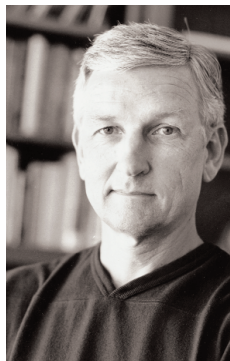




DRUG IMPORTATION Poses Risks



America's top public-health officials have found that importing drugs will expose our citizens to increased health risks without significantly lowering the cost of pharmaceuticals, says David Gollaher, President and CEO of CHI.

A federal HHS Task Force has warned in its Report on Prescription Drug Importation against the public health risks and economic effects of legalizing the importation of drugs from Canada and other countries with price controls.

"This study confirms the deep flaws inherent in drug-importation schemes," says David Gollaher, president and CEO of the California Healthcare Institute (CHI). "America's top public-health officials have found that importing drugs will expose our citizens to increased health risks without significantly lowering the cost of pharmaceuticals."

Canadian drug importation has been a lightning-rod issue in federal and state politics. Gov. Arnold Schwarzenegger vetoed legislation that would have encouraged importation to California.

The House of Representatives passed a pro-importation bill, though the measure stalled in the Senate.

"The FDA has a world-leading record in ensuring drug safety, but it is facing serious threats," Mr. Gollaher says. "The cost of creating a major new program to inspect foreign drugs would be high and would weigh heavily on the FDA. Beyond that, according to the report, Americans assume that foreign drugs are much cheaper than they actually are. Generics, which account for the majority of American prescriptions, are less expensive here than in Canada. Ultimately, the study rightly concludes that importation would erode innovators' IP rights and dramatically weaken economic incentives for the creation of new medicines for Americans."



Companies that historically focused more on late-stage deals are now shifting to early-stage deals, which are more risky, but the focus is on accessing a pipeline of products to mitigate some of the risk due to the higher attrition rate developing earlier-stage products, says Sian Renfrey, a Principal Consultant at Wood Mackenzie.

LICENSING REVENUE at the Top 20 Global Pharmaceutical Companies WILL REACH \$100 BILLION BY 2008

According to a recent Wood Mackenzie study, Licensing Insight 2004, revenue from licensed products will reach \$100 billion over the next four years. This represents nearly one-third of the pharmaceutical industry's total projected revenue by 2008.

The study finds that while revenue will continue to soar in the next four years, the actual number of deals overall has dropped since 1998.

Specifically, more companies are shifting to early-stage deals due to the lack of late-stage products in development.

"Our study shows that as R&D development slows and licensing continues to be a key factor in driving growth, many pharmaceutical companies are re-examining their strategies," says Sian Renfrey, a principal consultant with Wood Mackenzie.

Recent CME GUIDELINES Pave the Way for NEW STRATEGIES IN 2005

As regulatory pressures increase for commercial sponsors to limit their involvement in continuing medical education (CME), pharmaceutical companies and commercial sponsors are finding they need to take a new approach to planning and delivering CME.

A recent report from Manhattan Research LLC finds that the online CME, or eCME, market continues to expand, providing a prime opportunity for commercial sponsors to redirect funds from offline tradi-

eCME MANHATTAN RESEARCH STUDY FINDINGS:

THE eCME MARKET IS STEADILY EXPANDING, with 423,000 physicians using eCME in 2004, an increase of 14% from the previous year.

AN ADDITIONAL 79,000 PHYSICIANS report interest in using eCME in the future, with more than a quarter of these physicians being female.

ALMOST ONE-FIFTH OF PHYSICIANS browsing CME (i.e., not receiving CME credit) for more than half of their eCME report a need to make options easier to find, while those more likely to receive credit for eCME report a need for increased variety of CME content online.

THE PHARMACEUTICAL INDUSTRY can highlight the advantages of eCME by focusing on interactivity and personalization.

VENDORS MUST FOCUS on creating expanded content and eCME directories, with simple navigation and streamlined registration to maximize physician participation.

