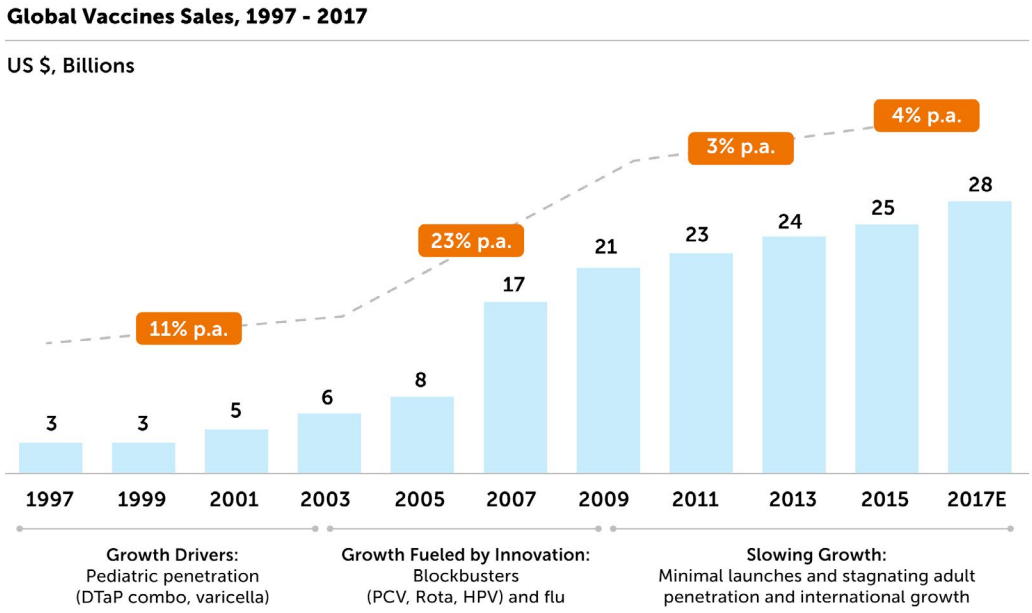
INTRODUCTION

From a global public health standpoint, vaccines are considered one of the most important inventions in human history. Some notable achievements of vaccines include the eradication of smallpox and the near eradication of polio viruses. Approximately 300 million people died of smallpox between 1900 and 1979 — millions more were disfigured; however, by 1979, vaccination programs had completely wiped out the disease (Fenner, Henderson, Arita, Jezek, & Ladnyi, 1988). In 1988, at the onset of a global campaign to end polio, there were 350,000 new cases per year; nearly 30 years later, only 22 cases were reported in war-stricken areas where immunization was not possible (World Health Organization [WHO], 2018).

The past 20 years have seen a rejuvenation of innovation in vaccines, including pneumococcal, rotavirus, HPV, and varicella. Indeed, in its 2017 annual letter, the Bill & Melinda Gates Foundation reported that 122 million children's lives had been saved since 1990 — and that vaccines were the biggest reason for this decline in childhood deaths (Gates & Gates, 2017).

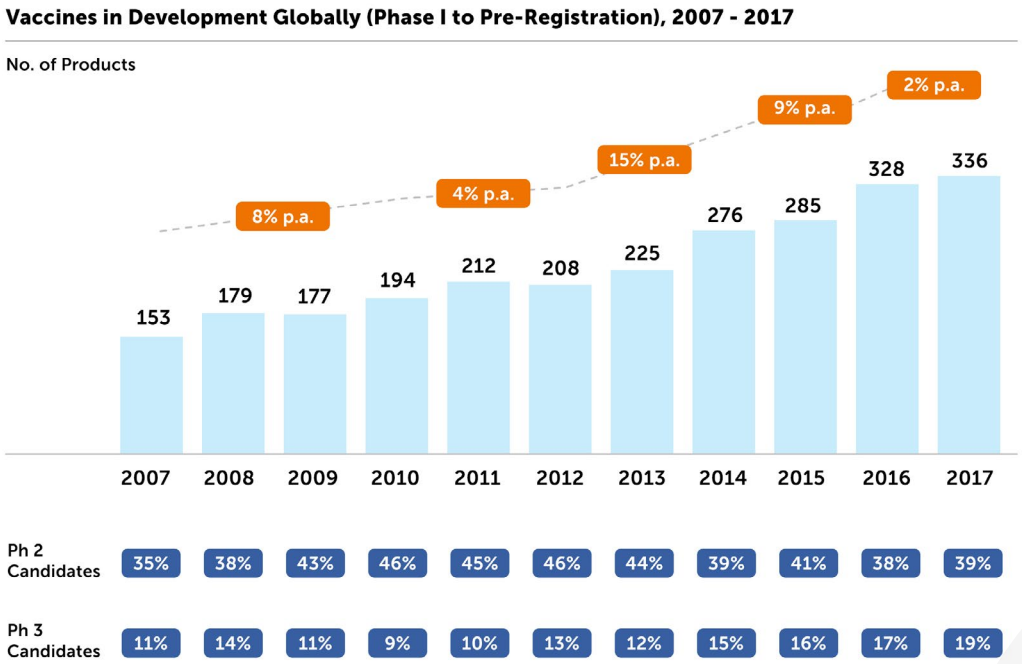
These statistics are in line with the historically high growth rate of the vaccine industry — 12 to 15 percent year on year over the past 2 decades — double the rate of the rest of the pharmaceutical industry (Figure 1). In the past 10 years, the number of vaccines in the pipeline has also doubled to 336 vaccines in 2017 (Figure 2). And while, to date, vaccines have mostly focused on disease prevention, we expect them to increasingly play a role in treatment (for example, therapeutic vaccines for cancer) and thus have even greater impact in the future.

