BY ELISABETH PENA

PUBLICATION PLANNING

The SCIENCE Behind It All

Scientific publications are the foundation on which a drug's identity is created, **SERVING A VITAL ROLE** for all **MARKETING AND COMMUNICATIONS EFFORTS** behind the brand.

The publication plan for a pharmaceutical product is one of the most important elements of a communications strategy. Publishing clinical-trial results not only provides a valuable source of information for the scientific community, but also a powerful tool for marketers to build awareness for their products.

"Publication planning is integral and essential to the entire marketing plan," says Norma-Jeanne Hennis, president of MedPharm Communications. "Even though doctors have limited available time, they'll still read the abstracts and conclusions or pick up a journal that a colleague recommends. Publications create noise, interest, and discussion. They also create quotes and references for visual aids. Publication planning is the seed from which everything else grows."

Marketing depends on science to back up claims about a product, and the best, most trusted, and most accessible sources for that scientific information are the scientific articles published and referenced in medical journals.

"Nothing in our industry is done without good science; we have a saying here — 'it is real when it can be read,' " says Richard F. Lamb, director of scientific publications, U.S. medical research, at Aventis. "No matter how much money a company puts into education or promotion, everything is based on how good the science is. The science comes from the studies and then how well the publications reflect those studies."

Neil Matheson, CEO of AXIS Healthcare Communications LLC, agrees that a strategically driven publication program creates the scientific foundation for all communications programs.

"Product positioning is supported by published data from the peer-reviewed literature,"

NEIL MATHESON

PUBLICATION OF DATA IS THE MOST IMPORTANT PART OF A MEDICAL-COMMUNICATIONS PROGRAM. Without a strong publication effort, a company has lost the major scientific foundation for its product.

GISELA PAULSEN

The publication plan is one of the most integral parts of a marketing strategy. **ONCE THERE IS A STRONG CLINICAL PLAN,IT'S TURNED INTO PEER-REVIEWED PAPERS,WHICH BECOME THE FOUNDATION FOR MEDICAL EDUCATION, ADVERTISING, AND ALL OTHER MARKETING EFFORTS.**

DR.DESTRY SULKES

THE KEY TO PUBLICATION PLANNING is to understand the levers in the market.

he says. "Without a citation, it is very difficult to reference data sources in presentations, advertising, detail materials, and educational programs. At the end of the day its all about 'show me the data.'"

With publications as the hub of the marketing wheel, those who work to publish clinical-trial results are at the center of all communications for the product. Although the publication of clinical-trial results is the foundation for all of a brand's promotional efforts, the two are separated to ensure the integrity of the science.

"We meet with a lot of departments, but we are part of the medical-affairs department; we work with our own medical directors and we have our own unit to manage the process to get the data published quickly," Mr. Lamb says. "We report to the business units about where the science is going and what the studies are. Also, our business units will raise issues so our medical directors can assess whether there are some studies that can be designed to answer those questions. We also pay attention to what the issues are so we can make sure our science is addressing the questions that are being raised."

"We think of publication planning as a scientific enterprise," says James Gurr, Ph.D., associate director of clinical publications at Wyeth Research. "We take marketing into consideration because we have to sell the product. We take into consideration how our publications will support our products, but we don't have any relationship with advertising in the publication-planning process."

Putting a Plan Into Action

Experts find that a solid, well-organized publication plan contributes strongly to a product's success in the marketplace.

"A lot of companies don't get organized early enough and therefore don't optimize the time they have available to publish the review articles that prepare the marketplace for release of the primary data that support the positioning of their new product," Mr. Matheson says. "The most successful products of the past 10 years to 15 years have all been launched on the back of a very well-implemented publication strategy."

The average time to get clinical-trial findings written and published is about nine months. Therefore, the publication-planning process has to begin at least three years to four years prelaunch to ensure that publications are timed appropriately to support both educational and data-dissemination objectives, Mr. Matheson says.

Ms. Hennis believes publication planning should begin about two years before launch, during Phase I/II trials, although an earlier start should be considered in certain instances, especially if the product is a new chemical entity.

