

Vaccines: Emerging Technologies, Trends, and Market Opportunities, 2nd Edition

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Based upon a worldwide emphasis of cost reduction with concurrent improvements in care, vaccines have resurfaced as desirable tools for disease management—with the potential of preventing many of the leading causes of global fatalities. Now is a great time to enter the market that promises to become a cornerstone treatment approach, replacing some of today's therapies. **D&MD's Vaccines Report** will provide you with answers to the following questions critical for positioning your company for success in this re-emerging market:

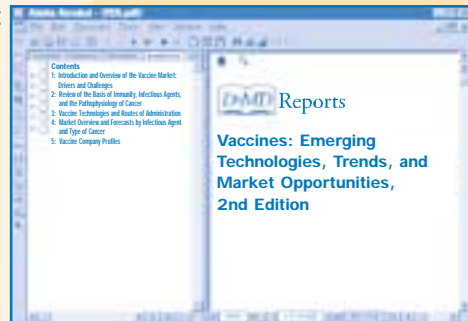
- ✓ How are pharmaceutical industry trends driving growth in the vaccine segment?
- ✓ What are the environmental issues that will impact the vaccine market?
- ✓ How is the business model of successful vaccine companies evolving to ensure profitability?
- ✓ What is the potential for profit in the vaccine market?
- ✓ Which companies are positioned to take advantage of near-term growth opportunities?
- ✓ What role will the government play in structuring the market, and how can changes in government outlook alter the business structure to potentiate growth?
- ✓ Which segments of the market will support the fastest growth?

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Emerging Technologies, Trends, and Market Opportunities, 2nd Edition

By Pamela Bassett, D.M.D., M.B.A.

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Vaccines: Emerging Technologies, Trends, and Market Opportunities, 2nd Edition

New technologies in the vaccine market will heighten competition and spur additional opportunities and growth.

Contents

Historically, vaccines have been treated as commodity products—now the advent of new technologies and the potential for patented technologies and products has infused life into the business—along with new profit potential due to improved pricing possibilities and higher margins. With well over 1,000 vaccines in research and development worldwide for infectious diseases, cancer, and other diseases, vaccines have become the fastest growing segment of the pharmaceutical industry. **D&MD's** thoroughly revised and updated version of its best-selling 1998 report, *Vaccines: Emerging Technologies, Trends, and Market Opportunities*, will inform you of the latest developments in vaccine technologies and how they will continue to play a critical role in the successful formulation of vaccines.

Unique Benefits of this Report:

- ✓ Examination of the underpinnings of the fastest growing segment in the pharmaceutical industry, outlining key trends in the vaccines market
- ✓ Analysis of the leading technologies and delivery systems driving emerging opportunities in vaccine development, putting you a step ahead of competitors
- ✓ Comprehensive analysis of infectious disease and cancer market segments, identifying where the greatest opportunities lie
- ✓ In-depth profiles of leading biopharmaceutical companies developing and delivering vaccines, highlighting industry leaders and strategy insights

- ✓ Evaluation of the impact of vaccine strategic alliances, mergers, and acquisitions restructuring the market, recognizing the impact of the key collaborations
- ✓ Discussion of the many issues that may prevent effective safety, reimbursement, distribution, and utilization of vaccines, informing you of possible obstacles to overcome

D&MD projects the vaccine market will exceed \$10 billion by 2010.

Without the development and use of new vaccines and continued emphasis on global prevention using existing vaccines, more and more of the population is at risk of contracting new diseases and diseases that were previously under control. The changing environment and increased travel between industrialized nations and developing countries will continuously enable the rapid spread, sharing of, and resultant mutation of microbial genetic information. How to ensure the future of those microbes with the potential consequence of both the resurgence of old infections and the rise of new outbreaks is hitherto unknown. Get the answers needed for success—order your copy of **D&MD's Vaccines** Report today!

