As prospects dim for many pharmaceutical sectors, vaccines represent a major source of new growth. But markets for the new wave of vaccines will not be a simple extrapolation of the past. Indeed, the vaccine sector is changing rapidly, and companies searching for sustained, profitable growth will have to break from old habits and re-think their approach.
Throughout much of the pharmaceutical world, companies face diminishing prospects because of declining research and development productivity, increased regulatory scrutiny, generics competition for off-patent products, and greater pressures on pricing. The vaccine sector, by contrast, represents an increasingly attractive market characterized by strong growth prospects, increased R&D activity, and higher valuations from the capital markets.

For many years, the vaccine sector was characterized by government price controls, a mature product group based on a limited set of technologies, and sub-scale participants that included operations run or controlled by the state. These characteristics constrained the level of investment and the resulting pace of technological innovation. But in recent years, the outlook has brightened for several reasons.

First, it is now possible to create “blockbuster” revenue streams. Wyeth’s pneumococcal conjugate vaccine, Prevnar, reached sales of $700 million in the U.S. within 15 months of launch, and had sales of almost $1.5 billion in 2005 (Exhibit 1). Prevnar was the first vaccine to rank among the top 10 new product launches for a major pharmaceutical company, and it quickly established itself among the top three products in Wyeth’s portfolio. Beyond Prevnar, at least seven potential blockbuster products (for HPV, Rotavirus, Meningitis prophylaxis, Pneumococcal disease, and Shingles) will likely be released over the next three years (Exhibit 2).

As new vaccines have been introduced to replace older technologies and address new disease areas, the pricing environment has also improved. For example, a diphtheria, tetanus, and pertussis (DTP) treatment course that in the U.S. was priced at roughly 30 cents in 1980 is now priced at $20, in part through the substitution of an acellular pertussis antigen. Vaccine players are increasingly able to capitalize on the health impact of new products, with some emerging vaccines priced at $300 or more per treatment course. The combined effect of a higher number of on-schedule vaccines and improved pricing has been a 40-fold increase in cumulative annual expenditures on childhood immunizations in the U.S. over the past 20 years. Adjusted for inflation, the cumulative annual spending on a child during the first six years of life has risen from under $10 in the early 1980s to approximately $400 today (Exhibit 3).

Vaccine prospects have also improved because of industry consolidation, which has winnowed more than 25 sub-scale players into five major manufacturers: GlaxoSmithKline (GSK), Merck, Sanofi Pasteur, Chiron, and Wyeth. These firms have the capabilities and

---

**A Market Perspective**

**Exhibit 1 Blockbuster potential**

![Bar chart](image)

*Source: Wyeth, estimates by Bear Sterns and Citigroup*

**Exhibit 2 Major vaccines in the pipeline**

<table>
<thead>
<tr>
<th>Disease name, company, vaccine name, estimated year of peak sales, and the value of peak sales</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rotavirus</strong></td>
</tr>
<tr>
<td>GSK (Rotarix) Peak estimate: 2015: $429m</td>
</tr>
<tr>
<td>Merck (RotaTeq) Peak estimate: 2013: $762m</td>
</tr>
<tr>
<td>Merck (Zostavax) Peak estimate: 2010: $664m</td>
</tr>
<tr>
<td>Merck (Gardasil) Peak estimate: 2009: $2.5bn</td>
</tr>
</tbody>
</table>

*Source: Oliver Wyman analysis, Morgan Stanley, and Citigroup*
appropriate scale to achieve attractive returns within vaccines. Profit margins for the vaccine units of these companies are comparable with levels experienced in their core pharmaceutical businesses. We estimate that EBITDA margins (a proxy for cash flow) for the vaccine division of GSK Biologicals is in the low 40% range, compared to 35% in its other businesses. Because of higher capital expenditures (and the resulting depreciation expense), the margin deteriorates at the EBIT level (26% vs. 30%), but is still close to that of the core business. However, profit margins at the corporate or product level only provide a snapshot at one point in time. Just as important is the sustainability of that margin over time. Barriers to entry such as manufacturing complexity and regulatory compliance expertise hinder competition from generics in high-income markets and from producers in low-cost locations, resulting in sustained pricing and margins for successful vaccines well beyond patent expiry.

