Regulatory Deficiency is High Among **NON-U.S. CLINICAL INVESTIGATORS**


Kurt Brykman

The Global GCP Compliance Report helps companies better understand the key issues and roadblocks to effective clinical compliance, says Kurt Brykman, President of Parexel Consulting and Medical Marketing Services, Parexel International Corp.

In a sharp reversal of previous trends, good clinical practice (GCP) deficiency rates for non-U.S.-based clinical investigators have surged past the corresponding rates for U.S.-based investigators.

This is the finding of The Global GCP Compliance Report 2006: U.S., E.U., and Japan, published by Barnett Educational Services, a division of Parexel Medical Marketing Services, a business unit of Parexel International Corp.

About 55% of all non-U.S. clinical investigators inspected by the Center for Drug Evaluation and Research (CDER) in fiscal 2004 were cited for failure to follow the protocol. Only 29% of U.S.-based investigators received citations during that period. Records-related citations increased dramatically for non-U.S. investigators, rising to 48% in 2004 from 19% the previous year. In contrast, about 21% of U.S. investigators received such citations in 2004.

The Global GCP Compliance Report indicates that both U.S. and European regulators are attributing inadequate sponsor follow-up and clinical investigator training to the GCP problems detected at trial sites. FDA officials are now assessing whether to respond to the situation with increased inspectional scrutiny, educational initiatives, or both.

Side Effects and Communication Gaps Impact **ASTHMA TREATMENT COMPLIANCE**

The first-ever global, quantitative survey on unmet needs in asthma treatment illustrates significant discrepancies between physician and patient assessments of current asthma treatment on issues that may affect health outcomes, including medication side effects, patient education, and physician-patient communication.

23% of patients say during office visits no time is spent discussing techniques for successful asthma management.

The Global Asthma Physician and Patient (GAPP) Survey, a 16-country worldwide research study, was conducted by Harris Interactive on behalf of the World Allergy Organization to highlight the global impact of asthma.

There is a disparity between actual patient awareness of side effects and perceived patient awareness of side effects among physicians. Findings suggest that 31% of patients say they are unaware of the potential for long-term side effects associated with inhaled corticosteroid steroid (ICS) asthma treatments. Only 7% of physicians, on the other hand, believe patients are unaware of the potential for long-term side effects.

Additionally, patients and physicians report dramatically different assessments of how much time is spent on education during office visits: 23% of patients estimated that no time during their office visits is spent discussing techniques for successful asthma management; yet, 87% of physicians estimated that up to one-half of their office visits with asthma patients are spent on the topic.

Patients and physicians agree that currently available asthma treatments are less than ideal. While 95% of physicians believe ICS is the gold standard for asthma treatment, they report being least satisfied with side effects of currently available products; and 85% said they would be likely to prescribe a new ICS if it included an improved safety and tolerability profile.

INTERNET IS ESSENTIAL to European Physician Practices

European physicians rely on information technology and the Internet as critical tools in their practices, according to analysis conducted by Manhattan Research LLC.

The study found that 65% of practicing European physicians agree that access to the Internet is essential to their practice of medicine. Additionally, 86% of European physicians have Internet access in their offices, and a majority report having high-speed access.

This analysis is included in Taking the Pulse Europe v5.0: Physicians and Emerging Information Technologies, a research study and advisory service focused on European physician information technology trends in the United Kingdom, Germany, France, Spain, and Italy.


Meredith Abreu

While the Internet plays a significant role in healthcare practices across all of the countries in the study, one cannot lump all of Europe together as far as technology adoption is concerned. There are substantial differences between countries in terms of how physicians use technology in their practices and for professional education, says Meredith Abreu, VP of Research at Manhattan Research LLC.

BREAST CANCER THERAPEUTICS MARKET Shows Growth

As the breast cancer therapeutics market moves into an era of personalized medicine, Frost & Sullivan anticipates high growth within the biologics sector, with more products being integrated into an adjuvant setting or used as preventive measures.