Figure 1: After a period of rapid growth, vaccines sales have slowed in recent years



Source: EvaluatePharma, September 2018; McKinsey & Company internal analysis of data

Figure 2: The number of vaccine programs in development has flattened over the past 2 years

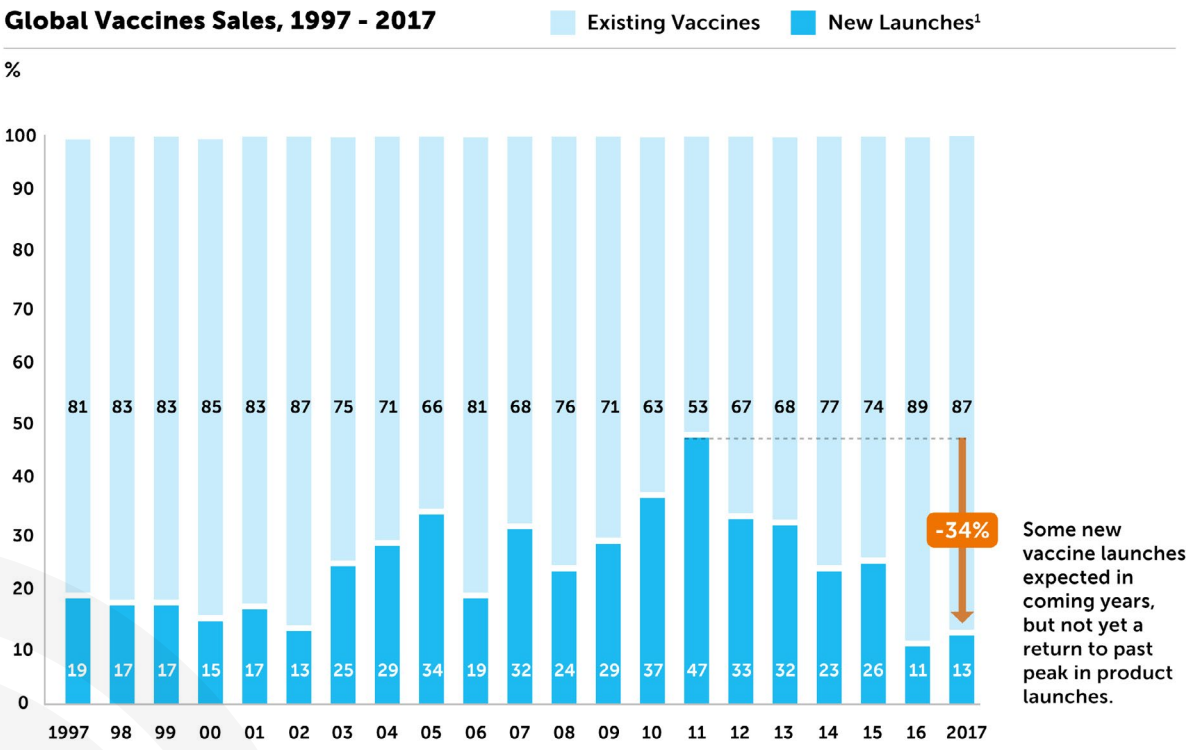


Source: Pharmaprojects, September 2018; McKinsey & Company internal analysis of data

However, we have seen four signs of slowing innovation in vaccine development over the past 5 years:

- Revenue growth has slowed to below five percent in the past 5 years (Figure 1).
- We are now seeing a flattening development pipeline (Figure 2), with the share of growth from new vaccines launched down from almost 50 percent in 2011 to less than 15 percent in 2017 — the lowest level in 20 years (Figure 3).
- We are recording higher attrition rates for vaccine development programs relative to other biologics (that is, pharmaceutical drug products manufactured in, extracted from, or semi-synthesized from biological sources), with fewer shots on goal, meaning fewer vaccine candidates are advanced to clinical studies (Figure 4).
- There are remaining unmet needs cutting across multiple categories of vaccines, including high-income endemic diseases (such as HIV and norovirus) and those endemic to low-income regions (for instance, tuberculosis and malaria).