Source: Manhattan Research LLC, New York.
For more information, visit manhattanresearch.com.

tional venues to online channels in 2005. In September 2004, the Accreditation Council for Continuing Medical Education (ACCME) approved guidelines designed to ensure CME independence from commercial bias. The guidelines require speakers and planners to disclose financial ties to pharmaceutical and medical-device companies. The guidelines also bar speakers with relevant connections from presenting recommendations.

According to Erika Fishman, a senior analyst at Manhattan Research, many in the industry are concerned that offline CME will become less effective when speakers with industry ties are pulled from the roster.

"Two forces are clearly at work: market forces that are shifting physicians to the online sector and policy forces that are limiting options for offline CME," Ms. Fishman says.



Two forces are clearly at work: market forces that are shifting physicians to the online sector and policy forces that are limiting options for offline CME. With the alignment of these two forces, it's an ideal time for proactive pharmaceutical companies to leverage the Internet as a strategic channel for CME, capitalizing on its timeliness, variety, effectiveness, and potential for innovation.

Big Pharma Incorporates **COMPETITIVE INTELLIGENCE** at a **RATE OF 87%**



Market research is no longer a secondary, data-collection function, says Elio Evangelista, Senior Analyst at Cutting Edge Information. It can be used as a proactive tool, a strategic advisor, and a project manager, especially in early development stages, to ensure a product's success in the future.

A new study from Cutting Edge Information finds that 87% of pharmaceutical market-research groups incorporate competitive intelligence, allowing their companies to shape the market for future success.

By incorporating competitive intelligence into market-research techniques marketing teams can position new products by Phase II.

Cutting Edge Information found, however, that 60% of pharmaceutical companies fail to take full advantage of their capabilities, causing them to

quickly fall behind competitors.

Competitive intelligence and market research are closely aligned in strategy and execution. In the report, Pharmaceutical Market Research: Decision Support for Brand Growth, pharmaceutical executives point out that any information a company collects on competitor products, positioning, or strategy is, in fact, competitive intelligence. This connection opens doors for market research to support R&D and marketing strategies with competitive intelligence data.

Wellness Index Compares State of **HEALTH AND FITNESS**

Across the Globe

NOP World's Culture Score Wellness Index offers a global perspective on health and fitness values, attitudes, and behaviors across 31 countries.

The Wellness Index compares the average of three dimensions in each country surveyed: the personal value people put on health and fitness; their interest in the topics of health and fitness; and the extent to which they exercise to keep fit.

Globally, 30% say health and fitness are extremely important values. Slightly fewer, 27%, say they are very interested in health/medical science and or

wellness/fitness topics. Somewhat more, 37%, say they exercise on a weekly basis.

With two-thirds of Koreans (68%) saying health and fitness are extremely important personal values, Korea ranks first on the Wellness Index. Koreans also are above average when it comes to keeping fit, with 41% of the population exercising at least weekly. But, at 27%, their interest level in wellness-related topics is significantly lower than other nations.

Australia ranks second to Korea on the Wellness Index because of its significant propensity to take action. Two-thirds (67%) of Australians say they exercise on a weekly basis. Surprisingly, however, only 25% say health and fitness are extremely important values. Similarly, while the United States and the United Kingdom ranked 10th and 15th respectively, these countries are more likely to exercise on a weekly basis (51% and 56% respectively), but are less likely to consider health and fitness extremely important personal values (28% and 17% respectively).

"Health and fitness seem to be an anomaly with some taking a 'Just Do It' mentality, while others have not yet learned to practice what they preach," says Nick Chiarelli, European director of NOP World Market Opportunity Center of Excellence. "Each country has an interesting story to tell. Local economic pressures and cultural norms must be examined to understand the complicated relationship between values, attitudes, and behaviors."

