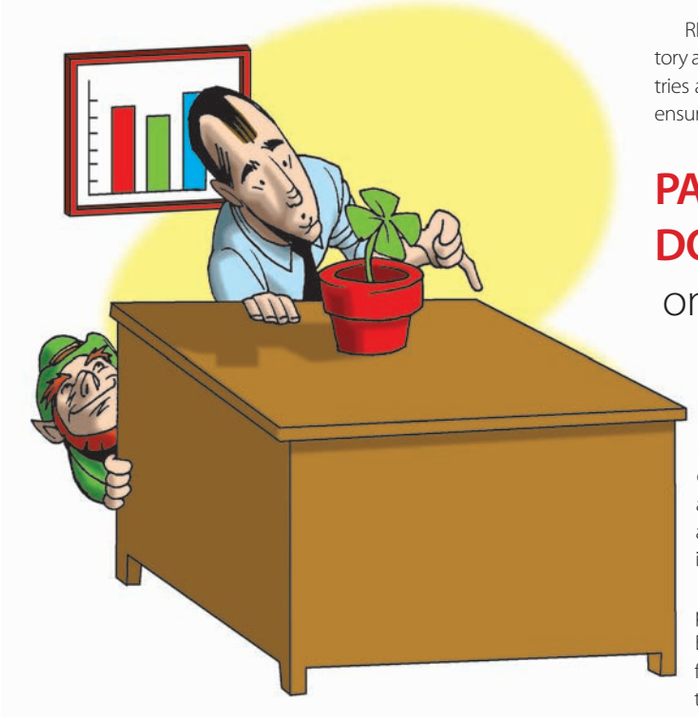

Drug Counterfeiting **CREATES NEED FOR RFID** in European Markets

Globally, about 5% to 8% of prescription drugs are counterfeit, which is a big liability for pharma companies, says V. Sriram, Research Analyst at Frost & Sullivan.

The use of radio frequency identification (RFID) by Europe's pharmaceutical industry continues to be driven by increasing counterfeit products in the market. Such counterfeiting is largely due to deficiencies in the supply chain and the legalized parallel trade in pharmaceuticals between EU member nations.

Frost & Sullivan estimates the European pharmaceutical market for RFID was $18.0 million in 2005 and expects this to reach $464.8 million by 2012.

"Globally, about 5% to 8% of prescription drugs are counterfeit, which is a big liability for pharma companies," notes Frost & Sullivan Research Analyst V. Sriram. "The absence of integration across the supply chain and the inability to track products at every stage have intensified this trend, while creating a real and urgent need for RFID."

Despite the scope for the use of RFID to track and manage products in the pharmaceutical industry, the lack of interoperability and harmonization of standards remain key issues. EU member nations must arrive at a consensus so that even as the initial cost of implementation is minimized, long-term sustainability can be achieved.

Mr. Sriram says an important step will be to alleviate misconceptions about RFID and interoperability concerns and fully address any uncertainties about the effectiveness of RFID.

RFID vendors need to keep abreast of the regulatory and technological requirements of various countries and work closely with government agencies to ensure a smooth transition from bar codes to RFID.

PATIENTS AND DOCTORS DISAGREE on Essential Issues

A survey of 39,090 patients and 335 primary-care physicians, conducted by Consumer Reports National Research Center, reveals discrepancies between doctors' and patients' perceptions about the role of prescription drug ads in the exam room, following medical advice, and the value of online research of medical conditions.

Patients almost unanimously said they completely or mostly followed their doctor's advice. But 59% of doctors said their patients often failed to adhere to the prescribed course of treatment.

Regarding drug ads, 40% of doctors say advertising directly to consumers did not serve the public interest. But 78% of doctors surveyed said patients asked them at least occasionally to prescribe drugs they have seen advertised on television, and 67% said they sometimes did so. And 54% of the doctors said they sometimes declined to prescribe requested medications. According to the survey, patients most frequently ask about advertised drugs for acid reflux, impotence, allergies, and insomnia.

Almost 40% of patients researched their medical conditions online, but 41% of doctors surveyed said their patients often showed up poorly informed because of bad information found online.

Consumer Reports' survey results reveal that doctors think the healthcare system works much better for drug and health insurance companies than for primary-care doctors and their patients.

Among patients who received prescriptions from their doctors, 31% reported that their doctor didn't adequately explain possible side effects, and 9% of patients said their doctor did not review their other prescriptions to check for potentially harmful interactions with the newly prescribed drug.

Two-thirds of patients reported that doctors never brought up the costs of treatments and tests.

More Disease Management and Patient Adherence Program **BUDGETS ARE OUTSOURCED**

A recent report by business intelligence firm Cutting Edge Information reveals that companies participating in the study spend on average 41% of their overall disease management and patient adherence budgets on outsourcing activities. Outsourcing specific program activities allows for companies to more effectively manage several key steps in program development.