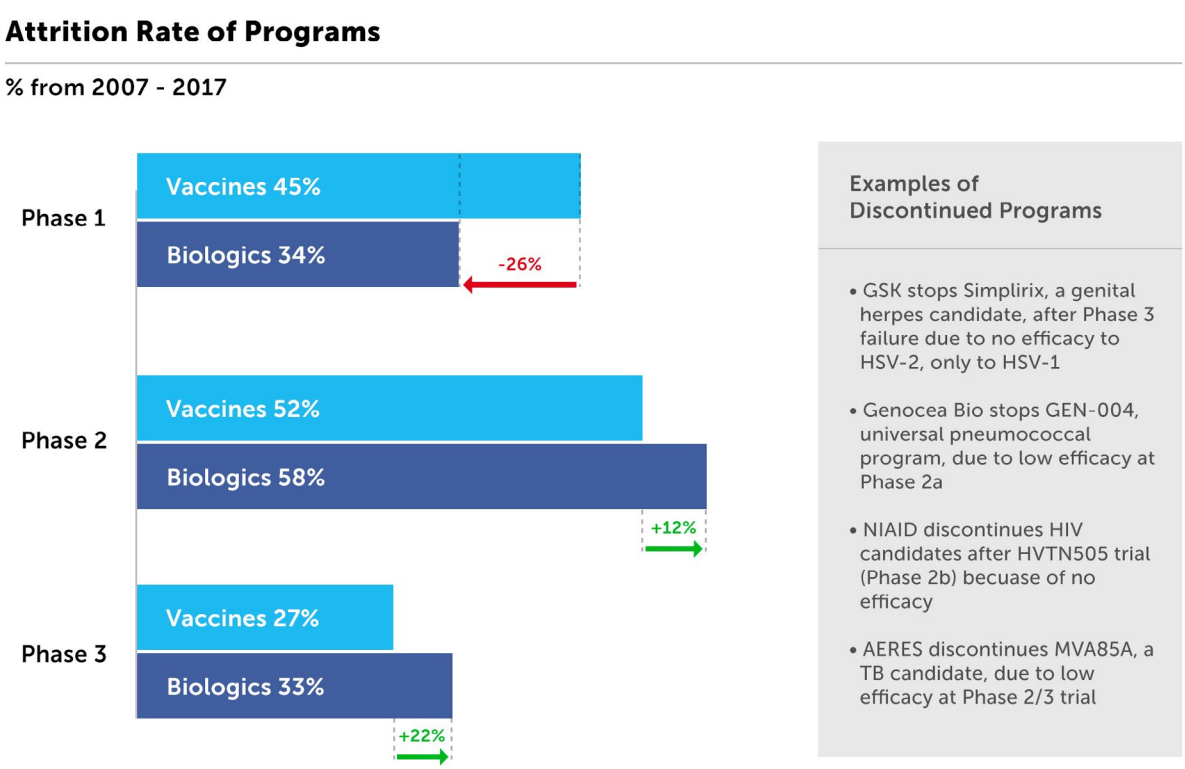
Figure 3: The proportion of sales from new vaccines has declined in recent years



[1] Defined as any vaccine that received FDA approval in the preceding 5 years.

Source: EvaluatePharma, September 2018; McKinsey & Company internal analysis of data

Figure 4: Vaccine candidates receive fewer "shots on goal" relative to other biologics

