Genomics Will **DRIVE DRUG DEVELOPMENT**


Mike Goodman

Once clear, unambiguous pathways and procedures are laid out, genomic applications will blaze a path through the clinic, the physicians' offices, and eventually into the hands of consumers, says Mike Goodman, General Manager of CHA Advances Reports.

In 2005, the FDA issued guidelines for applications of genomics in drug development, with the stated hope that genomics would improve the safety and effectiveness of medicines. Given this mandate, clinical genomics applications appear to have crossed a threshold, marked by the recent approval of several products, including Roche Diagnostics' AmpliChip Cytochrome P450 Genotyping Test and Third Wave Technologies' Invader UGT1A1 Test.

Drug-safety concerns in the pharmaceutical industry also are driving the increased use of clinical genomics. With the recent high-profile drug withdrawals, growing pressure is being brought to bear on drug companies and the FDA to improve safety in the clinic and postmarket. Genomic technologies are viewed as a promising solution, and thus, more companies are investing in these areas. The strategic use of genomics in preclinical and early clinical development is also gaining momentum so that it can be used in later stages of drug development.

A new CHA Advances report, The Impact of Genomics on Clinical Trials and Medical Practice, evaluates recent developments in the advancement of clinical genomics and the improvements it will drive in drug development and the delivery of care.

It is now estimated that about 20% of U.S. clinical trials use some type of genomics approach, with the highest percentage in oncology trials. According to the report, this trend will accelerate during the next few years.

Applications in Phase I and Phase IIa clinical trials include assessing or demonstrating a drug's mechanism of action. Genomic assays can also help explain pharmacokinetic and pharmacodynamic outliers and help determine drug dose and dosing schedule. Pharmaceutical companies would realize significant cost savings if they could assess patients' adverse reactions early on or if genomic assays could help them decide whether to continue a drug's development.

Analysts note, however, that the field still faces considerable regulatory, technical, economic, and sociological hurdles; and the promise of clinical genomics applications may not be fully realized for at least another decade. Regardless, some pharmaceutical companies have made genomics testing a high priority in their drug-development programs.

Global Medical Devices and Diagnostic Market to **TOP $300 BILLION IN FIVE YEARS**

In 2005, the global medical-device and diagnostics (MD&D) industry generated almost $220 billion in revenue. According to a comprehensive report from Health Research International, Opportunities in Global Medical Devices and Diagnostics, almost one-half of those earnings were concentrated in four major technology segments: *in vitro* diagnostics (IVD); cardiovascular disease therapies; diagnostic imaging equipment, services, and contrast; and orthopedic and spinal products.

Health Research analysts suggest that the aging global population — accompanied by increases in cardiovascular disease, musculoskeletal conditions, cancer, and other degenerative conditions — will drive future MD&D growth, including the development of technologies designed to diagnose and treat conditions less invasively at an earlier stage.

The result will be a healthy 7.5% annual increase in MD&D sales, which are expected to reach $312 billion in 2010. This growth will be led by spinal products, neuromodulation devices, sleep apnea products, advanced molecular diagnostics, cardiac rhythm management products, orthopedic implants, endoscopy devices, and energy-based technologies.

2005 Year of **ROBUST GROWTH FOR BIOTECH**

By virtually every performance indicator, the global biotech industry showed robust growth in 2005, according to Ernst & Young LLP.

Revenue of the world's publicly traded biotech companies increased 18% last year, reaching an all-time high of $63.1 billion. As revenue increased, the industry's net loss decreased by a dramatic 30%, to $4.3 billion. The United States, Canada, and the Asia-Pacific region collectively improved their bottom line by about $3 billion.

Additionally, the industry secured 32 new product approvals in the United States last year, including 17 first-time approvals. The pipelines of Europe's publicly traded biotech companies increased by 28%, with the strong growth in late-stage development.

The global biotech industry raised $19.7 billion in capital in 2005, its second highest total since the bubble of 2000.

These are among the key findings of Ernst & Young's 20th anniversary edition of Beyond Borders: The Global Biotechnology Report 2006.

Additionally, analysts observed that 2005 was a deal-heavy year for biotech. Big pharma's acquisitions in the biotech space increased dramatically; and the lackluster performance of initial public offerings in the United States drove venture capitalists and their portfolio companies to look to deals for exits or sources of financing. In Europe, mergers and acquisitions reached an all-time high of 66; while China and India continued to attract attention and deals — fueled by drug developers' desires to increase access to these growing markets and lower drug-development costs.

Biotech companies around the globe experienced positive returns last year. The U.S. biotechnology sector enjoyed it's third consecutive year of solid growth in 2005. Product successes boosted sector revenues, which increased by about 16%. The European sector finally emerged from a lengthy restructuring period and experienced revenue increases of 17%. The Asia-Pacific region outpaced all other parts of the world, posting a 46% increase in revenue.

GAO Calls for Improvements in **FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS**

A new report from the U.S. Government Accountability Office (GAO) suggests that, to improve the decision-making process for postmarket drug safety, Congress consider expanding the FDA's authority to require postmarket studies when needed.

