

## Reprint

### Medical Science Liaisons: Working between Two Worlds

By Mark Schmukler

Since their inception in 1967, Medical Science Liaisons (MSLs) have assumed a pivotal role interfacing between pharmaceutical and biotechnology companies and the opinion and thought leaders (OTLs) who influence how medicine is routinely practiced. Today's MSL navigates between the unbiased, evidence-driven world of hands-on patient care and the business imperatives of pharmaceutical and biotechnology companies.

These professionals—most with advanced medical, pharmacy or science degrees—offer the OTL the credibility and objectivity of a peer, but also provide an insider's knowledge of their companies and products. Their ability to coordinate the flow of clinical information and manage important relationships can be critical to a product's success at any stage of its life cycle. At the same time, the current regulatory climate puts MSL's and their activities under greater scrutiny than ever before.

A recent Pharmaceutical Education Associates' seminar, *Best Practices*

*for Medical Science Liaisons* (Princeton, New Jersey, January 2004), highlighted how MSLs can maximize their unique position to help improve medical care while they enhance their companies' bottom lines.

#### It's All about Perception and Intent

A post to the *Medical Science Liaison Quarterly* newsletter ([www.mslquarterly.com](http://www.mslquarterly.com)) online forum spoke about the FDA's opinion of MSL "call quotas."

"During an audit of some of my company's sales and marketing materials, the FDA inspector reamed the group director and the marketing/sales people up one side and down the other," said the poster, "and told them in no uncertain terms that call quotas or anything of the kind were not only seen as sales-type activities, but were also worthy of a cease and desist letter."

"The FDA said that all MSL activity was to be unsolicited, spontaneous and in valid response to a clinically relevant scientific, medical or clinical question and therefore imposing call quotas were a violation because they looked like the company was soliciting off-label questions that by definition were to be unsolicited and therefore unanticipated and could not be reliably predicted or acted upon otherwise. That is the language from their report to management, and they dropped the call quota for fear the FDA would put them under a consent decree."

"It's all about perception and intent," said another poster. "If the MSL program is but one facet of a concerted off-label selling effort, then no matter how you separate it—even if you take the MSL program and put it under R&D—it is still illegal."

#### Diverse Responsibilities

According to Kyle Kennedy, Senior Vice President of MSL Programs at SOS, many companies give MSLs titles that emphasize their research and educational function, such as AstraZeneca's "Medical Information Scientist" and Aventis' "Professional Education Specialist". Traditional MSL responsibilities span field-based research and educational activities, but their emphasis is fluid, generally shifting from research to education along a product's life cycle's time line. Prior to product launch, MSLs increase awareness and expand use through clinical research activities. Post-launch, MSLs help drive approved label use through education. Kennedy notes that while there is no "typical" MSL, the "true" MSL is likely to be an outstanding multitasker.

That multitasking requires a broad set of skills. Walter Tatarowicz, Ph.D., of EMD Pharmaceuticals, describes the "ultimate new-hire MSL" as

*Continues on next page...*

someone who:

- Has previous MSL experience.
- Is well-published and well-respected in their field.
- Is able to handle 75% overnight travel.
- Has excellent communications and interpersonal skills.
- Is a really nice person.

He also points out that a hire's skills alone are not enough. The company should provide a structured training and mentoring program and continuing education, and management should add reasonable expectations and timely feedback.

EMD's Mary Ann Watson, Pharm. D. goes on to explain that the MSL's role is not easily defined. Depending on the company, the MSL may report to Sales or Medical Affairs and perform a function that is primarily educational, clinical/research-oriented, or a hybrid of the two. Corporate expectations of the MSL differ with respect to working with sales representatives, with the most effective relationships benefiting both the rep and the MSL (however, see "It's All about Perception and Intent", box on Pg. 6).

### Lessons Learned

Navigating corporate culture can be a major challenge for MSLs says Jane Chin, Ph.D., former senior MSL at Aventis and now publisher of a forthcoming MSL newsletter and field guide. Cultivating strong relationships on the inside can be just as important as developing them in the field. Chin applies marketing wisdom, encouraging MSLs to create and manage their own "brand"—the image their colleagues have of them—and to speak the company's language or business jargon. At the same time, she warns against losing sight of the need to maintain a fair balance. "Your responsibility as a scientific professional," says Chin, "is critical discernment of scientific information and accurate presentation of information to clients."

When that balance is lost, the results can be devastating. Chin cites the case of one company where a whistleblower exposed a pattern of misrepresentation among MSLs: of data, of their credentials, and of their roles. She counters that sad tale with simple, practical advice:

- Know the regulatory rules and don't break them.
- Don't promise what you can't deliver.
- Exercise integrity.
- Communicate with internal customers, too.
- Keep all customers informed.
- Handle change in personal and professional life.
- Focus on science AND business.

### Field Trials

One key activity of MSLs is coordinating investigator-initiated trials (IITs). EMD's Director of Medical Information and Science Liaisons and Global Head of Field Medical Affairs, W. David Dawson, sees the uniform goals of any IIT program as:

- Adding to the base of knowledge for a product.
- Generating abstracts and publications to be shared with the medical community at congresses or meetings.
- Increasing familiarity of key physicians with the use of a product in specific disease states.
- Producing advocates for the use of a product in specific disease states.