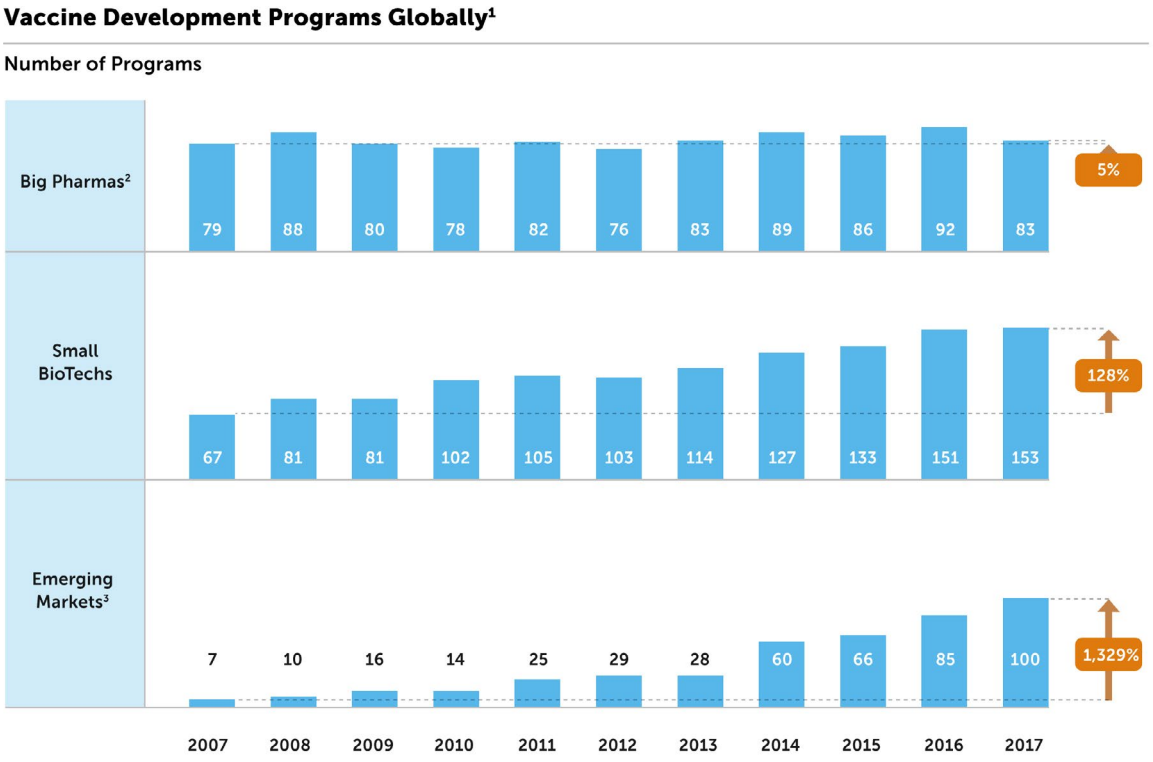


Attrition in Phase 1 driven by 3 factors: (1) limited funding, especially for Phase 2, (2) biologic complexity of candidates, and (3) evidence that identifies unviable candidates earlier than for biologics

Source: Pharmaprojects, September 2018; McKinsey & Company internal analysis of data

Historically, the "Big 4" global vaccine manufacturers (i.e., Merck, GSK, Pfizer, and Sanofi) have driven most innovation. However, in the past 5 years, their pipeline growth has been flat, and the majority of new programs in the pipeline have been driven by emerging market players with "me too" vaccines (that is, vaccines undifferentiated from those already on market) and by smaller biotechs (Figure 5). While there is potential for significant innovation from biotechs, there is an open question around whether sufficient absorptive capacity exists in the system to bring these programs through development. Indeed, our observations on the pharmaceutical industry suggest that manufacturers vary broadly in their ability to identify, acquire, and gain from external innovation.

Figure 5: The market is starting to see an increase in the number of overall new programs, largely driven by small biotechs and emerging market players



[1] Includes only infectious disease vaccines, both prophylactic and therapeutic; excludes all cancer vaccines.
[2] Refers to top 20 players with vaccines pipelines, including in-licensed products.
[3] Including Japan.

Source: Pharmaprojects, September 2018; McKinsey & Company internal analysis of data

The external market expects a return to growth, with analysts forecasting six percent to nine percent growth in the global vaccine market over the next 5 years (EvaluatePharma, 2018). In addition, there is considerable potential for new antigens as well as novel synthetic modalities (i.e., mRNA-based products). Inherent in these market assumptions is the successful Phase 3 completion of several vaccines in development as well as further advancements in innovation. The key question is whether the vaccine industry can overcome several challenges that are currently impacting innovation.

CHALLENGES TO INNOVATION IN VACCINES

Our research on industry trends suggests reinvigorating vaccine innovation will require addressing three underlying issues:

- Increased investment requirements for research and development (R&D) and manufacturing.
- Increased opportunity cost as relative investment economics converge with biologics.
- Higher technical complexity and commercial uncertainty compared to recent innovations.

