



Survey Reveals
**PHYSICIANS NOT
PLEASED** with
PhRMA Guidelines

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Meetings and events are effective ways for pharma companies to convey their messages to doctors. But, according to a Verispan study — Sales Force Effectiveness 2002: The Physician Perspective — many doctors have had a negative reaction to the guidelines from the Pharmaceutical Research & Manufacturers of America (PhRMA) that are designed to restrict some of these activities.

The study suggests that physicians are less than enthusiastic about the new code. Of those who were familiar with the new guidelines, only about 26% voiced support, while more than 40% indicated some level of opposition.

Many respondents were particularly displeased that spouses and family members would no longer be invited to company-sponsored events under the new guidelines.

The report asked respondents about the relative effectiveness of specific tactics that are used by pharmaceutical sales reps. More than 66% of physicians surveyed by Verispan said they found meetings and events to be more effective than traditional detailing. From a list of tactics, doctors also judged meetings and events to have the most impact on their prescribing behavior.

Meetings and events were broadly defined to include everything from company-sponsored symposia to informal luncheon meetings.

Breast-Cancer
**TREATMENTS AND
OUTCOMES DIFFER
WIDELY** Among
Different Races

Important disparities in breast-cancer diagnosis, treatment, and survival among American women of various racial and ethnic backgrounds have been documented in a study by researchers at the Fred Hutchinson Cancer Research Center. The findings are based on the largest, most comprehensive study of its kind to evaluate the relationship between race/ethnicity and breast-cancer stage, treatment, and survival. The study, Differences in Breast Cancer Stage, Treatment, and Survival by Race and Ethnicity, evaluated data from about 125,000 women representing major racial/ethnic populations and sub-populations in the United States.

“One of the most disturbing trends identified by our research is that we have known since the 1970s that certain racial/ethnic groups have poorer breast-cancer outcomes,” says Christopher Li, M.D., Ph.D., one of the report’s researchers.



Dr. Christopher Li

The results of our study and other recent reports strongly suggest that socioeconomic factors are a much larger contributor to poor breast-cancer outcomes among certain racial/ethnic groups than are biologic or genetic factors. Thus, these findings present a challenge to society because these discrepancies in outcomes are preventable.

Among Asian/Pacific Islanders and Hispanic whites, significant differences were uncovered in the stage of the cancer at diagnosis, treatment, and outcome among women in various racial/ethnic sub-categories, including Japanese, Filipino, Indian/Pakistani, Mexican, and Puerto Rican. Japanese women fared best overall and were 30% less likely to be diagnosed with late-stage breast cancer while women of Filipino, Hawaiian, Indian-Pakistani, Mexican, South and Central American, and Puerto Rican descent were 20% to 260% more likely to be diagnosed with late-stage breast cancer when compared with non-Hispanic white women.

Treatment differences included Mexican and Puerto Rican women being found more likely than non-Hispanic whites to receive inappropriate treatment for breast cancer, and Japanese, Filipino, Chinese, Korean, and Vietnamese women being found more likely to receive appropriate care. Japanese and Chinese women had better survival rates after breast cancer, while Hawaiian and Mexican women had 30% poorer survival rates when compared with non-Hispanic whites.

Data for the study were obtained from 11 population-based tumor registries from racially and ethnically diverse communities throughout the United States, all of which are part of Surveillance, Epidemiology and End Results, a national cancer registry operated by the National Cancer Institute.

DIFFERENCES IN BREAST CANCER STAGE, TREATMENT, AND SURVIVAL BY RACE AND ETHNICITY

BLACKS, NATIVE AMERICANS, AND HISPANICS were more likely to be diagnosed with tumors that were more advanced than were non-Hispanic whites and Asians/Pacific Islanders. Specifically, blacks, Hispanics, and Native Americans faced a **1.7 TO 2.5-fold** higher risk of being diagnosed with later-stage tumors and Puerto Rican women fared the worst, with a **3.6-fold** increased risk of being diagnosed with late-stage breast cancer.

PUERTO RICAN WOMEN were **50%** more likely to receive substandard, inappropriate treatment for breast cancer. Black women were **40%** more likely to undergo initial treatment for breast cancer that was below national standards as compared with non-Hispanic whites.

BLACKS, NATIVE AMERICANS, AND HISPANICS faced a **10% to 70%** greater risk of dying after a breast-cancer diagnosis as compared with non-Hispanic whites.

Source: Fred Hutchinson Cancer Research Center, Seattle

NEW CATEGORIES of
Antiretroviral Drugs
Expected for HIV/AIDS

While antiretroviral drugs in existing categories continue to be the mainstay of the HIV/AIDS therapies market in the United States, the development of new drugs in both existing and novel categories offers growth prospects, according to a recent report by Frost & Sullivan.

“Existing categories — nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, and protease inhibitors — as well as novel categories such as entry inhibitors, immune-based therapies, zinc finger inhibitors, and integrated inhibitors have several drugs in the pipeline that can address the urgent requirement for new antiretroviral drugs,” says Raghunath Tantry, research analyst at Frost & Sullivan.