Besides these pricing and scale issues, the public sector is taking substantive steps to spur development of new vaccines and creation of capacity for existing vaccines. In high-income countries, bioterrorism and pandemic flu initiatives are employing a range of “push” and “pull” mechanisms, from long-term purchasing contracts to increased funding for discovery, that are fueling private sector investment. In poorer nations, public sector support is helping to create a viable market. The Bill & Melinda Gates Foundation has led the way by giving over $1.5 billion to form and develop the Global Alliance for Vaccines and Immunization (GAVI). Many of the initiatives funded by GAVI and the Gates Foundation have fostered collaborations between the public and private sectors; for example, the partnership between the Malaria Vaccine Initiative and GSK demonstrates that vaccines targeted to poorer nations can be developed in a fashion that benefits all parties.

**Attracting Investment**

These factors have caught the attention of pharmaceutical companies, biotechnology firms, and the broader investment community. The vaccine market is expected to more than double between 2004 and 2009 (Exhibit 4), and R&D spending is growing at even greater rates. GSK Biologicals, for example, tripled its total R&D spending on vaccines from 13% to 28% of sales during the eight-year period ending in 2000.

Increased spending has helped to fill the pipelines of the major vaccine companies (Exhibit 5). Promising candidates exist throughout the various stages of development and span a wide range of current disease areas, including HPV, HSV, influenza, HIV, and SARS, as well as defense-oriented products, such as anthrax and smallpox. We expect to
see a broad set of new product introductions soon; for example, analysts project that 75% of Merck’s vaccine business will be composed of new products over the next five years. As a result of this activity, vaccines are expected to make up a growing share of the total revenue of the major firms; at Merck, for example, vaccines should grow from less than 5% of revenues today to more than 16% by 2009 (Exhibit 6).

The promise of this market is not limited to the largest pharmaceutical companies. Smaller players are seizing opportunities as well. ID Biomedical (recently acquired by GSK Biologicals), Acambis, Avant Immunotherapeutics, and other biotechnology firms have developed a thriving discovery role as the market expands, comparable to the evolution of other pharmaceutical markets. Avant discovered, developed, and licensed its rotavirus compound to GSK, which will allow Avant to extract value as GSK commercializes Rotarix. These biotechnology players are also applying vaccine technologies to non-traditional therapeutic areas, as Avant is doing with cholesterol. Beyond discovery, players have been innovating in other aspects of vaccine technology as well. For example, the dominant adjuvant over the past 50 years has been simple alum, but companies such as Corixa Corp., Coley Pharmaceutical Group, and CSL Limited are developing new adjuvants that may revolutionize the field. Other biotechnology and medical device firms are advancing production mediums and delivery mechanisms.

Capital markets and the investment com-

Exhibit 5 Pipelines for the leading manufacturers (not exhaustive)

Select major vaccines, year-end 2005

<table>
<thead>
<tr>
<th>GSK</th>
<th>Merck</th>
<th>Sanofi Pasteur</th>
<th>Chiron</th>
<th>Wyeth</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HIV</td>
<td>• N/A</td>
<td>• SARS</td>
<td>• Men B</td>
<td>• Group A Strep</td>
</tr>
<tr>
<td>• S. Pneumoniae</td>
<td></td>
<td>• Melanoma</td>
<td>• HCV</td>
<td></td>
</tr>
<tr>
<td>• TB</td>
<td></td>
<td>• HIV</td>
<td>• Hep C</td>
<td>• HIV</td>
</tr>
<tr>
<td>• Zoster</td>
<td></td>
<td>• Hepatitis E</td>
<td>• SARS</td>
<td>• Men B</td>
</tr>
<tr>
<td>• Prostate cancer</td>
<td></td>
<td>• Flu</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Breast cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Phase 1