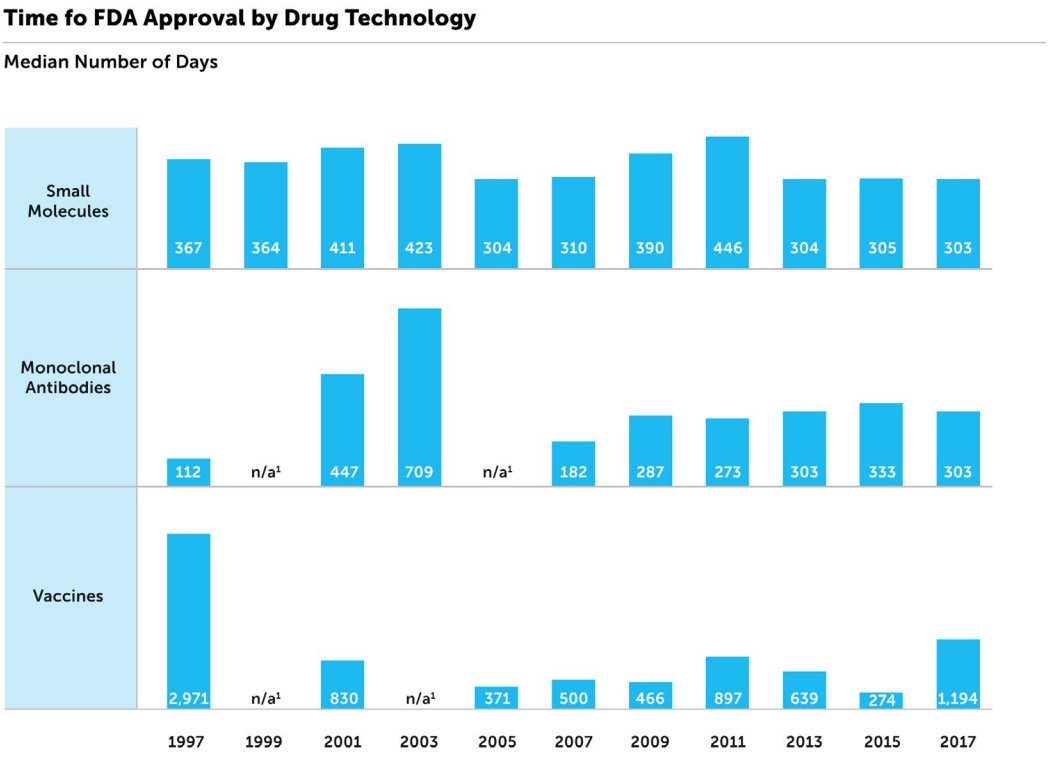
These challenges have the potential to impact different categories of vaccine manufacturers in different ways: On the one side, they could create opportunities for innovation by new players; on the other side, they may create structural barriers that offer an advantage to existing players.

Increased Investment Requirements for R&D and Manufacturing

One emerging trend contributing to a progressively challenging environment for innovation is an increase in investment requirements for R&D and manufacturing. These shifts in the broader infrastructure impact the overall economic equation of the vaccine industry by increasing the length of time and costs associated with innovation.

On the R&D side, regulatory scrutiny overall is on the rise across more complex products (e.g., biologics, vaccines, and other sterile injectables), with longer timelines for vaccine approvals (Figure 6). Given the preventive nature of these drugs, vaccines also face a heightened bar for quality and safety, thereby adding both complexity and additional costs throughout the development process.

Figure 6: Time to regulatory approval for vaccines is consistently higher than other drug categories



[1] Data not available due to no FDA approvals recorded in this year.

Source: EvaluatePharma, February 2018; McKinsey & Company internal analysis of data

In addition, many of the pipeline programs have lower incidence rates than prior vaccine innovations and thus face evolving clinical trial requirements. Clinical trials need to elicit a strong and lasting immune response and require a natural incidence of the disease where the trial is being conducted. Developing a vaccine for diseases with a lower incidence requires many more participants and sites to demonstrate efficacy, increasing both the cost and the duration of the trials.

On the manufacturing side, we have seen shortages, recalls, and other manufacturing challenges in recent years — recent examples include typhoid and varicella recalls due to efficacy concerns, as well as shortages and prequalification removals for pediatric combination vaccines due to manufacturing reliability issues. These issues have resulted in lost sales and significant investment requirements to transform vaccine manufacturing networks.

Increased Opportunity Cost as Relative Investment Economics Converge with Biologics

Increased technical challenges are resulting in the convergence of success rates for bringing vaccines to market with those of biologics. However, given the higher revenues derived from blockbuster biologics compared to vaccines — for example, the largest biologic's revenues are more than two to three times greater than those for the largest vaccine, pneumococcal conjugate, with peak revenues of $6 billion (EvaluatePharma, 2018) — this convergence of success rates reduces the relative attractiveness for investment in vaccines compared with the past, especially as the largest global vaccine manufacturers all have competing priorities. As pharmaceutical companies allocate capital to opportunities with the highest return on investment, this change in the relative investment economics will be a consideration in future decision-making for vaccine innovation.

Higher Technical Complexity and Commercial Uncertainty Compared to Recent Innovations

Many vaccine industry leaders consider the recent major innovations (such as pneumococcal, rotavirus, and HPV) to be lower-hanging fruit in immunization — these vaccines had high commercial potential and higher relative technical feasibility. The remaining potential innovations face increased commercial uncertainty and technical complexity in an environment of increasing R&D and manufacturing investments, as described above.