"When a company has a product with a new chemical pathway or mechanism of action, it really has to educate the doctors and the allied health professionals," she says. "And

TIM BACON

However creative an agency or medical education group is, everything ultimately comes down to the data to support the claims **AND THOSE DATA SHOULD BE PUBLISHED IN REASONABLE OR GOOD QUALITY JOURNALS.**

NORMA-JEANNE HENNIS

Despite what the promotion side says, an ad in a journal serves only as a reminder. **IT KEEPS THE BRAND NAME IN THE PHYSICIAN'S HEAD, BUT IT DOESN'T PERSUADE. PUBLICATIONS PERSUADE AND THAT IS THE DIFFERENCE.**

DR. JAMES GURR

WE DEVELOPED OUR OWN INTERNAL PUBLICATION POLICY. We want the process by which we develop publications to be transparent to outside scrutiny.

DR. LAURENCE J. HIRSCH

USING QUALITY, PEER-REVIEWED ARTICLES IN PROMOTION IS WHAT WE WOULD CALL EVIDENCE-BASED MARKETING. Publication and use of good publications in promotion are responsible practices.

that should be done well ahead of launching the product."

Mr. Lamb says Aventis' criteria for beginning work on study manuscripts varies by product, although a plan should be in place as soon as clinical studies get underway.

"For disease states where there has been little research, planning should begin as early as two years before the expected launch," he says. "But for disease states that are well documented and fairly common, publications should begin six to eight months ahead of launch."

At Merck, the publication strategy generally begins during late clinical development, around the time the product candidate transitions into Phase III. Laurence J. Hirsch, M.D., executive director of medical communications at Merck Research Laboratories, points out that the timing varies for each product and the expected length of the Phase III trials.

"We believe that if we develop strategies much earlier we will be planning for a number of product candidates that may fail in the clinic or have a higher likelihood of failing," he says. "And if we wait much beyond that it is going to be too late."

Dr. Gurr says publication planning at Wyeth is beginning earlier and earlier.

"We used to start in Phase II, and now are starting toward the end of Phase I," he says. "Publications from our discovery group are becoming more important than in the past because of shorter timelines between product development and launch. Also, we are emphasizing the scientific basis of the clinical work."

Typically, publication planning is performed internally at the earliest stages, taking into account preclinical and early Phase I work, says Destry J. Sulkes, M.D., managing director at Medsn. In these early stages, the goal is to publish studies that present the research data in the right context and in publications that will reach the right physicians. Intensive publication planning involving an outside partner should begin during Phase II when planning activity increases, he says.

"Bringing in an outside resource or a strategic partner generally happens in Phase II or sometimes Phase III, when larger budgets become available and everyone is reasonably sure that the product is moving ahead," Dr. Sulkes says.

Experts agree that there is no magic number of publications that can be set as a benchmark for a product; each product will demand a certain number of publications based on varying factors. Criteria that should be considered when determining the number of publications include: the projected sales of the product, potential prescribers, the breadth of the market, the number of competitive publications, and a product's budget, to name a few.

Tim Bacon, president and CEO of PeerView, says a product should have at least as many publications as it does clinical trials.

According to Pharmaceutical Research and Manufacturers of America estimates, an average of 70 different studies are conducted during human clinical trials per approved drug.

"There is not a cookie-cutter answer to the number of publications a product should have," Mr. Lamb says. "With every product that we are given, we analyze the environment, where the product is in its life cycle, and

how many other similar therapies are available. Those things make a difference in how many papers are published."

Speed and Prestige

Successful publication strategies need elements of both speed and prestige, experts advise. Companies need to target the prestigious and specialty journals specific to their product, as well as strive to get the data out as quickly as possible.

"Planners want to have the high roads and the low roads covered," Dr. Sulkes says. "It's important to get the latest data in as many hands as possible as well as the best data in the best journals."

The prestige that can be attained through publishing in the top-tier journals is very important to a product's first impression. But, this needs to be balanced against the length of time to publication. Prestige doesn't make up for a message that arrives too late. Early publication planning helps to ensure both goals are achieved.

