ACRP CONFERENCE

Record Attendance

JeanMarie Markham, President of Clinlogix, presents Cindy Maniaci from Sanofi-Aventis with one of two grand prizes sponsored by PharmaVOICE and Clinlogix.

The 2007 ACRP Global Conference and Exposition in Seattle drew more than 2,700 attendees, making this year's event one of the most successful for the organization.

The association is positioned as the primary resource for clinical research professionals in the pharmaceutical, biotechnology, and medical-device industries, as well as those in hospital, academic medical centers, and physician office settings.

PharmaVOICE was one of the many proud sponsors and exhibitors at this year's event. To break the ice with attendees as they walked the aisles, **PharmaVOICE** partnered with Clinlogix, a global clinical research organization, to sponsor a putting contest and raise awareness around the 7th Annual PharmaLinx Golf Outing to be held Monday, Sept. 17, 2007, at the Jericho National Golf Club, New Hope, Pa. This charity golf outing benefits the Lankenau Institute for Medical Research.

The two grand prizes were awarded to Cindy Maniaci from Sanofi-Aventis and Kathleen Brown from Hoffmann-La Roche.

Congratulations to ACRP for a great conference, and we look forward to seeing everybody at the annual conference April 25-29, 2008, in Boston.

CLINICAL-TRIAL TRENDS

What's Hot in 2007

- **Russia is on track** to become the next big clinical-research market.
- Global pharmaceutical R&D spending is projected to top **$100 billion in 2007.**
- **Convenience is the No. 1** concern of patients participating in clinical trials.

SOURCE: THOMSON CENTERWATCH, 2007 ANNUAL SOURCE BOOK, BOSTON.

ONLINE UPDATE

Doctors Continue Shift to the Internet

Physicians are shifting away from reading offline clinical information sources in favor of online alternatives, according to recent analysis by Manhattan Research.

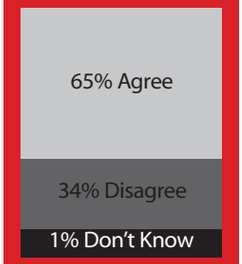
As a general statement, physicians have shifted away from traditional forms of medical education, news, textbooks, journals, and conferences over the past several years. But the movement has been much faster and more pronounced in some areas, namely, the shift toward online professional journals and online conferences.

When comparing 2005 with 2007 information access patterns, the shift to online journals and online conferences outpaced the shifts for other resources by a margin of almost 5 to 1. In other words, the value advantage of online journals and online conferences was greater than the advantage in some areas such as medical education.

Physicians are also getting clinical information from their PDA. The latest research reveals that 50% of U.S. physicians now report using a PDA.

The survey also found that most physicians in the United States think it's a good thing when patients bring health information from the Internet. According to the latest research, 65% of physicians agree that an educated patient is a good thing and they approve of patients bringing information to the appointment.

IT'S A GOOD THING WHEN PATIENTS BRING INFORMATION FROM THE INTERNET



116 million U.S. adults are now using the Internet for health information.

SOURCE: MANHATTAN RESEARCH, NEW YORK

PATIENT ADHERENCE

Lack of Confidence in Drug Safety

A Harris Interactive survey finds that patients' lack of confidence in drug safety and their experiences with adverse reactions lead to nonadherence, which includes not taking prescriptions as directed (noncompliance) and not filling prescriptions over time (lack of persistence).

- **94% of people** who have had an adverse reaction reported they had stopped taking a medication because of an adverse reaction.
- **Almost 50% of patients** report they are concerned about adverse reactions and more than **33%** report having had an adverse reaction to a prescription medication.
- **49% of adults** who have ever taken a prescription medication report they are only fairly confident, somewhat confident, or not at all confident in their knowledge about these medications.
- **46% of adults** currently taking prescription medications report they are only fairly confident, somewhat confident, or not at all confident that their prescribed medications are safe.
- **46% of all adults** report they are extremely concerned or very concerned about adverse reactions (i.e. unexpected and severe reactions) to prescription drugs when taken as directed.
- **35% of all adults** who have ever taken a prescription medication report having had an adverse reaction.
- **35% of people** who have ever taken a prescription medication reported they had decided not to take a prescription because they had a concern about a potential adverse reaction.
- **27% of people** who have ever taken a prescription medication reported they had decided not to fill a prescription because they had a concern about a potential adverse reaction.

SOURCE: HARRIS INTERACTIVE INC., ROCHESTER, N.Y.

