DOCTORS PREFER DETAILS by Specialty Reps

In the past three years, specialty sales representatives have become an increasingly important promotional investment for pharmaceutical companies, according to Verispan's latest strategic study, Specialty Reps 2003: An Evolving Force. The study, which surveyed more than 4,600 office-based and hospital-based doctors across 22 specialties, found that 93% of physicians reported seeing specialty reps on a regular basis and 90% said they prefer to be detailed by a specialty sales rep rather than a general rep. More than one-third of doctors surveyed said between 81% and 100% of the reps they see are specialty reps. In addition, SpecialtyReps 2003 offers in-depth profiles of nine specialty groups: cardiologists, gastroenterologists, neurologists/neurosurgeons, obstetricians/gynecologists, oncologists, ophthalmologists, pediatricians, psychiatrists, and urologists.

Physicians also indicated that specialty reps, compared with their general rep counterparts, have more knowledge of specific therapeutic areas, are better prepared to answer complex questions, and are more focused on a smaller base of products. Overall, doctors rated current product knowledge, responsiveness to inquiries, and therapeutic area expertise as the most important attributes of a specialty rep.

"In 2000, doctors indicated that specialty reps spent the most time dropping off samples; but, in 2003, physicians reported that specialty reps spent most of their time detailing products," says Albert Kilpatrick, a senior marketing research analyst and study contributor at Verispan. "Subsequently, the level of importance placed by doctors on the provision of samples declined in 2003 as well."

Excluding traditional detail calls, physicians in both 2000 and 2003 spent more time setting up meetings and events with specialty reps than on any other topic.

The first study, which was published in 2000, asked physicians to rate various types of events in terms of promoting interest in a specialty rep's products. Since the original version of this study, educational seminars have been the No. 1 type of event in terms of effectiveness. Pharmaceutical company-sponsored medical conferences/symposia increased from the third-most to the second-most effective. Entertainment and conference calls with reps remained the least effective types of events.

PRIMARY DIFFERENCES BETWEEN SPECIALTY REPS AND GENERAL REPS

Physicians were asked to report on the primary differences between specialty reps and general reps. According to the 4,675 physicians surveyed, "more knowledge of therapeutic areas" was the main difference that set specialty reps apart from their general rep counterparts.

PRIMARY DIFFERENCES BETWEEN SPECIALTY REPS AND GENERAL REPS

More knowledge of therapeutic areas	90%
Better prepared to answer questions	77%
Focused on a smaller base of products	66%
More knowledge of products	58%
Provide more pertinent patient info	51%
More knowledge of competition	45%
Caters better to physician needs	38%
More service-oriented than sales	25%
Other	1%

Source: Verispan, Yardley, Pa. For more information, visit verispan.com.

ATTRIBUTES OF SPECIALTY REPS

Verispan asked 4,675 physicians to rate the importance of several key attributes pertaining to specialty reps. Each attribute was rated on a scale from 1 (not at all important) to 5 (extremely important). The graph below depicts the mean breakdown of responses.

IMPORTANCE OF SPECIALTY REP ATTRIBUTES

	2003	2000
Current product knowledge	4.60	4.47
Responsiveness	4.42	4.30
Therapeutic area expertise	4.37	4.25
Provision of samples	3.87	4.06
Clinical data presentation	4.12	4.05
Competitor product knowledge	3.76	3.78
Provision of materials	3.94	3.77
Pipeline product knowledge	3.72	3.74
Autonomy in sales calls	3.18	3.22
Pricing policy explanation	3.15	3.20
Extensive sales experience	2.89	3.12
Selling skills	2.65	2.87
Web-based detailing info	2.45	2.29

Source: Verispan, Yardley, Pa. For more information, visit verispan.com.

FDA's Fast-Track Initiative CUTS TOTAL DRUG DEVELOPMENT TIME

The U.S. Food and Drug Administration's (FDA) fast-track program to speed new drugs to market has shaved almost three years off the time usually required to develop a new drug and win approval, according to an analysis by the Tufts Center for the Study of Drug Development.

The study found that clinical development time for fast-track drugs approved between 1998 and 2003 was, on average, 2 to 2.5 years shorter than for nonfast-track drugs.

"The fast-track program has had a significant public health impact by speeding access to new drugs, particularly those that treat AIDS, breast cancer, leukemia, and other diseases that afflict millions of patients and result in the loss of tens of thousands of lives every year in the United States," says Christopher-Paul Milne, Tufts Center associate director.

The Tufts Center examined the implementation of the fast-track program since it took effect in late 1997. The fast-track program aims to expedite development and approval of drugs that address unmet medical needs for serious or life-threatening conditions.

In addition to generating more designations and approvals, the fast-track program is being used for development programs focusing on a growing number of disease indications.

According to Mr. Milne, fast-track designations for products aimed at treating diseases other than cancer and HIV/AIDS grew from more than 30 in 2001 to more than 50 in 2003.

The Tufts Center analysis also revealed that although average approval time for fast-track biologi-

cals was shorter than that for priority or standard biologicals, longer average clinical development time resulted in a slightly longer total development time for fast-track biologicals.