Study Shows Marked Variation by States in **GENERIC DRUG** Use

Generic drug use varies widely by state, according to a new Express Scripts study that measured per capita generic drug use in 2003, using a random sample of

THE GLOBAL CULTURE SCORE WELLNESS INDEX

	VALUE, BEHAVIOR, ATTITUDE INDEX	VALUE: HEALTH AND FITNESS ARE EXTREMELY IMPORTANT PERSONAL VALUES	BEHAVIOR: EXERCISE TO KEEP FIT AT LEAST WEEKLY	ATTITUDE: VERY INTERESTED IN HEALTH/MEDICAL SCIENCE
KOREA	160	68%	41%	41%
AUSTRALIA	135	25	67	35
THAILAND	126	42	41	35
VENEZUELA	121	42	34	38
PHILIPPINES	120	49	37	27
CANADA	119	29	48	35
SAUDI ARABIA	119	49	27	36
SWEDEN	116	19	52	38
EGYPT	115	43	34	31
UNITED STATES	115	28	51	29
RUSSIA	111	38	31	35
INDIA	109	36	42	24
ARGENTINA	107	23	41	37
CZECH REPUBLIC	105	46	31	22
UNITED KINGDOM	104	17	56	25
FRANCE	101	37	36	22
JAPAN	100	19	30	45
CHINA	93	25	35	27
SOUTH AFRICA	93	36	29	22
BRAZIL	90	26	35	24
MEXICO	90	30	31	24
SPAIN	90	42	28	15
ITALY	88	17	34	32
SINGAPORE	85	28	34	18
GERMANY	82	28	21	28
INDONESIA	82	30	34	13
HONG KONG	79	25	33	16
HUNGARY	78	31	22	20
POLAND	71	32	22	13
TURKEY	69	27	26	12
TAIWAN	61	19	20	18
TOTAL GLOBAL	100	30	37	27

Note: The Culture Score Index Series is based on analysis of the NOP World Roper Reports Worldwide survey, which includes in-depth personal interviews with more than 30,000 people, ages 13 to 65 across 31 countries. The data are weighed to the sampled population in each country. The Wellness Index compares the average of three dimensions in each country, including values, behavior, and attitudes with that of the global population. Source: NOP World, New York. For more information, visit nopworld.com.

about 3 million pharmacy benefit plan members between the ages of 18 and 64.

The study revealed that Massachusetts had the highest generic dispensing rate, at 51%, followed by New Mexico and Oregon, with generic dispensing rates of about 50%.

Eastern states, such as New Jersey and New York, and southern states, including Texas, Louisiana, Florida,



Generic drugs are the key to managing the growing cost of prescription drugs, making it possible for plan sponsors to continue to provide an attractive prescription benefit for their members, says Brenda Motheral, VP of Research and Trend Management at Express Scripts.

and Mississippi, used generics to fill fewer than 43% of all prescriptions. New Jersey used generics for fewer than 40% of all prescriptions.

Possible explanations for the variations in generic fill rates include variations in prescribing patterns, state regulations, differences in disease prevalence, and varying use of drug benefit designs that encourage greater use of generics.

By the end of 2008, branded pharmaceutical products, which accounted for more than \$38 billion in sales last year, are expected to lose patent protection. Taking advantage of generics can result in significant savings for plan sponsors and their members.

Express Scripts statistics show that for every 1% increase in generic drug use, prescription benefit plan sponsors save about 1% off their cost for drugs in providing the benefit. The generic variation study is the second Express Scripts study to examine geographic variations in prescription drug use.

In 2001, Express Scripts research in geographic variation in prescription drug use found significant variation in the prevalence of use of prescription medication overall and across many therapeutic classes.

COMBINATION PRODUCTS' Share of Drug-Delivery Market to APPROACH \$40 BILLION

Combination drug-delivery products are growing at an annual rate of 14% across all segments and are expected to total \$38 billion in 2008. Growth will be led by inhaler devices, including intranasal and pulmonary systemic therapeutics. Transdermal delivery products, in particular drug patches capable of delivering two or more drugs, and patches based on microneedle technology also will contribute significantly.