Revenue in this industry totaled \$3.03 billion in 2002 and is projected to reach \$10.88 billion by 2009.

Antiretroviral drugs are usually recommended in combinations, which can increase the problem of patient noncompliance with treatment. Such com-

Raghunath Tantry



Experts from the healthcare provider segments are hoping that in the future, fixed-dose combinations of antiretrovirals will be available. This seems possible only if the manufacturers collaborate and synergize their core competencies in all three categories.

binations require the patient to take many different tablets several times a day, creating a cumbersome situation

and increasing the possibility that patients may forget to take some of the tablets.

To combat this challenge, many manufacturers are researching the feasibility of reducing the number of tablets per day for various antiretroviral drugs by enhancing tablet strength. Significantly, the Food and Drug Administration has given its approval for some important drugs to be taken in smaller numbers and at longer intervals. Rational fixed-dose combinations of the most recommended drugs belonging to one antiretroviral category are another way of addressing this problem. One example is GlaxoSmithKline's merging of its NRTIs, Efavir and Retrovir, into a well-accepted fixed-dose combination Combivir.

Pharmacy SATISFACTION LOWER Among African- Americans, Asians, and Hispanics

Wilson Health Information, a pharmacy satisfaction research firm, has released study results that show that multicultural pharmacy customers were less likely to receive prescription medications for many conditions and were less satisfied with treatment for conditions such as hypertension, hypercholesterolemia, depression, ulcer/GERD, osteoporosis, and menopausal symptoms.

Treatment incidence for diabetes was higher among Hispanic households (27%) compared with Caucasians (21%), primarily driven by a 32% higher incidence of type II diabetes. African-American households also reported a high incidence of diabetes (26%) with higher levels of both type II and type I diabetes. Asian households reported lower levels of treatment incidence and treatment satisfaction.

Asian, Hispanic, and African-American pharmacy customers were more likely than Caucasians to use chain and clinic pharmacies and less likely to use

independents, food store, and mail-order pharmacies to fill prescriptions.

Asian pharmacy customers were more likely to have a HMO insurance plan and African-Americans a government provided plan such as Medicaid or Medicare. Multicultural pharmacy customers as a group were considerably less likely to have pharmacy benefit coverage compared with Caucasian households.

"Multicultural markets need to be targeted differently to understand and manage customer expectations, particularly with disease treatment and medications," says Jim Wilson, R.Ph., MBA, president of Wilson Health Information. "For example, Asian customers were less likely to receive and be satisfied with written materials, yet they were more likely to have access to a computer to retrieve health information."

Hispanic customers were most likely to speak to their pharmacist but were less satisfied with written materials and counseling; African-American customers were least likely to be offered the opportunity to speak with their pharmacist, but spoke with their pharmacist the longest.

Toxicity Market Presents Opportunity for **IMPROVED PRECLINICAL TESTING**

Nearly \$2 billion of R&D costs are spent on adsorption, distribution, metabolism, elimination, and toxicity (ADME/Tox) failures annually, according to Drug & Market Development estimates. About one-third of all drugs fail preclinical or clinical testing because of apparent or suspected drug toxicities. In addition, during the past few years, several approved drugs have been withdrawn because of serious side-effects, resulting not only in huge financial losses for the companies, but also in diminished public trust in the FDAs and the industry's ability to bring effective and safe drugs to the market.

Preclinical toxicity is one of the major bottlenecks in drug development, according to Drug & Market Development's recent report, *Managing Toxicology for the Future: Improving Predictive Power Through Integrated Technologies*. Current approaches to predicting toxicity in humans

have serious limitations and thus invite substantial risk not only in terms of patient welfare, but also in terms of the cost of late-stage clinical-trial failure. The integration of novel and traditional approaches to preclinical toxicity assessment is expected to have a major impact on the ability to predict compound behavior in humans, reduce clinical-trial failure, and cut both risk and cost in drug development.

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JIM WILSON

The report's authors stress the requirement for an integrated and multidisciplinary approach to toxicology, although they acknowledge that no single technology will provide a complete ADME/Tox solution.

Improved **KNOWLEDGE MANAGEMENT NEEDED** for Biopharmaceutical Industry

Biopharmaceutical companies are missing a significant opportunity to improve research performance through better knowledge management, say the authors of a recently released white paper, *Knowledge Management in Pharmaceutical R&D*.

3rd Millennium Inc., which issued the white paper, stressed that significant changes to how biopharmaceutical research and development is conducted have greatly increased the need for improved knowledge management, but few companies have kept pace.

According to the white paper, cost and time to implement are not major obstacles. Instead, confusion about knowledge management strategies and technologies — partly caused by vendors, lack of experience, and disappointment with previous IT investments — are the main reasons companies have not pursued knowledge management initiatives despite their potential for high returns and relatively low risk.