Because current treatment regimens have harsh side effects, there is significant opportunity for new and innovative products to serve this patient population. Existing therapies for other cancer indications are being investigated for the treatment of breast cancer. Adjuvant settings also are being experimented across the market to investigate their applications. Extensive use of combination therapies and early-diagnosis systems is likely to offer more growth prospects.

Frost & Sullivan's World Breast Cancer Therapeutics Market analysis suggests the breast cancer therapeutics market will grow from its current size of $5.9 million to $11.5 million by 2011, with a compound annual growth rate (CAGR) of 9.8%.

The breast cancer market is expected to reach $11.5 million by 2011, with a CAGR of 9.8%.

But major challenges remain. This market suffers significant fluctuations because of the lack of consensus among physicians worldwide regarding the products to prescribe. The reasons for this disagreement include: the relative

merits of products in the market with efficacy relative to toxicity, the reimbursement provided by the government of each individual state, and the size of the sales and marketing force in each geographical region.

To expand the market further, companies must not only bring a drug successfully through the development process, they also must persuade payers that the high price of such novel therapies is justified due to increased survival periods, reduced hospital stays, and ability to reduce therapy costs.

Since cancer therapeutics are extremely expensive to market, it is a challenge for smaller companies to compete with the larger, better-established market leaders, according to Frost analysts. To support market penetration, such companies need to follow innovative drug discovery and targeting strategies, as well as establish strategic partnerships.

At the same time, the competitive landscape is set to change with the entry of generic companies. This will encourage entrants to introduce low-cost therapies.

2005 was a **RECORD YEAR FOR BIOTECH**

The U.S. biotech industry raised more than $17 billion through financings and $15 billion in partnering capital in 2005, according to industry analysis from Burrill & Co.

The industry's market cap hit an all time high of $488 billion at the end of November 2005, surpassing the previous record of $475 billion, reached in the summer of 2000.

The Burrill Biotech Select Index widely outperformed the NASDAQ and Dow Jones Industrial on a year-to-date basis. Biotech's blue-chip companies, such as Amgen and Genentech, led the way, and both reached the $100 billion market cap.

The capital markets remained extremely cautious throughout 2005, assailed by worries over rising interest rates, skyrocketing energy prices, and the aftermath of Gulf Coast hurricanes.

BURRILL PREDICTIONS FOR 2006

- In 2006, biotechnology will continue to fuel a major transformation in healthcare, one that emphasizes earlier disease detection, more targeted treatments, and adjunctive support through enhanced nutrition.
- Biotech stocks will continue to outperform NASDAQ, DJIA, and the pharma indices.
- There will be at least 30 U.S. IPOs and an even larger number internationally.
- The industry is expected to raise more than $35 billion in 2006.

Source: Burrill & Co., San Francisco.
For more information, visit burrillandco.com.

NANOTECHNOLOGY Benefits from an Increase in **VENTURE CAPITAL**

In 2005, institutional venture capitalists put $480 million into nanotechnology start ups. This brings total venture capital investment in nanotech to $2 billion since 1995, according to a report — Making Sense of Nanotech Venture Capital — from Lux Research Inc.

Nanotech venture capital investment to date has been highly concentrated; the top 10% of venture-backed start-ups account for 43% of total investment.

Of 143 nanotech start-up companies, 83% continue to operate.

"Venture capital investment for nanotechnology rose strongly in 2005 due to large, late-stage funding rounds for firms such as Aspen Aerogels, Nanomix, and Nanosys," says Matthew M. Nordan, VP of research at Lux and lead author of the report. "But venture capital still remains a drop in the bucket of total nanotech investment, outstripped by corpo-

rate R&D spending and government funding by a factor of 19."

According to the Lux report, venture capitalists are split in their attitudes toward nanotech. On one hand, most venture-capital partners see nanotech as a more attractive field for investment than other domains like biotech and enterprise software.

On the other hand, many partners that have made significant nanotech investments see their deals as high-risk placements with little visibility to an exit.

The success or failure of venture-capital investments in nanotech is too early to call, Lux analysts say. Of the 143 start-up companies assessed by Lux, only 9% have been acquired or gone public; 83% continue to operate; and 8% are dead or in danger.