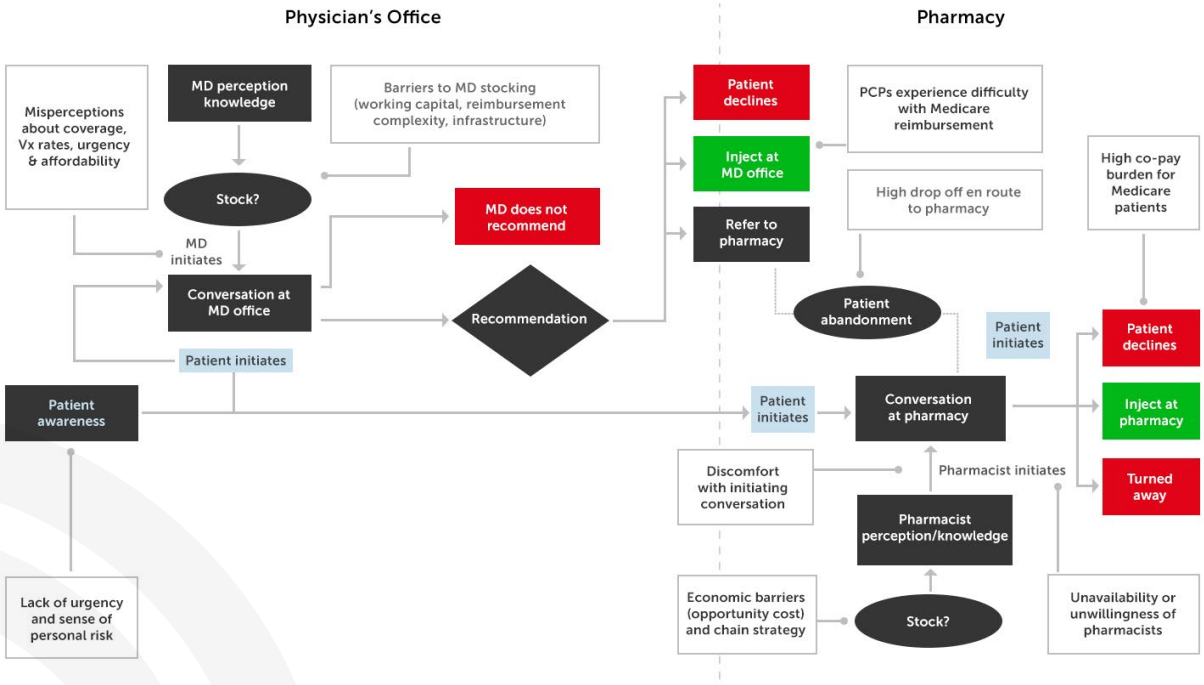
From a commercial perspective, the pipeline of remaining innovations has a different commercial profile (Figure 7) — the absolute size of relevant populations is smaller, and the programs have less established pathways compared to pediatric or adolescent vaccines, which have recommended immunization schedules. In this context, capturing the full market potential still requires navigating a complex vaccine care flow with many influences and inputs (Figure 8). Obtaining the recommendation for inclusion in immunization schedules is the most uncertain step, as vaccine manufacturers typically have limited visibility on what recommendations to expect. This step is critical to secure reimbursement and access to markets and builds additional uncertainty in relation to return on investment for vaccine manufacturers. Additionally, once a vaccine is on the market, capturing market share requires navigating a broad set of stakeholders (physicians, retailers, payers, and patients), often with uncertain pricing and market demand contributing to additional commercial risk. In terms of technical feasibility, the remaining pipeline innovations are challenging; in particular, the potential blockbusters are often long sought-after vaccines that have been tried (and failed) multiple times in the past (e.g., HIV and universal flu).

Figure 7: Drivers of commercial attractiveness and technical feasibility

Commercial Attractiveness		Technical Feasibility		
	Assessment of Commercial Attractiveness		**Assessment of Techical Feasibilty**	**Example of Challenging Vaccine**
Volume	• Is there a large population at risk? Does the disease have a high incidence?	**Natural Immunity**	• Does the pathogen trigger antibody response and confer immunity post-infection?	• HIV
Price	• Are people or payers willing to pay for the vaccine? • Are there other vaccines or treatments on the market?	**Adaptability of Pathogen**	• Is there high antigenic variability or does the pathogen mutate/evolve quickly?	• Universal flu
Ability to Access Market	• Are there existing commercial channels? • If not, is there a way to make the commercial access work?	**Strength of Immune Response**	• Can an adequate immune response be achieved? Are adjuvants necessary and do they work?	• Pertussis
		Clinical Trials	• How easy are clinical trials (i.e., finding population at risk, diagnosing, prevalence of disease)? Is there a correlate of protection?	• Clostridium difficile

Source: McKinsey & Company internal analysis (2018)

Figure 8: Capturing share requires navigating a complex vaccine care flow with many influences and inputs



Source: McKinsey & Company internal analysis (2018)

Stepping back, as the sources of growth shift from relatively low-hanging fruit to new opportunities for innovation, we see six vaccine archetypes emerging with varying levels of technical complexity and commercial opportunity (Figure 9).