GAO also recommends that the FDA systematically track postmarket drug-safety issues; revise and implement its draft policy on major postmarket safety decisions; improve the dispute resolution process; and clarify the Office of Drug Safety's (ODS) role in scientific advisory committees.

In response to several high-profile drug safety

cases, GAO examined four drug case studies and, in all cases, observed that the postmarket safety decision-making process was complex and iterative.

According to GAO, the FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues. The process has been limited by a lack of clarity about how decisions are made and about organizational roles, insufficient oversight by management, and data constraints.

GAO observed that there is a lack of criteria for determining what safety actions to take and when to take them. There also are weaknesses in the different types of data available to the FDA, and the FDA lacks authority to require certain studies and has resource limitations for obtaining data.

Some of the FDA's initiatives — such as the establishment of a Drug Safety Oversight Board, a draft policy on major postmarket decision making, and the identification of new data sources — may improve the postmarket safety decision-making process but will not address all gaps.

Commenting on a draft of this report, the FDA stated that GAO's conclusions were reasonable but did not respond to the recommendations.

Adjunctive Cancer Therapies Market to **TOP $24 BILLION BY 2010**


Melissa Elder

The inability to look beyond the "race for the cure" has left millions of cancer sufferers without adequate relief of their often-debilitating side effects, says Melissa Elder, Analyst, Kalorama Information.

With more than 10 million new cases of cancer diagnosed throughout the world every year, revenue from adjunctive therapies used to relieve the side effects of both primary cancer treatments and the disease itself are growing at an annual rate of 7.4%. This market is expected to reach $24.5 billion by 2010, according to The Global Market for Adjunctive Therapies in Cancer, a new study from Kalorama Information.

According to Kalorama, 2005 revenue for therapies addressing nausea, anemia, pain, and infections, among others, exceeded $17 billion. From 2003 to 2005, this market grew by almost 15%, primarily due to strong sales of biological response modifiers as well as therapies for nausea, emesis, and pain management.

The focus remains on cancer cures. The scope of therapy options has been limited by a variety of factors, including cost, poor healthcare infrastructure, lack of awareness of available therapies, and financial provisions encouraging aggressive cancer treatment rather than symptomatic relief. As a result, the development of therapies and delivery options to minimize side effects — such as pain, fatigue, immunosuppression, and memory loss — are not being adequately addressed, analysts say.

"Providers need to understand that aggressive management of ancillary symptoms can be vital to the ultimate success of primary treatment," says Melissa Elder, an analyst for Kalorama and the report's author. "More proactive messaging from manufacturers on this topic could lead to even greater revenue than we've projected."

Success of E.U. Pharmaceutical Industry **DEPENDS ON PROACTIVE REGULATORY LEGISLATION**

Across Europe, the emergence of new diseases and expanding drug pipelines is being accompanied by progressively stricter ethical and regulatory frameworks. In addition to protecting public health, drug-discovery legislation is attempting to address the entry of new E.U. member states through the implementation of a single, harmonized, E.U.-wide pharmaceutical market.

Against this backdrop, proactive legislation will be important for facilitating efficient, cost-effective, and rapid drug discovery to support the continued success of the pharmaceutical industry in the European Union.

Currently, the pharmaceutical industry is grappling with intensifying cost pressures, shorter product life cycles, and varied clinical-trial data management issues. Moreover, high failure rates have also caused anxiety. A host of regulatory challenges that threaten to stifle commercial operations have exacerbated this situation. For instance, the stringent requirements governing drug labelling in clinical trials have proven to be a major hindrance in obtaining rapid regulatory approval. At the same time, the lack of adequate follow-up procedures has meant that companies often confront unacceptable delays in getting approval — along with losing considerable time and money. This situation is more serious in countries where strict legislations and regulatory procedures are absent.


Amarpreet Dhiman

Fundamental drivers that will improve and strengthen the evolution of the drug-discovery process in Western and Eastern Europe are yet more strict regulations, mandatory good manufacturing practice (GMP) compliance, and improved legislations for clinical trials to create opportunities for an efficient, competitive environment, says Dr. Amarpreet Dhiman, Research Analyst at Frost & Sullivan.

To retain Europe's preeminent position in the global pharmaceuticals market, regulatory policies have continually aimed at maintaining, updating, and simplifying pharmaceutical legislation while also drafting new guidelines. Over the last seven years, the pharmaceutical industry has gained increasing familiarity with the centralized and mutu-

al recognition regulatory procedures. With the expiry of the so-called transition period in 1998, these two procedures have become the dominant pharma registration models within the European Union.

Since the mid-1980s, several directives have aimed at realizing a single, E.U.-wide market for pharmaceuticals. For instance, the E.U.'s Good Clinical Practice (GCP) directive, which was made fully effective in May 2004, ushered in important changes for harmonizing the key legal requirements and procedures for conducting clinical trials on medicinal products for human use in Europe.