<table>
<thead>
<tr>
<th>GSK</th>
<th>Merck</th>
<th>Sanofi Pasteur</th>
<th>Chiron</th>
<th>Wyeth</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HIV</td>
<td></td>
<td>• Dengue</td>
<td>• MenACWY</td>
<td>• RSV</td>
</tr>
<tr>
<td>• Others N/A</td>
<td></td>
<td>• Colorectal cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Gastric cancer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• CMV</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Typhoid</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Phase 2

<table>
<thead>
<tr>
<th>GSK</th>
<th>Merck</th>
<th>Sanofi Pasteur</th>
<th>Chiron</th>
<th>Wyeth</th>
</tr>
</thead>
<tbody>
<tr>
<td>• HB-Merc</td>
<td></td>
<td>• Dengue</td>
<td>• MenACWY</td>
<td>• RSV</td>
</tr>
<tr>
<td>• MenACWY</td>
<td></td>
<td>• Zoster/Shingles (Zostavax)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Flu improved</td>
<td></td>
<td>• Rotavirus (Rotarix)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Epstein-Barr Virus</td>
<td></td>
<td>• HIV (Gardasil)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Malaria (Malaria)</td>
<td></td>
<td>• Rotavirus (Rotarix)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Hepatitis E</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Dengue</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Lung cancer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Melanoma</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Phase 3/Submitted

<table>
<thead>
<tr>
<th>GSK</th>
<th>Merck</th>
<th>Sanofi Pasteur</th>
<th>Chiron</th>
<th>Wyeth</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Dengue</td>
<td></td>
<td>• Men A,C,Y-135, W (Menactra)</td>
<td>• Encephalitis</td>
<td>• Pneumo-adults (Prevnar)</td>
</tr>
<tr>
<td>• Zoster/Shingles (Zostavax)</td>
<td></td>
<td>• DTP P, and Hib (Pentacel)</td>
<td></td>
<td>• Men C</td>
</tr>
<tr>
<td>• Rotavirus (Rotarix)</td>
<td></td>
<td>• Pancreatic cancer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Does not include pre-clinical pipeline products   Source: Oliver Wyman analysis

Exhibit 6 A growing part of the portfolio

Revenues of vaccines at Merck, $ billions

Vaccines’ share of total revenues

Source: Oliver Wyman analysis, Morgan Stanley, Bear Stearns, Citigroup, CSFB
Community have begun to recognize the potential of vaccines, as evidenced by the valuation of vaccine businesses relative to core pharmaceutical businesses. We often look at the ratio of market value to revenue as a proxy for the value creation potential of businesses at different scales. This metric serves as a good indicator of the profitability, growth potential, and risks of a business. We estimate that the market value/revenue of one major pharmaceutical company’s vaccine business is three times that of its core pharmaceutical business (eight to 11 vs. three to four), driven by higher and more sustained profitability and a higher expected growth rate.

### Opportunities and Challenges

While the outlook for vaccines is quite positive, the market environment is becoming increasingly complex and dynamic. Senior executives in the industry should consider and address four particularly challenging, high-stakes issues:

- **Business design choices**
- **Go-to-market strategy**
- **Global market opportunities**
- **Alignment of product development with operational strategy**

### Business Design Choices

Every company makes explicit or implicit choices about the design of its business model. A business design involves choices along five dimensions:

- **Customer selection and value proposition.** Which customers and segments should we target, and with what distinct value proposition?
- **Value capture.** How does our business capture a portion of the value created for customers? What is our profit model?
- **Strategic control.** How do we maintain our profit stream over time and counteract customer or competitor power?
- **Scope.** Which activities do we perform in-house and which do we subcontract or outsource? How do we design our operations to support our value proposition to various market segments?
- **Organizational systems.** What organizational design, measurement, and talent systems do we employ to support the other elements of the business design?

Vaccine market participants to date have employed a variety of business designs. Some pursue a broad, nearly global set of customers, whereas others focus on a particular country or certain population segments. Some capture value through segmented pricing across a high base of volume, whereas others achieve high pricing on a limited set of products with relatively low volume. Some use scale as a strategic control lever, while others employ control of process technologies or inputs, first-mover advantage, or other levers.