In-depth Company Profiles

| | | | |
|------------------------|----------------------------|-----------------------------|---------------------------|
| Allerganics | Bioenvision | Entremed | Large Scale Biology |
| American Home Products | Biomira | Epimmune | MedImmune |
| Antex Biologics | BioPort | EVAX Technologies | Merck |
| Antigenics | Cangene | Galenica | Microscience |
| Apton Corporation | Cantab Pharmaceuticals plc | Genentech | Novavax |
| Argonex | Cell Genesys | Genzyme | OraVax |
| Avax Technologies | Celltech | GlaxoSmithKline | PowderJect Technologies |
| Aventis Pharma AG | Chiron Corporation | Imclone Systems | Progenics Pharmaceuticals |
| Avigen | Cortecs International | Immune Response Corporation | Serquest |
| Aviron | Coulter | Immunex | StressGen |
| AVI Biopharm | Crucell | Immune Response Corporation | Therion Biologics |
| Baxter | CSL Limited | Inex Pharmaceuticals | VaxGen |
| BioChem Vaccines | Dynagen | Innogenetics NV | Vical |
| BioDelivery Sciences | Endorex | Jenner Technologies | Viragen |

5.2. AMERICAN HOME PRODUCTS
Five Giralda Farms, Madison, New Jersey 07940
Tel: 973 660-5000
NYSE: AHP
Website: www.ahp.com

5.2.1. VACCINES AND VACCINE TECHNOLOGIES
American Home Products' Wyeth-Lederle Vaccines and Pediatrics is a major supplier of vaccines that prevent childhood and adult diseases including: whooping cough, diphtheria, poliomyelitis, meningitis, pneumonia and influenza. Important products include: HibTITER, a major contributor to the reduction of diseases in children caused by the *Haemophilus influenzae* type b organism; Orimune, the only oral polio vaccine sold in the U.S.; and Acel-Imune for infants, a vaccine launched in early 1997 that provides advanced protection against whooping cough, diphtheria and tetanus. AHP's

EXHIBIT 4 - U.S. CHRONIC MANIFESTATIONS

| Type | Agent | Manifestation |
|-----------|---|--|
| Viruses | Cytomegalovirus | Chronic hepatitis, cirrhosis |
| | Hepatitis B virus | Cervical carcinoma, laryngeal papillomatosis |
| | Hepatitis C virus | Post-herpetic neuralgia; congenital mental retardation |
| | Human papillomavirus | Lyme arthritis |
| Bacteria | <i>Borrelia burgdorferi</i> | Infertility |
| | <i>Chlamydia trachomatis</i> | Arthritis, Reiter's syndrome |
| | Enteric bacteria (<i>Shigella</i> , <i>Salmonella</i> , <i>Yersinia</i> , <i>Campylobacter</i>) | |
| | <i>E. coli</i> O157:H7 | |
| Parasites | <i>Toxoplasma gondii</i> | |
| | <i>H. pylori</i> | |
| Viruses | Enteroviruses | |
| | Hantaviruses | |
| Bacteria | <i>Campylobacter jejuni</i> | |
| | <i>C. pneumoniae</i> | |

EXHIBIT 1 - 11 FACTORS CONTRIBUTING TO THE EMERGENCE OF INFECTIOUS DISEASES

| Contributing Factors | Specific Examples |
|----------------------|--|
| Societal events | • Economic impoverishment • War or civil conflict • Population growth and migration • Urban decay |
| Health care | • New medical devices • Organ or tissue transplantation • Drugs causing immunosuppression • Widespread use of antibiotics |
| Food production | • Globalization of food supplies • Changes in food processing and packaging |
| Human behavior | • Sexual behavior • Drug use • Travel • Diet • Outdoor recreation • Use of child care facilities |

EXHIBIT 4 - 55 VACCINES BY SEGMENT AND DISEASE - DEVELOPMENT STATUS AND COMPANIES

| Segment | Field | Product | Stage | Company | Partner |
|--|--------------------------------|---------------------------------|------------------|---------|---------|
| Infectious Diseases - multivalent vaccines | Diphtheria, Tetanus, Pertussis | Triaselluvax/Dif-er-tet-all DPT | Market - Italy | Chiron | |
| | Measles, mumps | M-M-Vax | Market - Germany | Chiron | |
| | Measles, mumps, rubella | Morupar | Market - Italy | Chiron | |
| | Measles, mumps, rubella | M-M-R-Vax | Market - Germany | Chiron | |
| | Measles, rubella | Morubel | Market - Italy | Chiron | |
| | | | | | |

About the Author

Pamela Bassett, D.M.D., M.B.A.