1. **High Income:** Vaccines targeting diseases in high-income markets including health care-acquired infections (e.g., Clostridium difficile and Staphylococcus) as well as other disease areas (e.g., norovirus). These programs have moderate technical feasibility but vary in commercial potential. For example, nosocomial vaccines have high market potential but unclear commercial models and indications (i.e., they may not have a clear immunization schedule), whereas other high-income vaccines have moderate commercial potential and a mix of potential commercial models.
2. **Potential Blockbusters:** Vaccines targeting high-burden diseases with large potential patient pools (such as HIV and respiratory syncytial virus), thus carrying a high commercial potential. Challenging technical complexity results in low-to-moderate technical feasibility for these innovations.
3. **Therapeutic Vaccines:** Vaccines used as a method of treatment to fight an existing disease or condition, rather than as a preventive measure. Potential applications include oncology, smoking cessation, and addiction. High unmet need results in a high commercial potential for these programs, but technical feasibility is low to moderate.
4. **Incremental Improvements:** Improvements to existing vaccines to address unmet needs (i.e., improvements in efficacy, duration of protection, and ease of use). While technical feasibility is moderate to high, the commercial value is uncertain, particularly in assessing the price these incremental innovations can command.
5. **Emerging Threats:** Vaccines targeting emerging epidemiology threats and future priorities for innovation (e.g., Ebola and Chagas disease). These programs have an uncertain commercial demand profile given lack of clarity on the willingness of governments and agencies to stockpile significant amounts or pay more than "costs" to maintain supply options. The technical feasibility is moderate and varies by disease.
6. **Low Income:** Vaccines targeting diseases with a higher burden in low-income markets (e.g., tuberculosis and malaria) with moderate commercial potential and low-to-moderate technical feasibility. The evolution of supply and demand for vaccines in emerging markets creates significant ambiguity, compounded by the entrance of new local players. In addition, as Gavi, the Vaccine Alliance (Gavi), countries (developing countries that receive support from the Gavi public-private partnership to increase access to vaccines) transition to take over responsibility for financing vaccine programs, growth in those emerging markets may slow — as experienced in Angola and the Republic of the

Congo, where the governments have struggled to meet their co-financing requirements in recent years (Kallenberg et al., 2016).

Figure 9: We have identified six archetypes of vaccine innovation

ARCHETYPE	DESCRIPTION	PROFILE	EXAMPLES
1 **High Income & Nosocomial**	• Vaccines targeting healthcare-acquired infections with larger burden in high-income markets	• Moderate technical feasibility • Nosocomial: market potential high, but commercial model/indication unclear • Others: moderate commercial potential & mix of commercial models	• Clostridium difficile • Staphylococcus • Norovirus
2 **Potential Blockbusters**	• Vaccines targeting high-burden diseases with large potential patient pools	• High commercial potential - large burden of disease and large potential patient pools • Low-moderate technical feasibilty	• HIV • Universal influenza • Respiratory syncytial virus • Hepatitis C
3 **Therapeutic Vaccines**	• Vaccines used as a method of treatment to fight an existing disease/condition, rather than a preventative measure	• Commercial potential high • Low-moderate technical feasibility	• Oncology • Smoking cessation • Addiction
4 **Incremental Improvements**	• Improvement to existing vaccines to address unmet needs (e.g., in efficacy, duration of protection, ease of use)	• Uncertain commercial value for incremental improvements, especially on price • Moderate-high technical feasibility	• Pertussis • Typhoid • Measles
5 **Emerging Threats**	• Vaccines targeting emerging epidemiology threats and future priorities for innovation	• Limited reliable and large-scale commercial potential e.g., vaccine only stockpiles • Moderate technical feasibility	• Ebola • Zika • Middle East Respiratory Syndrome
6 **Low Income**	• Vaccines targeting diseases with higher burden in low-income markets	• Moderate commercial potential and mix of commercial models • Low-moderate technical feasibility	• Malaria • Tuberculosis

Source: McKinsey & Company internal analysis (2018)

WHERE DO WE GO FROM HERE?

Given these commercial and technical challenges and the criticality of vaccines in advancing public health, continued innovation in the vaccine industry can best be supported via a comprehensive and shared agenda across key stakeholders: researchers, manufacturers, government and policy makers, and payers. Several potential solutions might contribute to refueling the vaccines innovation engine.

- **Demand Clarity:** Earlier clarity on market demand would provide increased commercial certainty for vaccine manufacturers by helping to identify the priority innovations to address unmet market need. One potential method might be to publish target product profiles (TPPs) on the desired innovations. In addition, this could include advance

recommendations that would clarify likely recommendation and/or use given a specific profile and would be particularly relevant for high-income, nosocomial vaccines (Archetype 1), as well as innovation in therapeutic vaccines (Archetype 3).