When a market is relatively stable, business designs can endure and succeed for a sustained period. However, major changes in the market can render existing business designs obsolete in short order and open the door to new entrants. Waves of Value Migration—the flow of value from old, obsolete business designs to new, more economically effective ones—have played out across many industries. Consider how Nucor seized value from traditional steelmakers, Swatch from traditional watchmakers, Southwest and Virgin from traditional airlines, Dell from traditional PC makers, and Nokia from traditional cellphone makers.

The vaccine market is going through many changes that will require business design innovation. We will discuss a few key changes.

First, the flow of investment is filling pipelines targeted at key disease areas. As a result, extended periods of limited competition for a successfully licensed product, which
was the experience of Varicella for Merck and Prevnar for Wyeth, will become rare. The inter-pandemic influenza market is a good example of this trend, as nearly 10 products are currently in varying stages of development by companies including Baxter, GSK, and Chiron. These candidates, in addition to currently licensed products, are characterized by a wide range of technologies and features such as delivery mechanism, production medium (with implications for scalability, cycle time, and cost) and antigen form. To succeed in such circumstances, business design choices will need to adjust accordingly. Instead of solely focusing on how to create uptake for a new product, a vaccine company will have to differentiate the product from those of several competitors.

In response, executives will need to ask new questions and rethink answers to old ones: How do we design differentiated product features? How should we market the product? What method of distribution—direct sales or independent distributors—will give us a better position? How do we design our manufacturing network and processes to balance efficiency, flexibility, responsiveness, and cost performance?

Patient behavior is also profoundly affecting the market. The proliferation of information available on the Internet has made consumers, particularly parents of minors, more aware of the characteristics, risks, and benefits of various vaccines. As a result, patients and parents play a more prominent role in decisions about which vaccines to take. Valid or not, concerns over thimerosal, links to autism, and adverse side effects such as intussusception linked to Wyeth’s withdrawn Rotavirus vaccine pose a challenge to vaccine manufacturers and related players. In a 2003 survey of U.S. pediatricians, over half indicated that parental concern about general vaccine side effects and past intussusception issues with Rotashield would make reintroduction of a Rotavirus vaccine difficult. In addition, the growing number of vaccines on a recom-

Exhibit 7: A crowded schedule

Pediatric vaccine schedules in select high-income markets

<table>
<thead>
<tr>
<th>Country</th>
<th>BCG</th>
<th>DTP/DTaP/DTwP</th>
<th>OPV/IPV</th>
<th>Measles</th>
<th>MMR</th>
<th>Hep B</th>
<th>Hib</th>
<th>Men Conjugate</th>
<th>Pneumo Conjugate</th>
<th>Varicella</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
</tr>
<tr>
<td>Canada</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>High risk</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
</tr>
<tr>
<td>Mexico</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
</tr>
<tr>
<td>Australia</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>High risk</td>
<td>Voluntary vaccination</td>
<td>Voluntary vaccination</td>
</tr>
<tr>
<td>Japan</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>Voluntary vaccination</td>
<td>Voluntary vaccination</td>
<td>Voluntary vaccination</td>
<td>Voluntary vaccination</td>
<td>Voluntary vaccination</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>High risk</td>
<td>High risk</td>
<td>High risk</td>
</tr>
<tr>
<td>France</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>High risk</td>
<td>High risk</td>
<td></td>
</tr>
<tr>
<td>U.K.</td>
<td>High risk</td>
<td>On schedule</td>
<td>On schedule</td>
<td>High risk</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>High risk</td>
<td>Voluntary vaccination</td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>High risk</td>
<td>On schedule</td>
<td>Recommended</td>
<td>On schedule</td>
<td>Recommended</td>
<td>On schedule</td>
<td>Recommended</td>
<td>High risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>On schedule</td>
<td>High risk</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1New additions to the vaccine schedule (since 2005).

Source: Oliver wyman analysis, WHO, CDC, PHAC, Canadian Immunization guide (6th ed.), Infectious Disease Surveillance Center (Japan), National Ministries of Health
mended schedule for universal use in the high-income markets in North America, Europe, and Asia (Exhibit 7) could lead to more selective use of pediatric vaccines.