"Both ease to market and market dominance can be accomplished if a client truly has a long-term strategic plan," says Gisela Paulsen, general manager at Health Learning Systems. "For each client, we help facilitate this process by developing a unique educational blueprint to reveal the best communications platform for that brand. The product teams are then able to determine which messages should be published, where, and when."

Where and when to publish information varies by product, but is influenced by factors such as the intended audience, time to launch, important meetings and events, as well as whether the data are being published to reach an intended audience or for use as a reference in future communications activities.

"The three major factors influencing journal selection are the intended audience, the aims and scope of the journal, and the quality of the data being published," Mr. Matheson says. "Everyone would like to see his or her clinical data published in the *New England Journal of Medicine,* but we have to be realistic and recognize that the journal has a high rejection rate and only publishes breakthrough trials that will have a significant impact on the practice of medicine."

Experts agree that findings on breakthrough, first-in-class products are most likely to be published by top-tier medical journals, such as the *New England Journal of Medicine*, *Journal of the American Medical Association*, or *The Lancet*, which have rejection rates of more than 90%.

Companies, therefore, should be realistic and target papers to the most appropriate journal.

"If a company has a 'me-too' product, or a

Key Elements of a Publication Strategy

1. **KNOW THE PRODUCT.**
2. **KNOW THE AUDIENCE.** This includes primary-care physicians, specialists, allied health, managed care, hospital pharmacists, retail pharmacists, formulary managers. Speak to all of their concerns but in separate ways; ways that mean something to each group.
3. **KNOW THE JOURNALS.** Use different journals for different messages, levels of discussion, and speed. Take prestige over speed, if possible. Carefully balance speed, prestige, and likelihood of acceptance. Develop an exact list of how long it takes from submission to acceptance, from acceptance to revision, and from revision to publication. Look at impact factors: circulation, editorial policy, supplements (yes or no), cost of supplements, and level of peer review.
4. **DEVELOP THE MESSAGES.** And define them for market prep or drug-driven strategies.
5. **UNDERSTAND THE DIFFERENCE** between market prep and drug-driven papers. Explain the compound, explain the state of the art for that particular therapeutic area, and discuss the pros and cons of other drugs in that area. Mention all of the drugs in development that hold promise.
6. **KNOW WHAT THE COMPETITION DID,** what they will do, and who they are, now and in the next few years. Benchmarking is critical.
7. **MATCH UP PAPER RELEASE DATES** to coincide with important meetings. Have a presence at those meetings and have reprint carriers made by the ad agency or the medical-education agency to give the reps something solid to talk about. Use the papers as references for promotional visual aids. This is where the rubber meets the road — med ed and promotion. Just be sure CME and promotional don't cross-pollinate. Papers are one thing, CME is a whole other story.
8. **GET THE BEST KOLS** (key opinion leaders), study investigators, and internal pharma M.D.s to write the papers. Develop paper topics/titles that show which messages will be addressed, the rationale for the particular paper, a brief description of the paper, and at least two journal selections for each. Make sure there is a good mix of editorial, primary, secondary, and review papers. If affordable, create a supplement for a major journal.
9. **USE MEDICAL-COMMUNICATIONS COMPANIES** to help when needed.

Source: MedPharm Communications LLC, Randolph, N.J. For more information, visit medpharmcom.com.

drug that is very similar to something on the market, it doesn't make sense to try to attain publication in the *New England Journal of Medicine*, because these types of journals will be hesitant to publish the data," Ms. Hennis says. "If a company has a breakthrough drug with a great deal of potential, and it has the time, only then should it try for it go for the most prestigious journals. But companies have to function in reality. All companies want to have their publications in *The Lancet* or the like. But it can be a waste of time and money to go for those types of journals with every drug. Companies need to know their drug and their market, and go to the publications that will benefit them the most, given all the factors."

In medical publishing there is a direct relationship between speed to publication and the prestige of the journal.

"Typically, there is a time crunch when it comes to publications and decisions about target journals; there is a trade off as to how quickly the data need to be published and the quality of the target journal," Mr. Matheson says.

The Need for Speed

When speed is the top priority for a company, publishing in online journals can be the quickest solution. Although still working to gain credibility among long-standing print journals, the online arena is becoming a popular alternative when speed is important.