"Scientific technologies with the potential to transform the drug-discovery process have yet to create appreciable value," says Roland Carel, Ph.D., one of the authors of 3rd Millennium's white paper. "These technologies, along with specialization, functional compartmentalization, geographic separation, and other organizational divisions have made it more important than ever to leverage or integrate knowledge created within and across drug-discovery programs."

Even though knowledge management projects do not necessarily involve technology projects, when properly selected and implemented, information technologies can greatly enhance the knowledge management process. The technologies that support the knowledge management process can be segmented into four categories: data-centric knowledge, people-centric knowledge, program-centric knowledge, and portals.

The primary purposes of knowledge management are to foster communication between increasingly specialized and geographically dispersed research groups, make their results and the conclusions derived from these results broadly available, provide comprehensive and accurate reports of program advancement, and support decision-making processes.

Combination and Biologic Therapies Will DRIVE GROWTH OF THE ASTHMA MARKET

Researchers at Decision Resources Inc. expect combination therapies and the introduction of biologic therapies to drive total sales for asthma drugs in the major pharmaceutical markets of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Total sales for asthma drugs are expected to reach \$11.4 billion in 2011.

GlaxoSmithKline's combination inhaler, Advair/Seretide, is projected to capture a significant share of the asthma market because it is convenient and simplifies treatment regimens.

"Clinical studies have shown that the use of long-acting beta₂ agonists in combination with low to medium doses of inhaled corticosteroids are more effective and safer than the use of high doses of inhaled corticosteroids as a monotherapy," says Carole Gleeson, analyst at Decision Resources.

The group's study also finds that significant market opportunity exists for safe and effective therapies for severe, refractory asthma, such as Genentech's Xolair (omalizumab).

"A significant drawback to omalizumab is the requirement for subcutaneous injections, a factor that might limit its acceptance by both patients and physicians," Ms. Gleeson says. "Although this monoclonal antibody appears to be relatively free of side effects in clinical trials, long-term side effects have yet to be determined."

Local OPINION LEADERS UNDERUSED

Regional and national thought leaders are involved in 79% of key pharmaceutical marketing activities, according to a study by Cutting Edge Information. Compared with regional and national opinion leaders, local thought leaders participate in 32% fewer marketing activities. The study finds that companies can increase the value of these relationships by involving local thought leaders in more strategic marketing activities.

"Local thought leaders have just as much influence, if not more, within their spheres of influence than some nationally recognized physicians," says Jason Richardson, Cutting Edge Information's president. "Those companies that know how to increase local thought leaders' involvement benefit from greater awareness and market preparation."

Pharmaceutical companies that use medical science liaisons to involve local thought leaders were found to realize many advantages to the strategy. These advantages include lower costs associated

with identifying and selecting local thought leaders compared with national thought leader candidates.

According to Cutting Edge Information research, local thought leaders are the future generation of regional and national opinion leaders. Pharmaceutical companies should start building relationships with them early.

LOCAL THOUGHT LEADERS PARTICIPATE IN 32% FEWER MARKETING ACTIVITIES.

Antibiotics Market to FACE CHANGES and Experience Growth

The antibiotics market is expected to grow from \$27 billion in 2001 to \$32 billion in 2010, according to an analysis published by Datamonitor. This growth, however, will require substantial changes in

the nature of products developed and the way in which they are used.

One of the changes expected is that sales of the fluoroquinolone class of antibiotics will overtake those of the cephalosporin class. The growth of the fluoroquinolone class has attracted numerous companies that will exploit the class' revenue potential,

with one-third of the 21 new antibiotics due to reach the market by 2010 being fluoroquinolones.

Beyond 2010, Datamonitor research shows that it will be increasingly difficult for developers to ensure that antibiotics from leading classes generate sufficient revenue to be considered a worthwhile investment. In addition, researchers predict that efforts to reduce the risk of antibiotic resistance will be damaging to manufacturers. There are likely to be attempts to reduce their use in otitis media and community-acquired respiratory tract infections, which account for significant volumes of sales.

Follow up

3RD MILLENNIUM INC., Cambridge, Mass., is a life-science informatics consultancy that works with biopharmaceutical, government, and academic clients on a project basis to plan, develop, and integrate software systems critical to their research and discovery programs. For more information, visit 3rdmill.com.

CUTTING EDGE INFORMATION, Durham, N.C., is a business intelligence firm providing primary and secondary research reports. For more information, visit cuttingedgeinfo.com.

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DRUG & MARKET DEVELOPMENT

PUBLICATIONS, Westborough, Mass., is a research and market analysis company for pharmaceutical and biotechnology professionals. The company is part of the Informa Life Sciences Group. For more information, visit drugandmarket.com.

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VERISPAN, Newtown, Pa., a healthcare informatics joint venture of Quintiles Transnational Corp. and McKesson Corp., is a leading provider of patient-level, longitudinal data, with de-identified data from about 1.7 billion U.S. pharmacy transactions and 275 million electronic medical transactions annually. For more information, visit verispan.com.

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