In light of these developments, vaccine market participants should revisit their business design choices, asking: What age groups should we target? How are we positioning our products in the minds of patients and influencers and how do we reach them? How should the makeup of our product portfolio differ, and how does that affect the allocation of our R&D spending? Which technologies should we develop ourselves and which should we outsource, given risks, rewards, and comparative capabilities?

Shifts in the structure of the value chain are also changing the vaccine market. For decades, vaccine manufacturers took an integrated approach to their scope of activities, conducting most discovery, development, manufacturing, selling, and distribution in-house. The influx of new participants and capital has allowed companies more flexibility in this regard. In addition, the application of new technologies to core product design, production processes, and delivery mechanisms means that some organizations will have to seek outside partnerships in order to access such innovation.

Focused technology firms, for their part, must carefully consider which advancements will improve their customers’ systems economics. For example, a biotech venture’s decision about whether to develop a new viral or bacterial production medium will hinge not only on how much this innovation can improve yields in the bulk production process, but also to what degree such improvements solve a fundamental problem for applicable vaccine manufacturers, such as capacity constraints, quality issues, or cost position.

As value chain options expand, companies need to consider where value will migrate and which activities represent points of strategic control. Executives should ask: What portion of our resources and capital should be allocated among discovery, development, and ongoing sales and manufacturing? Which technologies do we want to control in-house and which should be developed through a portfolio of options on the outside? What organizational skills do we need to develop or acquire in order to engage a more complex set of partners?

**Go-To-Market Strategy**

Many of the emerging vaccine pipeline candidates depart from the traditional vaccine market. Some target adolescents and adults rather than children; some aim to enhance quality of life, rather than preventing diseases with limited treatment options and life-threatening consequences; others pertain to sensitive issues such as sexual activity, and will require difficult conversations among patients, their families, and their physicians. In addition, some of these new products will likely be “off schedule,” leaving greater discretion to physicians and patients and posing additional reimbursement challenges. As a result, this wave of new vaccines will face more complex go-to-market challenges.

Consider the experience of MedImmune in 2003 as it launched FluMist, a live attenuated flu vaccine. A highly efficacious product which is administered nasally, FluMist represented a real innovation. The timing of launch was fortuitous as well, given supply shortfalls in the traditional killed vaccine. Nonetheless, initial results fell far short of expectations, as MedImmune sold roughly 20% of the doses it produced for the 2003-2004 flu season. While product design features (e.g., refrigeration requirements) played a role, this disappointing outcome can be attributed in part to the go-to-market strategy: Pricing was more than twice the price of the traditional vaccine, marketing was an expensive, mass-market campaign, and distribution primarily through pharmacies instead of doctors’ offices constrained availability and awareness. HPV vaccines, currently finishing Phase Three trials for Merck and GSK, are among the upcoming class of products that may experience similar challenges.

With so much at stake, carefully designing a go-to-market strategy well in advance of launch will be central to the success of vaccine pipeline candidates. For the highest-
stake products, vaccine companies should employ a disciplined and rigorous process that accounts for the following factors:

- The full-range of key influencers and stakeholders and an appropriate segmentation of them

- Decision triggers and pathways for key constituents (see Exhibit 8)

- The absolute and relative impact on usage of altering specific attitudes and behaviors relevant to the vaccine (e.g., “I don’t regularly see my primary care physician”)

- The full range of go-to-market parameters (e.g., messaging, marketing methods, pricing) and how different choices for each can impact attitudes and behaviors

- The financial impact of these choices, individually and in combination, so that managers can quantitatively understand tradeoffs

- Competitor choices with respect to go-to-market parameters and resulting impact

Accounting for these factors represents a significant challenge and requires the use of statistical research and financial modeling tools in an integrated manner. This represents a departure from traditional methods within vaccine organizations that historically focused more on R&D and technology. Our experience suggests that outcomes as measured in share, uptake, or absolute financial impact can vary considerably based on the go-to-market strategy.