In Regulatory Hurdles in European Drug Discovery, Frost & Sullivan analysts predict that, by 2012, the European Union can look forward to enhanced centralized procedures, the introduction of specific measures for small and medium-sized enterprises, and increasing prominence of personalized medicine.

Life-Cycle Management **DRIVES VIABILITY OF MATURE DRUGS**

As the competitive landscape in the biopharmaceutical sector tightens, executives must continue to find ways to improve the revenue they derive from existing products. As such, life-cycle management continues to be an important issue for executives who understand that extending the life of a blockbuster drug can mean hundreds of millions, even billions, of dollars more for a company.

As product pipelines become slimmer and generic drugs appear poised to outstrip branded products' revenue over the next several years, brand managers face the daunting task of extending the patents on their marketable drugs for even longer periods.

Best Practices LLC has found that even with the increasing competitive pressures, the most popular life-cycle-management strategies that companies use in the later stages of a product's life are new formulations and new indications.

In a new study, Effectiveness of Pharmaceutical Life-Cycle Management Tactics, Best Practices analysts observe that the most popular strategy — employed by 71% of companies — is to develop new formulations. New indications came in second, with 60% of companies following this plan of action.

Examining 18 brands at 11 best-in-class companies, the study found that, when choosing a life-cycle management approach, companies consider the cost of extending a brand, the expertise necessary to undertake certain tactics, and the overall cost of implementing those tactics.

Taking these factors into consideration, executives reported that new formulations had a 92% success rate of extending patent life, while line extensions and new indications had a 100% success rate. Actual dollar gains for new indications ranged from $50 million to $500 million. Pediatric indications ranged from $50 million up to $2.25 billion, representing the largest revenue gain.

Genetic Disease Market **TO REACH $7.3 BILLION BY 2010**

The U.S. market for therapeutics and diagnostics for genetic diseases was estimated at $4.8 billion in 2005. Analysts predict this category will increase at an average annual growth rate (AAGR) of 8.7% to reach $7.3 billion by 2010, according to Diagnostics and Therapeutics for Genetic Diseases, a technical market research report from BCC Research.

Transfusions and dialysis comprised 44% of the total market in 2005 and are projected to grow at an AAGR of 8.0%. Analysts predict this segment will retain the largest share of the 2010 market, at just more than 43%.

In 2005, pharmaceuticals for genetic disease treatment reached $1.7 billion. This segment is expected to see the largest growth through the forecast period — reaching $2.7 billion by 2010, at an AAGR of 9.4%. Within this segment, drugs for the treatment of hemophilia accounted for 56% of the 2005 market and are expected to grow at an AAGR of 7.2% through 2010. Drugs for cystic fibrosis comprised 30.5% of the market in 2005 and are expected to grow at an average annual rate of 13%.

U.S. MARKET FOR THERAPEUTICS AND DIAGNOSTICS FOR GENETIC DISEASES, BY SEGMENT THROUGH 2010

	2000	2003	2004	2005	2010	AAGR%, 2005-2010
Diagnostic testing	$322.55	$573.98	$622.44	$663.62	$1036.70	9.3%
Pharmaceuticals	1084.40	1448.30	1605.60	1743.40	2730.20	9.4
Transplants	123.70	204.50	239.80	280.60	416.10	8.2
Transfusions and Dialysis	1083.80	1696.40	1841.80	2111.00	3104.70	8.0
Total	$2614.45	$3923.18	$3923.18	$3923.18	$7287.70	8.7%

Note: $ are in Millions
Source: BCC Research, Norwalk, Conn. For more information, visit bccresearch.com.

Follow up

BCC RESEARCH, Norwalk, Conn., is an information resource producing high-quality market-research reports, newsletters, and conferences. For more information, visit bccresearch.com.

BEST PRACTICES LLC, Chapel Hill, N.C., is a research and consulting firm. For more information, visit best-in-class.com.

CHA ADVANCES REPORTS, Waltham, Mass., evaluates the latest advances in pharmaceutical R&D, their potential applications and business impacts, and their current and future positions in the marketplace. For more information, visit advancesreports.com.

ERNST & YOUNG LLP, New York, provides a range of services centered around the core competencies of auditing, accounting, tax, and transactions. For more information, visit ey.com.

FROST & SULLIVAN, San Antonio, is a global growth consulting company. For more information, visit frost.com.

HEALTH RESEARCH INTERNATIONAL, Cleveland, a division of Personal Medical Systems Inc., provides the pharmaceutical and medical-device industries with reliable, comprehensive, and meticulously researched custom market data and analysis. For more information, visit healthri.com.

KALORAMA INFORMATION, New York, a division of MarketResearch.com, develops industry-specific market-research reports for the life-sciences industry. For more information, visit kaloramainformation.com.

U.S. GOVERNMENT ACCOUNTABILITY OFFICE, Washington, D.C., is an independent, nonpartisan branch of the U.S. government that evaluates federal programs, audits federal expenditures, and issues legal opinions. For more information, visit gao.gov.