- **Value Communication:** Stakeholders could also consider becoming more active in articulating priorities and value associated with material improvements to an existing standard of care (e.g., addressing whether an improved Haemophilus influenza type B (Hib) vaccine would achieve market premium or whether universal flu vaccines are adequately valued). This improved transparency would be particularly relevant for innovation addressing incremental improvements in vaccines (Archetype 4).
- **Economic Incentives:** One potential approach to creating incentives for innovation is to facilitate funding for new models of industry partnership for both emerging threats (Archetype 5) and low-income unmet needs (Archetype 6). The Coalition for Epidemic Preparedness Innovations (CEPI) has made significant progress in building alliances to finance and coordinate the development of new vaccines to prevent and contain infectious disease epidemics. However, as CEPI primarily focuses on early-stage development (through Phase 2 clinical trials), additional solutions are still needed to address the challenge of funding the high-cost, late-stage development.
- **Collaboration and Data Sharing:** Improving transparency and data sharing could be valuable in overcoming technical challenges and achieving breakthroughs where they are most needed. Private-public partnerships may be particularly relevant for Archetype 4 innovations, such as HIV, tuberculosis, and respiratory syncytial virus (RSV) — in such cases significant need remains, but there are critical technical challenges and the expected economics do not currently warrant industry leadership. A second form of collaboration could be to develop new technology platforms that enable shared production across antigens; this would be particularly valuable for emergency response innovations (Archetype 5) to enable rapid scale-up. A third option could be to generate more data regarding the burden of disease for pathogens that may be emerging or simply poorly understood. Finally, enhanced clarity on the public end-to-end vaccines and immunization agenda — from funding early research to trial design and preferred clinical trial site networks and ultimately through approval and market access — could boost innovation.
- **Early Consultation on Innovation Design:** Meanwhile, manufacturers could seek early and active engagement with regulatory and recommendation agencies throughout the development lifecycle of new vaccines to obtain timely input to key decisions, including trial design, thereby helping to de-risk the commercial uncertainty of innovation.

CONCLUSION

After a period of significant growth over the past 2 decades, vaccine innovation faces several challenges going forward — namely increased investment requirements for R&D and manufacturing, higher opportunity cost as relative economics converge with biologics, and greater technical complexity and commercial uncertainty compared to recent innovations. However, we believe there remains significant opportunity for vaccine manufacturers and other stakeholders (regulators, policy makers, and payers) to facilitate the next wave of vaccine innovation.

Michael Conway, J.D., is the Managing Partner of McKinsey's Philadelphia office. Since joining McKinsey in 1993, he has worked across a broad range of health care clients, splitting his time between biopharmaceutical/vaccine and global public health clients. On the global health side, Conway has worked across bilaterals/major funders, developing countries, and multilaterals. He led McKinsey's Global Health Practice from 2005-17 and is now part of the Operating Committee for the Public and Social Sector practice as well as the global leader for McKinsey's work with major donors.

His work on vaccines has included vaccine development, commercial models, global and country financing issues, coverage expansion, and supply chain issues. He has also worked on emergency response issues related to the polio, Ebola, and Zika viruses. Conway is a co-leader of McKinsey's Vaccines Practice and has co-authored several articles on related issues. He holds a B.S. in biochemistry from Texas A&M University and a J.D. from the University of Chicago Law School, where he was a contributor and staff member of the University of Chicago Law Review.

Adam Sabow, M.B.A., is a Senior Partner in McKinsey & Company's Chicago office, where he co-leads the firm's Vaccines practice and leads the Social Sector Practice in North America. He has worked extensively with pharmaceutical companies, biotechnology firms, NGOs, and government agencies across a range of geographies on health topics. With his private-sector clients, he has worked on commercial and operations transformations across the pharmaceutical space. With his global health clients, he has helped tackle a range of complex problems: helping define new strategies to combat infectious diseases, accelerating the introduction and uptake of new vaccines, and transforming developing country delivery of health products.

He is a recognized vaccine expert, often sought out to speak and advise on this topic. He has worked end-to-end on vaccines topics, including on development of new vaccines, commercialization strategies across all major geographies, supply chain optimization, market dynamics, and emergency response. He holds a B.A. with honors in economics and applied math from Northwestern University, where he graduated summa cum laude, and he also holds an M.B.A. from the Kellogg School of Management.

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Her work in vaccines has been focused on strategy and commercial transformations — new market entries and product launches as well as how to bring in human-centered design and digital technologies to improve vaccination rates; Gila works very closely with her clients to help them navigate the course of change. Gila holds a Master of Business Administration from the University of Chicago Booth School of Business and a bachelor's degree from Adelphi University.

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ABOUT THE SABIN-ASPEN VACCINE SCIENCE & POLICY GROUP

The Sabin-Aspen Vaccine Science & Policy Group brings together senior leaders across many disciplines to examine some of the most challenging vaccine-related issues and drive impactful change. Members are influential, creative, out-of-the-box thinkers who vigorously probe a single topic each year and develop actionable recommendations to advance innovative ideas for the development, distribution, and use of vaccines, as well as evidence-based and cost-effective approaches to immunization.

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