Global Market Opportunities

As governments worldwide commit more funding to vaccine procurement, and support for lower-income country vaccine demand grows, a truly global vaccine market is emerging. Successfully pursuing these global market opportunities will require new approaches. Many of the most threatening diseases in the developing world, such as malaria and cholera, are not endemic to

Exhibit 8 Decision triggers and key constituents (illustrative)
high-income countries. Vaccine companies choosing to address these diseases will need to look beyond the traditional profit model of recouping R&D from high-income countries and then discounting the product to lower-income markets. Early pioneers in these markets have formed development partnerships with the public sector, such as the one between GSK and MVI for malaria, but the winning model has yet to be determined.

Moreover, even among diseases that are endemic to regions with varying income levels, the requirements for these vaccines are diverging along the dimensions of disease characteristics, such as specific serotypes prevalent in each region, and the desired product characteristics, such as cost, efficacy, and dosage. This divergence poses a quandary for companies seeking to address global markets: Should they develop a single vaccine with applicability to all regions or develop separate vaccines? The answer will depend on the market characteristics and competitive dynamics that apply to the vaccine.

One company wrestled with these trade-offs when developing a new vaccine for a potentially large high-income market. Executives recognized that this vaccine could also generate demand in other regions if configured with the right characteristics. The development timeframe was an important consideration, as the competitive environment would be intense and the first mover within the primary high-income market would

---

**Still a Unique Market**

In some respects, the vaccine arena increasingly resembles other pharmaceutical sectors. Individual products have the potential to generate more than $1 billion in annual revenue, the marginal profitability of each dose sold is high, and go-to-market strategies must address a complex array of stakeholders, including direct interaction with end-users. Yet potential entrants and investors should be aware of differences that persist.

<table>
<thead>
<tr>
<th>Business design elements</th>
<th>Vaccines</th>
<th>Other pharmaceuticals</th>
</tr>
</thead>
</table>
| Customer selection and value proposition | • Larger government role, particularly for pediatric vaccines  
• Private sector for many adult and traveler markets | • Physicians and private consumers have become key customers |
| Profit model | • More sustained profit stream on lower volumes; tiered pricing | • High profits on a small number of high-volume blockbuster drugs until patent expires |
| Strategic control | • Regulatory and manufacturing technology  
• Patents less important | • Patent protection, technology access, and marketing firepower  
• Significant generics competition post-patent |
| Scope of activities | • Manufacturing is a larger part of the cost structure  
• Capacity and technological challenges for new products, and greater quality control risk | • Manufacturing is a smaller part of the cost structure; large sales organizations are often the biggest cost |
| Organizational system | • High regulatory burden in operations, requiring more resources and attention  
• Less intensive selling requirements and cost | • Focus on disease areas with blockbuster potential  
• Organization aligned to deliver high-speed drug development and sales efficiency |
likely gain an advantage. Developing a single product to serve several markets would impact the timeframe for several reasons: A single product that addressed key serotypes across regions would be more difficult to develop and challenging to manufacture; in addition, the company could use an existing technology for its target market but would need to develop a more efficient production process if the vaccine were to be affordable and competitive over the longer-term in other markets. With both significant near-term revenue and long-term sustainability at stake, and in some respects in conflict, the company had to carefully consider its options (i.e., single product and appropriate design versus parallel development) and associated tradeoffs.

Companies should answer several questions early in the development process when faced with similar dilemmas: How much more challenging will it be to develop a product that will meet the requirements of multiple markets? What adjustments could be made to the production process (e.g., batch size, technology) to reduce cost, and how difficult will this be? Can we manufacture the vaccines (bulk or finishing) in alternative locations? What are the competitive dynamics in each market, and what are the true costs and potential benefits of making these changes?

Alignment of Product Development with Operational Strategy

Vaccine companies have traditionally separated product design and manufacturing process development decisions, with limited involvement of process engineers until later in the development cycle. However, the decisions made by R&D teams often place considerable constraints on the manufacturing process options that will ultimately be available. For example, the R&D team may choose to increase the dosage of a particular vaccine from 25 mcg to 50 mcg instead of using a more complex adjuvant; this reduces effective capacity at the bulk production step by 50% for any given fermenter size.