Challenges Significant for **RX-TO-OTC SWITCHES** in Japan

Drug companies lobbying to switch their prescription medications to over-the-counter (OTC) status in Japan face significant obstacles. Not only must they state their case to the Ministry of Health, Labour and Welfare (MHLW), but they must also take into account the strong influence certain industry associations hold with the MHLW.

This is the conclusion of a recent Kline & Co. study, International Rx-to-OTC Switch Forecasts, which examines the relationships between these organizations and their influence on the opportunities for Rx-to-OTC switches in the Japanese market.

According to Kline analysts, groups such as the Japanese Medical Association (JMA) and the Japan Pharmaceutical Association can significantly influence the ultimate success of Rx-to-OTC switch applications in Japan — and even whether such applications are filed at all.

"On the whole, the JMA does not view Rx-to-OTC switches favorably; because of its strong influence over which prescription drugs physicians prescribe, the JMA's stance tends to have a stifling effect on switches," says Laura Mahecha, healthcare industry manager for Kline's research division.

Because of the influence brought to bear by third parties such as the JMA, most candidates for switch in Japan are newer-generation drugs, according to Kline. These products generally fall in therapeutic areas in which competing products have already made the switch and little innovation is seen regarding the creation of new OTC categories.

REPOSITIONING A PRODUCT Depends on Efficacy

The need for product repositioning or relaunch is most frequently triggered by poor execution, off-target brand identity, or flawed product positioning, according to Best Practices LLC.

FINDINGS OF RELAUNCH STUDY

- **Almost 75%** of relaunch brand managers identified product efficacy as the most effective factor for redefining the product's core message.
- **Almost half** of the benchmark class found targeting unmet medical needs and new patient subpopulations to be highly effective strategies.
- **Almost two-thirds** of relaunches revealed a careful cascade of physician segments, targeted and synchronized at relaunch.
- **More than 55%** of relaunches found that sharpening the product message was the most effective approach for resetting product positioning, followed closely by changing or sharpening the target audience.

Source: Best Practices LLC, Chapel Hill, N.C.
For more information, visit best-in-class.com.

In a recent study, Product Relaunch Excellence: Transforming Lackluster Pharmaceutical Products into Market Success Stories, Best Practices provides insights into how leading companies drive successful product relaunches.

The study offers a comprehensive overview of field-proven relaunch strategies, practices, and experiences from 14 leading pharmaceutical and biotech companies.

The study finds that redefining the brand for highest possible market uptake is a cornerstone for all products that find second life and marketplace success through relaunch.

NANOMEDICINE AND NANO DEVICE PIPELINE Surges

According to the NanoBiotech News 2006 Nanomedicine, Device & Diagnostic Report, 130 nanotech-based drugs and delivery systems, as well as 125 devices or diagnostic tests, have entered preclinical, clinical, or commercial development. As a result, the clinical pipeline for nanotech has increased 68% since 2004.

"There is a growing community of nanobiotech drug and device developers that are digging in their heels — and surviving," says Lynn Yoffee, associate publisher of National Health Information LLC, which produces *NanoBiotech News* and the 2006 report. "Additionally, there are numerous product candidates marching beyond concept well into trials, ever closer to market. The industry is experiencing an evolution similar to what happened in biotechnology, but the nanobiotech developers are putting together therapies and diagnostics with an even more astonishing 'wow' factor."

PROMISING PRODUCTS IN THE NANOBIOTECH PIPELINE

- A nanoviricide for Avian flu
- Nano-based coatings for medical implants that will permit safe magnetic resonance imaging
- A multifunctional nano device that selectively binds to cancer tumor cells and destroys them

Source: The 2006 Nanomedicine, Device & Diagnostic Report, NanoBiotech News, National Health Information LLC, Atlanta.
For more information, visit nhionline.net.

This pipeline surge is due, in large part, to a plethora of new deals that developed in 2005. Nearly one-third (30%) of all products are being developed as part of collaborations or licensing deals, another trend similar to the biotechnology industry growth.