The convergence of computerized design tools, engineered materials, and particle technology are enabling the creation of drug-device combination products that were unattainable just a few years ago.

Healthcare practitioners and medical researchers have known that for certain diseases combining drugs can have a synergistic, and sometimes dramatic, effect on therapeutic outcomes. While combining two or more drugs in a single delivery package already is established for certain conditions such as asthma and hormone replacement therapy, promising clinical evidence of the therapeutic potential for administering multiple drugs is creating a growing list of afflictions and conditions that can benefit from multi-drug delivery technology,

Recognizing the growing impact of combination

products, the FDA established a new organizational entity in December 2002 to coordinate the regulatory process for the rising number of applications comprised of two or more regulated components. Integrating the drug with the delivery device results in a synergistic merging in which therapeutic benefit is increased and outcomes are improved.

"Cooperation between device designers and drug developers is occurring much earlier in the drug-development cycle, allowing device designs in many cases to be tailored to the bioavailability targets and pharmacokinetic profiles of specific drug therapies," says George Perros, managing director at Greystone Associates. "The new devices are typically patient-friendly, easing compliance concerns, have a non-negligible effect on drug formulations and delivery decisions, and are a significant factor in the prescribing decisions of most physicians."

PATIENT SAFETY Brings More DATA INTEGRATION PROBLEMS for Pharma Companies

To give a complete picture of a clinical trial, pharmaceutical companies must integrate data from trial protocols, patient records, clinical records, adverse event reports, and genomic data.

Currently, no solution capable of meeting these needs exists. Life Science Insights predicts that the

LIFE SCIENCE INSIGHTS' OUTLOOK FOR 2005

- ▶ **TECHNOLOGY SPENDING WILL INCREASE** in later stages of the pharmaceutical value chain, in areas such as clinical-trial management systems, electronic data capture, and electronic lab notebooks. Spending on technology for classic discovery and development will remain flat.
 - ▶ **BIG PHARMA IT DIVISIONS ARE MOVING AWAY** from the mother-ship model. Individual business units are making more and more IT decisions and those units (genomics, medicinal chemistry, and preclinical development) are willing to pay for informatics technologies that will enable innovation or enhance productivity.
 - ▶ **PHARMACEUTICAL COMPANIES ARE INCREASINGLY SEARCHING** for a low-cost edge. R&D is a good place to look, especially as countries such as China and India ramp up their R&D capabilities. Academic institutions will play a more significant role in commercial drug discovery.
 - ▶ **COMPUTATIONAL BIOLOGY AS A DISCIPLINE WILL GO AWAY** as most biology becomes computational. The controversial art of *in silico* property prediction will become more acceptable over time. Core versus non-core IT functions will be further divided and noncore IT will become increasingly outsourced.
 - ▶ **CIOs WILL HAVE A LARGER SEAT AT THE R&D TABLE.** While CIOs managing noncore busi-
- nesses will be spending more time in Asia, funding sources will increasingly come from both corporate IT and the business unit itself.
 - ▶ **ALTHOUGH NOT REQUIRED, A GROWING NUMBER OF STANDARDS**, including SDTM (study data tabulation model), SAFE (secure access for everyone), and SEBIX (secure electronic biopharmaceutical information exchange), for submitting and managing clinical data will become de rigueur.
 - ▶ **IT ORGANIZATIONS ARE SCRAMBLING TO COMPLY** with a growing list of regulatory mandates and to meet deadlines. Pharma lawsuits by states attorneys-general will drive a new market for compliance software and make Sarbanes-Oxley look like a picnic. Look for biopharmas to hire chief compliance officers.
 - ▶ **THE 2002 NIH ROADMAP**, proposed by director Elias Zerhouni, could lead to a dramatic, but welcome, reduction in the number of NIH institutes, with other government agencies looking to fill the void. Life Science Insights predicts a growing role for venture philanthropists, such as the Bill and Melinda Gates Foundation.
 - ▶ **THE PENDULUM IS SLOWLY SWINGING BACK** to tools and platforms and the rush to revenue is decreasing. Technologies that enable the drug discovery and development process will realize increased funding in the near term.