Dr. Bassett is President of BioTrend Corporation, a New York City-based biopharmaceutical industry information company. BioTrend works with a selected number of clients to develop strategic positions for leadership in emerging market segments based upon the application of significant technological advances. BioTrend is developing decision tools and provides biotechnology industry information and analysis to pharmaceutical and healthcare companies worldwide.

Dr. Bassett received her M.B.A. from Wharton Graduate School, University of Pennsylvania, completed a residency in anesthesiology at the Medical College of Pennsylvania and Hospital, and received her D.M.D. from Tufts University School of Dental Medicine.

Disclaimer: Information within this brochure is representative of the time at which it was created. Changes may be made at the time of Report publication.

Section 1: Introduction and Overview of the Vaccine Market: Drivers and Challenges

- Establishes the framework for understanding and analyzing the market for vaccine technologies and applications
- Examines the emerging trends in the vaccine segment—both technological and market drivers are discussed
- Reviews the FDA process and international issues regarding the development of new vaccines and related delivery systems

Section 2: Review of the Basis of Immunity, Infectious Agents, and the Pathophysiology of Cancer

Section 2 reviews the basics to establish the foundation of understanding how vaccines work in the body. The pathways that can be used to alter the body's reaction to invading organisms are examined. How various processes can be converted from healthy responses to pathology are how these processes might be disrupted to benefit patient well-being are discussed, including:

- Basics of how the immune system functions
- Overview of how infectious agents invade the body and result in disease
- Presents a review of the pathophysiology of cancer

Section 3: Vaccine Technologies and Routes of Administration

The current technological approaches to approved vaccines are reviewed in this section. Certain technologies are key to the development of new vaccines, including the use of genomics to identify new antigen targets, adjuvants, and a wide variety of drug delivery systems. The technologies impacting the development of improved existing vaccines and new vaccines are also examined including:

- Current Vaccines—live, killed, and subunit
- DNA Vaccines—multi-component, naked DNA, anti-idiotypic, modification of virulence genes, and conjugate vaccines
- Vaccine Adjuvants—subunit antigens, aluminum salts, calcium phosphate, surface-active agents, bacterial products, cytokines and hormones, unique antigen constructs, polyanions, and polyacrylics
- Drug Delivery Systems—nanoparticles, various vectors, gene-gun, cochleates, microencapsulation, and biodegradable polymers

Also discussed are the key functions of delivery systems and how they can enhance overall treatment by improving the efficacy of vaccines. Current and developing delivery technologies are presented. Lastly, an examination of how changes in system composition and morphology alter delivery functions and the factors governing the delivery system-physiology interactions is provided.

Section 4: Market Overview and Forecasts by Infectious Agent and Type of Cancer

Vaccines have a wide-ranging application both for the prevention of infectious diseases and as therapeutics, particularly to deter the re-occurrence of cancer. This section reviews the key market segments for the applications of vaccines, including the size of each opportunity and how it will be affected by key current strategies. Also presented are sales forecasts of the market segments, including the underlying reasons for growth, arranged by therapeutic category. Some of the market segments reviewed include:

- Infectious Agents—Hepatitis A, B, and C, HIV, RSV, Influenza, CMV, Rhinovirus, HPV, Rotavirus, Dengue, H. pylori, Salmonella, E.coli, and much more
- Cancers—colon, lung, breast, melanoma, prostate, ovarian, and many more

In addition, this section identifies the key patents due to expire and the overall trends that are currently influencing the pharmaceutical industry and affecting the development and use of vaccines.

Section 5: Vaccine Company Profiles

As the importance of vaccine use emerges, product differentiation and positioning in the marketplace will continue to take on enhanced stature. In this section, the role and position of some of the key vaccine and drug delivery systems companies are reviewed. The review includes:

- Analysis of vaccine company positioning and emerging trends
- Company profiles, which is a comprehensive review of some of the leading companies with vaccine technologies