Almost 10% of fast-track designations in 2003 were for diabetes and obesity, reflecting the FDA's recent emphasis on conditions that contribute significantly to healthcare costs and that would benefit from innovative treatments.

As more AIDS and AIDS-related medicines became available during the late 1990s, the share of AIDS fast-track designations fell by more than half between 2001 and 2003.

Off-Label Promotion **PROSECUTIONS LEADING THREAT TO DRUG COMPANIES**

According to Rx Compliance Report's Off-Label Promotion issue, the federal government is expanding its fraud investigations of pharmaceutical companies' off-label promotion.

In the past two years, drug companies have paid an unprecedented $2.27 billion in criminal and civil penalties. Former U.S. Justice Department trial attorney Reed Stephens and OIG officials recently warned that this is just the beginning. Rx Compliance Report offers practical first-hand advice from industry executives, government officials and outside experts on how to respond to this menacing trend through effective compliance programs, salesforce training, monitoring, and auditing.

"Off-label promotion is an area that will get increasing scrutiny from prosecutors around the country," says Michael Loucks, chief of the healthcare fraud unit, assistant U.S. attorney, in Boston.

According to the Rx Compliance report, while traditional FDA concerns in this area continue to loom large, the scope of investigations is expanding considerably with the concern shifting toward the promotion and marketing of pharmaceutical products. The Rx Compliance Report focuses on the non-FDA entities now leading these fraud and abuse investigations. These include the U.S. Department of Justice, HHS Office of Inspector General, state Attorneys General, state Medicaid Fraud Control Units, and the Federal Trade Commission.

DEPARTMENT OF JUSTICE INVESTIGATIONS AND THE PHARMACEUTICAL INDUSTRY

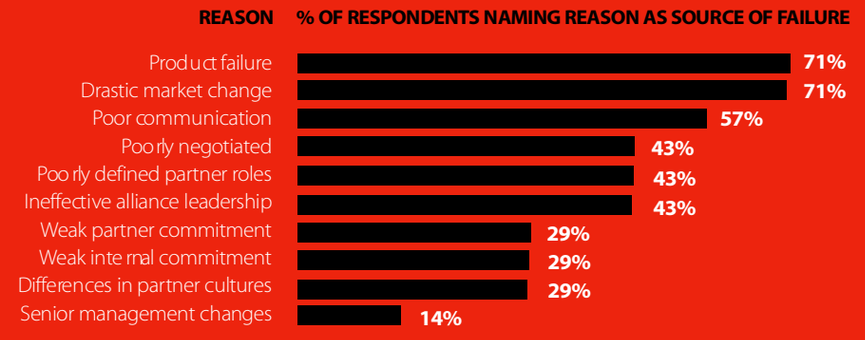
PHARMACEUTICAL INDUSTRY CASES

Company	Fines	Criminal Fines
TAP	$885 million	$290 million
Abbott	$600 million	$200 million
AstraZeneca	$355 million	$63.9 million
Bayer	$257 million	$6 million
GlaxoSmithKline	$87.6 million	—
Pfizer	$49 million	—
Dey Laboratories	$18.5 million	—
Bayer	$14 million	—
Total since 2000:	$2.27 billion	$593.9 million

Source: Michael Loucks, Chief healthcare fraud unit, assistant U.S. attorney, District of Massachusetts, Boston. For more information, visit usdoj.gov/usao/ma.

REASONS FOR ALLIANCE DEAL FAILURES

Though product failures and drastic market changes are the most common reasons for alliance failure, poor partner communication, an easily manageable problem, still ranks among the highest.



Source: Cutting Edge Information, Durham, N.C. For more information, visit cuttingedgeinfo.com.

Investments in Alliances Rising, **POSTALLIANCE MANAGEMENT DIFFICULT**

According to a study from Cutting Edge Information, alliance management may account for 20% of the business development and licensing budget at the most sophisticated companies. Pharma's investment in alliance management is resulting in more than 25% of top companies drawing revenue from drugs discovered in other companies' labs. To support those efforts, the biggest alliance management teams work with annual budgets of $5 million. Midsize teams draw on budgets of $2 million or $3 million.

The study, Pharmaceutical Alliances, Licensing and Deal-Making, has found, however, that postalliance management is the most difficult aspect of the alliance process to master. Often, easily manageable situations transform into deal-killers or end up causing the alliance to fail. For example, poor partner communication accounts for 57% of in-licensing failures and 43% of out-licensing failures, according to survey data.

Follow up

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

RX COMPLIANCE REPORT, Costa Mesa, Calif., published by Biomedical Market Newsletter Inc., is the only news source devoted exclusively to the government's crackdown on pharmaceutical sales and marketing. For more information, visit biomedical-market-news.com.

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

VERISPAN, Yardley, Pa., is a healthcare informatics joint venture of Quintiles Transnational Corp. and McKesson Corp., which provides a broad array of information products and services to the healthcare industry. For more information, visit verispan.com.