Source: Life Science Insights, Framingham, Mass. For more information, visit life-science-insights.com.

first vendor to market with a comprehensive solution will own the space.

The recent Vioxx withdrawal and suspicion over other blockbuster drugs have intensified pressures on pharmaceutical companies to disclose all negative as well as positive results of industry-sponsored clinical trials.

But for most pharmaceutical companies, processes for monitoring drug safety are scattered throughout the organization.

Marketing Strategies Can **INCREASE** **BRAND LOYALTY** and Rx Purchasing **AMONG SENIORS**

Research from Health Strategies Group identifies essential components that pharmaceutical manufacturers and marketers need to include in strategies aimed at seniors.

"Pharmaceutical manufacturers have a significant opportunity to shape seniors' direct product experience by communicating the improvement in lifestyles that treatment affords, which is an important determinant of their perceptions of value," says David Rees, principal at Health Strategies Group. "But our research indicates that few seniors currently associate

MYTHS AND FACTS ABOUT SENIORS' RX PURCHASING BEHAVIOR	
MYTHS	FACTS
Seniors use more drugs than juniors	Rx usage correlates with comorbidities more than age; an average insured senior takes only one additional Rx per month compared with an average junior
Seniors use or purchase more generics	Use of generics reflects the absence of Rx benefits more than age; insured consumers, young and old, use equal numbers of generic products each month
Seniors are more sensitive to cost than juniors	Sensitivity to out-of-pocket costs also reflects insurance status more than age; insured seniors respond to copay surprises three times more often than other seniors
For seniors, symptom relief is a drug's most important feature	Seniors value products' effects on their experiences key functional benefits more than symptom relief

Source: Health Strategies Group, Lambertville, N.J. For more information, visit healthstrategies.com.

their prescription products with lifestyle improvement."

Several factors point to the need to create strategies that focus exclusively on seniors:

- Seniors and juniors (individuals under 65 years of age) value Rx products differently.
- The Rx decision-making styles of seniors who

don't have Rx benefits in 2004 will change when they begin to receive benefits in 2006.

- Employers are paring back or eliminating the Rx benefits they provide for retirees.

Health Strategies Group's findings also show that several widely held beliefs about seniors' Rx purchase decisions are, in fact, myths (see box above).

Follow up

CALIFORNIA HEALTHCARE INSTITUTE (CHI), La Jolla, Calif., which represents more than 225 biotechnology, medical-device, diagnostics, and pharmaceutical companies, and public and private academic biomedical research organizations, has a mission to advance responsible public policies that foster medical innovation and promote scientific discovery. For more information, visit chi.org.

CUTTING EDGE INFORMATION, Durham, N.C., provides research and consulting to the pharmaceutical industry and the financial services industry. For more information, visit cuttingedgeinfo.com.

EXPRESS SCRIPTS INC., St. Louis, is one of the largest pharmacy benefit management (PBM) companies in North America, providing PBM services to more than 50 million patients through facilities in 13

states and Canada. For more information, visit express-scripts.com.

GREYSTONE ASSOCIATES, Amherst, N.H., is a medical and healthcare technology consulting company that provides services in strategic planning, venture development, product commercialization, and technology and market assessment. For more information, visit greystoneassociates.org.

HEALTH STRATEGIES GROUP, Lambertville, N.J., is a research and consulting firm working primarily with healthcare product manufacturers. For more information, visit healthstrategies.com.

LIFE SCIENCE INSIGHTS, an IDC company, Framingham, Mass., provides market research, analysis, and consulting services to decision makers in life-sciences markets, including pharmaceutical and biotechnology companies, contract research organizations, government research organizations, and technology vendors.

For more information, visit life-science-insights.com.

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