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IMAGINE THE POSSIBILITIES

POSTMARKETING STUDIES

Results Mixed on Postmarketing Studies of New Drugs

While drug developers over the past six years have stepped up the number of postmarketing studies they conduct on newly approved medicines, sponsors believe that those studies have contributed little to their understanding of safety, efficacy, or quality, a recently completed assessment by the Tufts Center for the Study of Drug Development shows. PDUFA, which authorizes the FDA to request postmarketing study reports, is due for renewal in Congress later this year.

SOURCE: TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, BOSTON.

TUFTS CSDD POSTMARKETING STATS

- **68%** of clinical study sponsors and **79%** of nonclinical study sponsors **said results contributed either marginally or not at all** to their understanding of the safety, efficacy, or quality of their product.
- **32%** said clinical studies significantly or very significantly **increased their understanding of their products.**
- More than **50%** of all postmarketing studies for which final study reports were submitted **were finished by their projected completion date.**
- **45% were delayed** because of enrollment problems, technical difficulties, additional FDA requirements, or sponsors expanding the scope of their own studies.
- Clinical studies, on average, **took 10 months longer** to complete and cost nearly nine times as much as nonclinical studies.
- Postmarketing studies are typically **the responsibility of applicable R&D departments**, e.g., clinical development, preclinical, toxicology, laboratory, not marketing departments, as some PDUFA critics claim.
- Between 1998 and 2005 sponsors spent, on average, **$5.3 million** per clinical postmarketing study, compared with **$610,000** per nonclinical study.

ON THE MARKET

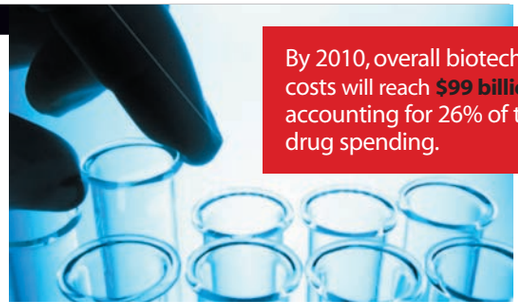
Spending Increases for Biotech Drugs

According to Express Scripts' 2006 Drug Trend Report, spending on high-cost biotech drugs increased 21% in 2006. This increase excludes spending for biotech drugs within the medical benefit, such as those administered in physician offices. The increase reflects the growing demand for biotech medications once prescribed to treat only rare genetic diseases. These drugs, which require special handling as well as close supervision and monitoring of the patient, have recently been proven effective to treat more common conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, and infertility.

Of the six top biotech drug classes, spending increased for five:

- **Cancer therapies had the largest increase in spending at 39.5%;** the increase was driven by new treatments, including three drugs introduced in 2006 (Nexavar, Revlimid, and Sutent).

SOURCE: EXPRESS SCRIPTS INC., ST. LOUIS.



By 2010, overall biotech drug costs will reach **$99 billion**, accounting for 26% of total drug spending.

- **Spending on multiple sclerosis drugs increased 19%** as a result of higher drug prices.
- **Spending on growth hormone deficiency drugs rose 22.8%** because of a 10.7% increase in the number of units per prescription and an increase for uses other than growth deficiency in children.
- **Drugs to treat inflammatory conditions had a 22.7% spending increase** based on additional treatment indications and an overall confidence in this class of drugs.
- **Hepatitis C was the only therapy class in the top six with a decrease in spending.** This class experienced an 8.3% drop as a result of lower cost per prescription and lower use.

REGULATORY INITIATIVES

FDA Looks at Generic Drugs

In May, the FDA issued a report that looked at the unanswered scientific questions that impede the development of generic versions of commonly used drugs.

The report, Critical Path Opportunities for Generic Drugs, is part of FDA's Critical Path Initiative.

While straightforward tests of blood plasma levels are sufficient to demonstrate bioequivalence for most generic drug candidates, these common tests generally are not appropriate for certain drugs, including asthma inhalers, nasal sprays, and topical skin applications such as antifungal creams. As a result, few generic versions are available in these product categories.

The report calls for research on new bioequivalence methods tailor-made for each challenging drug class. These include lung function tests and molecular level imaging for inhalation drugs; particle size distribution tests for nasal sprays; and methods for direct measurement of drug delivered to the skin.

In addition, the report highlights possible research projects that might lead to new modeling and simulation tools for drug absorption, drug release, and other drug-development issues and to alternative methods for seeking waivers from clinical bioequivalence studies.

SOURCE: FDA, ROCKVILLE, MD.