For relatively simple vaccine technologies with low annual demand, a margin for error existed in such decisions—a single fermenter might have been able to serve the entire annual demand of the vaccine and still have excess capacity. But such decisions will have a greater impact on the economics of new vaccines with more complex production processes and demand levels that may exceed 25 million doses. For a new vaccine where a company is considering alternative dosages and adjuvants, what will be the cost and capacity implications of alternative dosages? That depends on the efficiency of the manufacturing process itself: If the contemplated production process is characterized by good expression and high yields, higher dosages will have a relatively limited impact on capacity and cost, and the converse is also true (Exhibit 9).

Given the interdependent effects of product features and operational realities on cost and capacity, vaccine companies should aim to strengthen the internal procedural links between marketing, product design, and operations functions. Executives should ask: How can we more effectively involve process engineers earlier in the development process? What are the economic (cost and capacity) implications of key product design decisions? Can we make changes to the product design (e.g., technology choice, adju-
vant choice, dosage, number of valents) in order to improve the economics of the vaccine?

* * *

The upcoming wave of products represents enormous profit potential for companies and investors in the vaccine space, as well as the opportunity to benefit millions of people. But the old rules of thumb may no longer apply, and failures will be increasingly large and visible. To succeed in these new markets, companies will need to rethink their strategies, approaches, and business designs.

This white paper was prepared by Andrew Pasternak, Adam Sabow, and Andrew Chadwick-Jones. Pasternak is a Chicago-based director, Sabow is a Chicago-based principal, and Chadwick-Jones is a London-based principal of Oliver Wyman. They can be reached at andrew.pasternak@oliverwyman.com, adam.sabow@oliverwyman.com, and andrew.chadwickjones@oliverwyman.com.
Oliver Wyman has consulted in the vaccine arena for more than 15 years, having advised a mix of clients, including vaccine manufacturers, biotechnology enterprises, governments, non-governmental organizations, and private investment funds. Our diverse clientele provides us with a unique perspective on key strategic issues, combining an understanding of core economics, market dynamics, customer and supplier priorities, and vaccine technologies and processes.

Oliver Wyman

Oliver Wyman is building the leading global management consultancy, combining deep industry knowledge with specialized expertise in strategy, operations, risk management, organizational transformation, and leadership development. The firm works with clients across a range of industries to deliver sustained shareholder value growth. We help managers to anticipate changes in customer priorities and the competitive environment, and then design their businesses, improve their operations and risk profile, and accelerate their organizational performance to seize the most attractive opportunities.

For more information contact one of the following country representatives:

**Americas**

**Canada**  
John Calhoun, 1 416 868 2727  
john.calhoun@oliverwyman.com

**Mexico**  
Daniel Silva, 52 55 5063 9001  
daniel.silva@oliverwyman.com

**United States**  
George Faigen, 1 212 345 8296  
george.faigen@oliverwyman.com

**Europe**

**France**  
Karine Jullien, 33 1 45 02 32 51  
karine.jullien@oliverwyman.com

**Germany**  
Pierre Derœd, 49 89 939 49 599  
pierre.deraed@oliverwyman.com

**Portugal**  
Soledad Ménendez, 34 91 212 6336  
soledad.menendez@oliverwyman.com

**Spain**  
Soledad Ménendez, 34 91 212 6336  
soledad.menendez@oliverwyman.com

**Switzerland**  
Joris D’Inca, 41 1 208 7749  
joris.dinca@oliverwyman.com

**United Kingdom**  
Anne Hughes, 44 20 7935 5444  
anne.hughes@oliverwyman.com

**Asia**

**China**  
Jeff MacCorkle, 8610 6505 9628  
jeff.maccorkle@oliverwyman.com

**Hong Kong**  
Jonathan Gove, 852 2110 3314  
jonathan.gove@oliverwyman.com

**Korea**  
Young-joon Kim, 82 2 399 5533  
young-joon.kim@oliverwyman.com

© Copyright 2006, Oliver Wyman  All rights reserved