Outsourcing can eliminate costs of maintaining the infrastructure needed to support some specific activities, as well as the difficulty in managing these tasks. Patient confidentiality issues also encourage companies to outsource specific portions of a program. Doctors and patients are more comfortable with outside vendors handling patient records than allowing pharmaceutical companies to manage them. This also eliminates the perception that pharma companies could place their own interests over those of the patient.

OUTSOURCING TRENDS

- **61%** of companies surveyed outsource at least part of their material development activities
- **50%** outsource call center activities
- **50%** outsource market research
- **44%** outsource communication with program users

Source: Pharmaceutical Patient Adherence and Disease Management: Program Development, Management and Improvement, Cutting Edge Information, Research Triangle Park, N.C.
For more information, visit cuttingedgeinfo.com.

OPTIMISM Grows for Drug Development

Despite a growing list of development challenges — including rising R&D costs, increasing regulatory stringency, and mounting public hostility regarding safety and end-user costs — drug developers have cause for optimism, according to the Tufts Center for the Study of Drug Development (CSDD).

Contributing to that optimism is greater use of new technologies to reduce late-stage development failures and contain rising costs, increased reliance on global outsourcing to speed development and reduce costs, and more coordination between U.S. and European regulators.

These trends were cited in the Tufts CSDD's Outlook 2007 report on pharmaceutical and biotech development.

The number of new drugs entering clinical testing by the top 10 companies increased by 52% in the first part of this decade. Also, new product development at small- and mid-tier pharma and biotechnology companies is increasingly filling the product gap that large pharmaceutical firms have been experiencing.

"Most notably, drug companies are improving


Dr, Kenneth I. Kaitin

While drug developers have understood that their long-term viability depends on improving R&D productivity and have taken steps to address the issue, they're about to see their efforts pay off in terms of improved success rates and greater numbers of new medicinal products reaching the marketplace, says Tufts CSDD Director, Dr, Kenneth I. Kaitin.

their management of risk, especially by actively lowering late-stage attrition rates through greater use of information technology and other development practices," says Tufts CSDD Director, Kenneth I. Kaitin, Ph.D.

Other near-term trends include:

- Companies, acting alone and in consortia, will seek to improve drug discovery by examining pre-competitive data to identify and validate new targets.
- The high cost and low success rates of human studies will lead small- and mid-tier pharma companies to adopt outsourcing and other clinical practices that big pharma increasingly uses to control costs and manage risk.
- Biotech firms will escalate biodefense and pandemic disease related R&D, emphasizing translational research and development of effective countermeasures.
- Instead of directly addressing off-label uses of existing prescription drugs, the FDA will evaluate current studies and likely request new ones before deciding whether to further regulate off-label uses, and within two to three years, up to 65% of FDA-regulated clinical trials for top pharmaceutical companies will be conducted abroad.
- The European Medicines Agency (EMEA) will focus on implementing new legislation and integrating drug regulatory agencies of new European Union members into a comprehensive pan-European system.
- U.S. third-party payers will move away from a binary coverage model in which prescription drugs are either covered or not covered. Instead, more than 90% of prescription drugs will be covered with a variety of limits.

Pharmacy Management Tools Drive **PRESCRIPTION DRUG SPENDING DOWN** to 5.8% in 2005

New data from the Centers for Medicare and Medicaid Services (CMS) reveal that increased use of pharmacy benefit management (PBM) tools in private and public health programs helped reduce the rate of growth in prescription drug spending in 2005.

The rate of growth, the lowest level in more than a decade, was just 5.8%. The PBM tools include formularies, rebates, generic drugs, and mail-service pharmacies.

"These data are the result of a sustained effort by PBMs to help consumers, clinicians, and payers change the way they think about prescription drugs, particularly with formularies and increased use of generic drugs and mail-service pharmacies," says Mark Merritt, president of the Pharmaceutical Care Management Association (PCMA).


Mark Merritt

PBMs have played a huge role in helping to drive the prescription drug spend to an historic low, says PCMA President Mark Merritt. This approach is proof-positive that the prescription-drug cost challenge can be addressed without sacrificing access to needed drugs.

The statistics are contained in a report, National Health Spending in 2005: The Slowdown Continues, authored by researchers from the CMS.

The slowdown in prescription drug spending represents a 33% reduction from the 2004 growth rate of 8.6% and a decline from 1999, when the drug spending trend was running at 18.2%.

Among the reasons the authors cite for the historic slowdown in prescription drug spending are: tiered copayment benefit plans and formularies; a decreased number of new drug introductions; a reduced consumption associated with drug withdrawals; a continued shift to use of generic drugs; and continued strong growth in mail-service pharmacy, which helped increased the use of generics.