SPECIALTY DRUGS Fill Pipeline Gaps

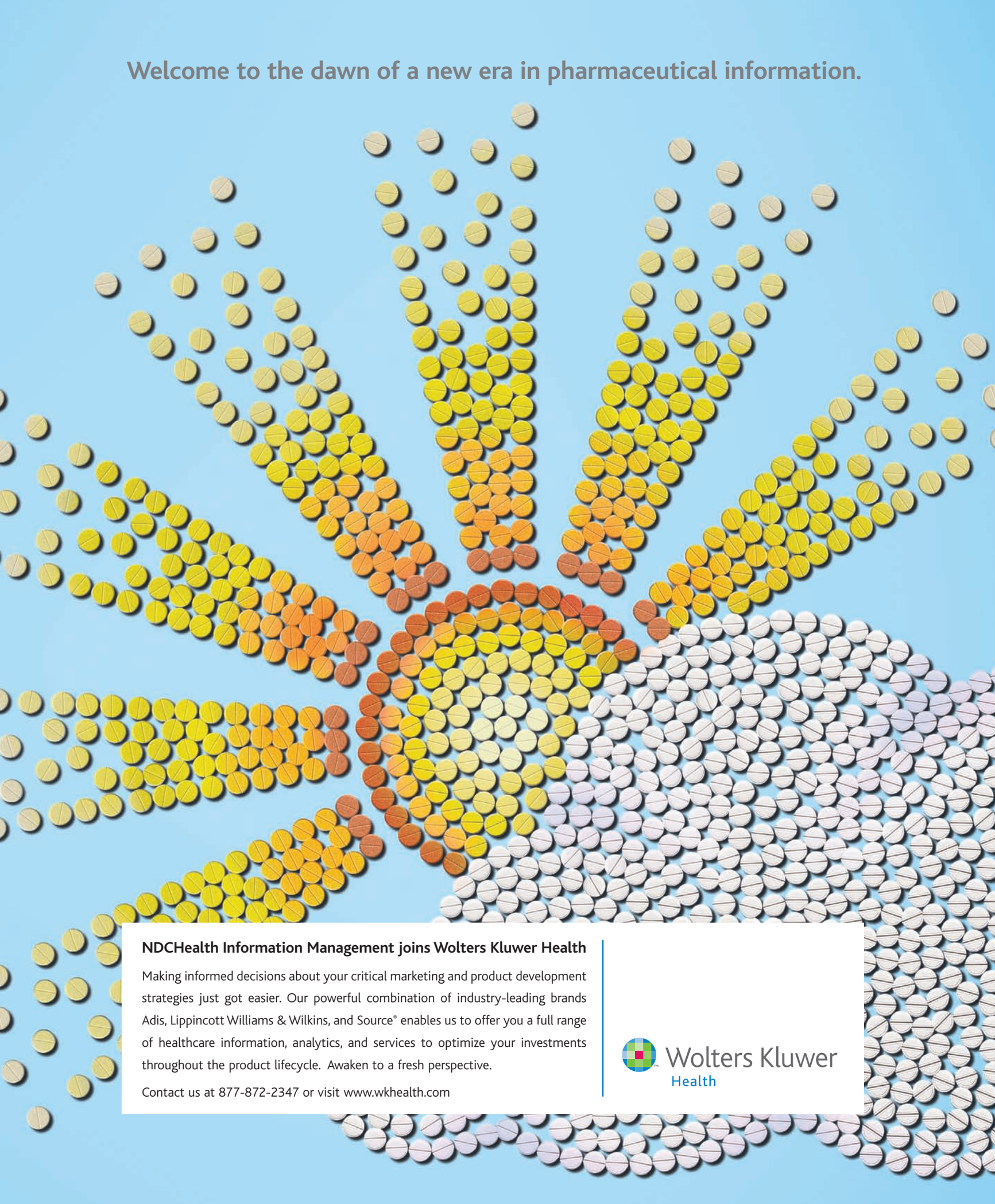
From small biotechnology firms to large pharmaceutical organizations, an increasing number of product pipelines include specialized niche drugs rather than blockbuster-hopeful products. This trend signals untapped profitability in dozens of niche drug markets, according to a new report from Cutting Edge Information.