Merck has experience publishing in online journals, and Dr. Hirsch says the company has generally been pleased with the process.

"We have found the peer reviewing to be good and to improve the quality of the manuscripts," he says. "The process was certainly faster in terms of getting the paper from submission to acceptance to publication."

He does note, however, that the major trade off when turning to online publications is physician impact. "Online publications are still gaining in popularity and building circulations," Dr. Hirsch says.

Experts say online journals that are nothing more than a Web extension of a print journal will not be successful, since physicians prefer the portability and convenience that print journals offer. The opportunity for online journals lies in enhancing the learning process.

P.R.I.N.T. Approach to Publication Planning

P LAN EARLY
- Comprehensive clinical program
- KOL (key opinion leader) relationships
- Commitment to long-term publication plan

R ESPOND TO CHANGES IN ENVIRONMENT

The only constant is change

I NSTITUTE CONSISTENT PROCEDURES
- SharePoint portal; 24/7 access to information
- Web-based, access-controlled reviews
- Version control
- Unified access to U.S. and global teams
- Compliance and adherence to guidelines

N EVER STOP REASSESSING

T EAM WITH A STRATEGIC PUBLICATION PARTNER
- Strategic vision
- Scientific strength
- Sophisticated technology

Source: Health Learning Systems, Wayne, N.J. For more information, visit commonhealth.com.

"We are missing a big opportunity with online journals to increase current journal learning by not combining the e-technology with traditional journals," Mr. Lamb says. "Together it will expand learning and understanding. There should be links to Websites that provide either more in-depth knowledge or 3-dimension graphics to enhance the learning process. If the power of online could be tied to a paper journal there would be a more meaningful learning process. Physicians are ready but they are not getting what they need."

Currently, experts believe the online arena is better used for providing information relative to a physician's practice, as opposed to full-length publications.

"I wouldn't publish primary research online yet," Mr. Bacon says. "But I would certainly put commentaries and other observations there. Online is currently much more relevant to practice than it is to primary dissemination of research results."

Internal Guidance

Along with most facets of the pharmaceutical industry, internal publishing criteria have been under increased scrutiny, especially following the editorial "Sponsorship, Authorship, and Accountability," which was published simultaneously by the International Committee of Medical Journal Editors (ICMJE) in 13 leading medical journals in September 2001.

The editorial warned that companies were playing too much of a role in analyzing data and writing papers and that the editors of the journals would refuse to publish papers that didn't satisfactorily disclose the role of the author and the sponsor or meet with the guidelines established by the committee.

In response to this editorial, companies began to make public the practices they employ for their publications.

"When we read the editorial from the medical journal editors, we formed a cross-divisional task force and spent a considerable period of time developing Merck's publication guidelines for clinical trials and related works," Dr. Hirsch says. "This was not something new, but we codified our approach and put it into a guideline format. These guidelines have been made public and can be found at merck.com/policies/clinicaltrialspublication."

Wyeth also is developing a publication policy to ensure medically and scientifically sound publications and ethical interactions with authors.

"We want the process by which we develop publications to be transparent to outside scrutiny," Dr. Gurr says. "We don't hide any data. We want the investigator/author to be fully involved in the development of the publication, interpretation of the data, in talks with the journals, as well as in outlining the analyses they would like to see of the data."

Mr. Lamb says Aventis is earnest about its publication processes, and he notes that this seriousness is reflected throughout the pharmaceutical industry.

"When I observe other pharmaceutical companies, I don't see them trying to play games with publications," he says. "Everybody understands how important a publication is in providing better healthcare and how important it is to get the science out quickly to be

debated. People who understand the scientific journal process do not want to undermine it."

A point raised by the ICMJE editorial was the lack of publication of negative results. Mr. Bacon observes that since that editorial, companies have been more forthcoming in this regard.

"The publication policies of many of the major pharma companies state the goal of publishing negative results, which is one of the things that the ICMJE editors and others have been clamoring for," Mr. Bacon says. "More companies are dealing with contentious issues, such as the publication of negative results. They also are involving the author at a very early stage."