Spending on prescription drugs in Medicaid

slowed noticeably in 2005 to just 2.8%. As the researchers note, this slowdown in Medicaid prescription drug spending was driven as "states continued to undertake aggressive cost-control initiatives, successfully secured higher rebates resulting from increased use of multistate purchasing pools, and changed their formularies to shift beneficiaries to drugs that offered higher rebates."

U.S. Adults Want ONGOING REVIEW OF PHARMACEUTICALS

According to a recent Harris poll of 2,429 U.S. adults, 71% believe that it is very, or highly, important that pharmaceutical drugs remain under close review by the FDA and drug companies, even after the medicines are made available to the public. An additional one in five (20%) say it is important that the drugs remain under close review. Only 9% say it is only somewhat or not very important. The FDA currently has a process in place to conduct postmarketing surveillance of drugs.

Many Americans are demonstrating consumerism by proactively seeking out information about drug safety. The poll, conducted online within the United States, indicates that 41% of respondents always or often seek information on drug safety for themselves and/or family members. One-third (35%) say they sometimes seek out information on drug safety, and one-quarter (24%) rarely or never seek out this information.

There are some age differences that emerge when looking at the data. While about three-quarters (74%) of baby boomers (those between ages 42 and 60) and 71% of matures (those 61 and older) say it is highly or very important for drugs to remain under close review by the FDA and drug companies, fewer than two-thirds of respondents (64%) of echo boomers (those from 18 to 29 of age) feel this way. Almost three-quarters (73%) of generation Xers (those between 30 and 41) believe it is highly or very important for this close review to remain. The report's authors note that it might be considered surprising that the attitudes of Xers weren't more in line with those of the younger generation rather than those of the baby boomers. The public's desire for drug-safety information and the belief that drugs should remain under continued review by the FDA and drug companies, indicates that Americans may have concerns regarding the full safety profile of all drugs.

IMPORTANCE OF CLOSE FDA REVIEW

IN YOUR OPINION, HOW IMPORTANT IS IT THAT DRUGS REMAIN UNDER CLOSE REVIEW BY THE FDA AND DRUG COMPANIES AFTER THEY HAVE BECOME AVAILABLE TO THE PUBLIC?

	TOTAL	ECHO BOOMERS (18-29)	GEN X (30-41)	BABY BOOMERS (42-60)	MATURES (61+)
Important (Net)	**71%**	**64%**	**73%**	**74%**	**71%**
Highly important	39%	38%	41%	41%	34%
Very Important	32%	26%	32%	33%	37%
Important	20%	23%	19%	19%	21%
Not important (Net)	**9%**	**13%**	**7%**	**7%**	**9%**
Somewhat important	7%	11%	7%	5%	7%
Not very important	1%	1%	1%	1%	2%

Note: Percentages may not add up to 100% due to rounding.
Source: Harris Interactive Inc., Rochester, N.Y. For more information, visit harrisinteractive.com.

SEEKING DRUG SAFETY INFORMATION

HOW OFTEN DO YOU SEEK OUT INFORMATION ON DRUG SAFETY FOR YOURSELF, A FAMILY MEMBER, OR SOMEONE YOU PROVIDE CARE FOR?

	TOTAL	ECHO BOOMERS (18-29)	GEN X (30-41)	BABY BOOMERS (42-60)	MATURES (61+)
Frequently (Net)	**41%**	**28%**	**39%**	**46%**	**48%**
Always	17%	12%	15%	22%	18%
Often	24%	17%	25%	24%	30%
Sometimes	35%	38%	34%	35%	36%
Infrequently (Net)	**24%**	**34%**	**27%**	**19%**	**16%**
Rarely	19%	27%	22%	16%	13%
Never	4%	7%	4%	3%	3%

Note: Percentages may not add up to 100% due to rounding.
Frequently = Always and often; Infrequently = Rarely and Never
Source: Harris Interactive Inc., Rochester, N.Y. For more information, visit harrisinteractive.com.

Follow up

CONSUMER REPORTS, Yonkers, N.Y., is published by Consumers Union, an expert, independent nonprofit organization. For more information, visit consumerreports.org.

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

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

HARRIS INTERACTIVE, Rochester, N.Y., is a worldwide market research firm. For more information, visit harrisinteractive.com.

THE PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION (PCMA), Washington, D.C., is the national association representing America's pharmacy benefit managers (PBMs). For more information, visit pcmanet.org.

TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, Tufts University, Boston, provides strategic information to help drug developers, regulators, and policymakers improve the quality and efficiency of pharmaceutical development, review, and utilization. For more information, visit csdd.tufts.edu.