The report, Pharmaceutical Sales: Driving Access and Influencing Prescribers, finds that niche products are attractive because they require smaller investments in clinical research, less commercialization dollars, and fewer sales reps, therefore the total cost to gain regulatory approval is much less than that of a blockbuster drug.

The total cost to gain regulatory approval on NICHE PRODUCTS is much less than that of a blockbuster drug.

Nevertheless, the majority of the pharmaceutical industry remains focused on general drug sales; on average, companies employ 75% of their salesforces to sell general drug products. But smaller firms regularly develop niche drugs to maintain a steady revenue source.

Specializing in niche products does not resolve the physician-access woes that are plaguing the pharmaceutical industry. But analysts suggest the limited target markets for niche drugs allow sales reps to focus on strengthening existing physician relationships.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Pharma Programs Provide HEALTH INTERVENTIONS TO THE DEVELOPING WORLD

Since the United Nations announced its Millennium Development Goals in 2000, the pharmaceutical industry has created 126 health partnerships and provided enough health interventions in the developing world to help as many as 539 million people.

According to a survey by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the pharmaceutical industry has made available to the developing world medicines, vaccines, equipment, health education, and manpower valued at about $4.38 billion.

The 10 most significant diseases addressed by these industry initiatives are elephantiasis (lymphatic filariasis), hepatitis, HIV/AIDS, influenza, malaria, polio, river blindness (onchocerciasis), sleeping sickness, trachoma, and tuberculosis.

"Our industry has learned from its experiences that the health of people in developing countries cannot be improved simply by increasing the amount of drugs that our companies donate," says Daniel Vasella, M.D., president of the IFPMA and chairman and CEO of Novartis AG. "It also requires more clean water, better sanitation, improved clinics and hospitals, as well as better training and retention of healthcare workers. Pharmaceutical companies are directly providing more and more of this kind of grassroots help."


Dr. Daniel Vasella

We recognize the enormity of the public health challenges raised by the UN Millennium Development Goals and know that continued success will require even more collaboration, creativity, and hard work. Our industry stands ready to do its part, says Daniel Vasella, M.D., President of the IFPMA and Chairman and CEO of Novartis AG.

Decision Resources Predicts BLOCKBUSTERS

Analysts at Decision Resources Inc. have identified products they anticipate will achieve blockbuster status within the next decade. Among these are: Genentech's Avastin for the treatment of various cancers, Neurochem's Alzhemed/Cerebril for the treatment of Alzheimer's disease, Merck and Novartis's oral dipeptidyl peptidase-IV inhibitors for the treatment of Type 2 diabetes, and Sanofi-Aventis' Acomplia for the treatment of obesity.

Blockbusters are drugs with annual sales of more than $1 billion. In 2004, blockbuster drugs generated worldwide sales of about $166 billion, which translated to about 30% of the pharmaceutical industry's total sales for that year.

In its report, Blockbuster Drugs: A 2005-2014 Forecast, Decision Resources' analysis concludes that to achieve blockbuster status, drugs will have to target diseases that continue to have substantial unmet clinical need.

POTENTIAL BLOCKBUSTERS

COMPANY	PRODUCT	CONDITION
Genentech	Avastin	Various cancers
Neurochem	Alzhemed/Cerebril	Alzheimer's disease
Merck/Novartis	Oral dipeptidyl peptidase-IV inhibitors	Type 2 diabetes
Sanofi-Aventis	Acomplia	Obesity

Source: Decision Resources Inc., Waltham, Mass.
For more information, visit decisionresources.com.

Follow up

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HARRIS INTERACTIVE INC., Rochester, N.Y., is a market-research firm and a leader in the online market-research industry. For more information, visit harrisinteractive.com.

THE INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS (IFPMA), Geneva, is a nonprofit, nongovernmental organization representing national industry associations and companies from both developed and developing countries. For more information, visit ifpma.org.

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