Merck's publication guidelines make note of this effort.

"A key point about our guidelines is that, regardless of outcome, Merck commits to publishing the results of its hypothesis-testing clinical trials," Dr. Hirsch says. "Also, if we do an exploratory study and it provides information that is medically important, we will work with the investigators to publish those results as well. The philosophy of the company is to always communicate information about the safety or the efficacy of our marketed products."

The ICMJE editorial also pointed a finger at marketing's role in the publication of clinical-trial data, noting that the "use of clinical trials primarily for marketing ... can be ... a misuse of a powerful tool."

Dr. Hirsch says there is another side to the issue.

"These same critics send reminders to us sponsors to buy reprints," he says. "They have done studies that show that reprints are very effective in communicating trial results and that physicians accept these as credible documents that enter into their prescribing decisions."

Mr. Matheson says the industry is adhering to very high standards in publishing ethics and that there are very strict guidelines relating to the roles of those within the company who sponsored the research, the investigators, the authors, and the medical writer who drafts the manuscript relating to data from a clinical trial.

"We have seen considerable efforts from pharma companies in terms of ensuring that the authors are managing the content of the manuscript from conception to journal submission," he says. "Everyone is working to make sure the authors are the ones who are communicating the data and that any inappropriate industry influence is removed from the publishing process."

Since pharmaceutical companies generally work with an outside company on publications, Ms. Paulsen says it is important that their partners also have high-ethical standards and internal guidelines.

"As a player in the publication-planning industry, we take a very serious approach to compliance adherence," she says. "Just as our clients are implementing guidelines, we take ethics as seriously as they do. To illustrate this, we have designated an overall organizational compliance officer, and each individual operating unit has its own officer."

Dr. Sulkes, however, says the increased scrutiny is creating confusion internally, with companies' legal departments trying to apply tighter controls to make sure everyone is adhering to the highest standards.

"As the legal departments are applying more scrutiny there tends to be a slowdown in the pace of the activity to make sure everyone is dotting all their 'i's and crossing all their 't's," he says. "This tends to drag out the process of getting data released and getting information out in the best way possible."◆

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

TIM BACON. President and CEO, PeerView Inc., Yardley, Pa.; PeerView provides a range of Web-based decision-support, program management, and competitive intelligence products that support publication strategy and other commercialization processes for its pharmaceutical and biotech clients. For more information, visit epeerview.com.

JAMES GURR, PH.D. Associate Director, Clinical Publications, Wyeth Research, Wyeth, Madison, N.J.; Wyeth is a research-based, global pharmaceutical company responsible for the discovery and development of some of today's most innovative medicines. For more information, visit wyeth.com.

NORMA-JEANNE HENNIS. President, MedPharm Communications LLC, Randolph, N.J.; MedPharm is a comprehensive medical-education and communications agency. For more information, visit medpharmcom.com.

LAURENCE J. HIRSCH, M.D. Executive Director, Medical Communications, Merck Research Laboratories, Merck & Co., Whitehouse Station, N.J.; Merck is a global research-driven pharmaceutical products company. For more information, visit merck.com.

RICHARD F. LAMB. Director, Scientific Publications, U.S. Medical Research, Aventis, Bridgewater, N.J.; Aventis is dedicated to treating and preventing disease by discovering and developing innovative prescription drugs and human vaccines. For more information, visit aventis.com.

NEIL MATHESON. CEO, AXIS Healthcare Communications LLC, Yardley, Pa.; AXIS provides healthcare communications services throughout the complete life cycle of a pharmaceutical product. For more information, visit axis-healthcare.com.

GISELA PAULSEN. General Manager, Health Learning Systems, Wayne, N.J.; HLS, a CommonHealth company, creates comprehensive and groundbreaking medical-education solutions that are changing the face of communications within the medical and scientific communities. For more information, visit commonhealth.com.

DESTRY J. SULKES, M.D. Managing Director, Medsn, Jersey City, N.J.; Medsn is a medical-education company that designs and implements balanced media-educational programs for pharmaceutical, medical-device, biotechnology, and healthcare organizations. For more information, visit medsn.com.