Beyond those goals there are important differences. For example, before product registration, the reporting of adverse events must go into the integrated safety report. This might raise questions from the FDA or jeopardize time lines. Post-launch, additional goals are to expand the potential patient population and possibly explore higher-risk patient populations.

The ITT process itself, which derives from the Clinical Development Plan, should be timed carefully. For pre-launch trials results and publications should come forward within 6 months of the anticipated launch. Dawson breaks the process into specific stages with clearly defined flows and projects a timeline of 12 to 16 weeks from the time an investigator indicates interest in an ITT to the beginning of patient enrollment.

### The Key to Opinion Leaders

To Kennedy, a key opinion leader (KOL) is one who drives a therapeutic area, has conducted significant research, is regarded by peers as an expert and is actively treating or advising on the treatment of patients. KOLs can be identified through a wide variety of sources from within the company and in the healthcare community as a whole. Once KOLs are identified, the MSL must build relationships to develop advocacy. Kennedy recommends:

- Building relationships with top-tier national KOLs, regional KOLs and local high-volume prescriber KOLs
- Engaging in scientific dialogue with KOLs influential to the business and lacking in awareness of key scientific data
- Conveying complete medical/scientific knowledge to KOLs
- Identifying KOLs' unmet needs that can be fulfilled by the MSL.

*Continues on next page...* 

Kennedy emphasizes that relationships are at the heart of any KOL advocacy initiative. The “successful MSL pyramid” is built on a base of technical expertise, KOL relationships, field-based relationships and internal corporate relationships. From these, influential activities flow, such as managed markets support, scientific convention support, training and research facilitation.

### Day-to-day Matters

MSLs have no “set” weekly schedule, points out Tatarowicz. The nature of the job and the life cycle stage of the product vary, and MSLs should be realistic about what they can accomplish in a week. He underscores the need to be realistic about how long travel takes, which is often longer than we think, and plan accordingly.

In any given week a wide range of activities may occur, including appointments with KOLs, presentations, sales meetings, Medical Affairs meetings, conventions, symposia and training meetings. In addition, MSLs need office time to prepare for meetings and presentations, respond to email, fill out expense reports, pay bills and file. Tatarowicz calls office days “your good friend” and prescribes them for those tasks, plus catching up on reading, returning phone calls and conferencing with management.

Mary Ann Watson, Pharm. D., an EMD MSL, advises care in maintaining a balance between work and

family. The MSL’s family has to understand how much travel is involved. She recommends keeping an up-to-date calendar available with all travel plans. Including the family in travel whenever possible can also help. Those important “office days” should be spent in a dedicated area complete with basic equipment. She notes that breaks are important, too.

### New directions

Today’s successful MSL has developed a rich network of deep internal and external relationships. Now is the time for companies to leverage those relationships to maximize their return on investment. Dawson points out that the scope of MSL activities touches on virtually every aspect of the healthcare system.

Clinician advisories impact healthcare organizations through advisory boards, investigator meetings and consumer advocacy groups. IITs yield abstracts and publications, resulting in increased physician awareness. Clinician sciences lead to new product search and discovery and business development. Clinical operations such as site selection for studies lead to more efficient use of company resources. MSL activities provide resources for medical information, writing and publications planning.

All this leads to better health—for the pharmaceutical and biotech companies, and for the patients they serve.

Pharma Marketing News

---

**Pharma Marketing News**


---

*Pharma Marketing News*—the First Forum for Pharmaceutical Marketing Experts—is published monthly by **VirSci Corporation** except for August. It is distributed electronically by email and the Web to members of the Pharma Marketing Network ([www.pharmamarketing.com](http://www.pharmamarketing.com)).

VirSci Corporation specializes in pharmaceutical marketing intelligence and best practices, development of sponsored newsletters and other educational programs, and consulting in privacy and HIPAA. Our goal is to help our clients gain access to *their* clients and do business via the Internet more effectively, with greater return on

**Publisher & Executive Editor****John Mack**

VirSci Corporation

[www.virsci.com](http://www.virsci.com)

PO Box 760

Newtown, PA 18940

215-504-4164, 215-504-5739 FAX

<mailto:editor@pharmamarketingnews.com>**Advisory Board****Jack Pfister**

Director, Business Development, Bruce Leeb &amp; Company

**Mark Schmukler**

Managing Partner, Sagefrog Marketing Group, LLC

**Harry Sweeney**

Chairman, CEO, Dorland Global Health Communications

**Richard Vanderveer, PhD**

Chairman &amp; CEO, V2

---

**Subscribe to Pharma Marketing News**


---

*Pharma Marketing News* (PMN) is the FREE monthly e-newsletter of the **Pharma Marketing Network**. Highlights are delivered to subscribers by e-mail. The full pdf version is available at [www.pharmamarketingnews.com](http://www.pharmamarketingnews.com). You also have the option to participate in 2-way, peer-to-peer e-mail discussions with your pharmaceutical marketing colleagues through the **PHARMA-MKTING list**. By subscribing to PMN, you agree to receive e-mail messages through this service as well as newsletter highlights. We do not sell or share your personal information with third parties.

**RED=REQUIRED INFORMATION**

FIRST NAME: \_\_\_\_\_ LAST NAME: \_\_\_\_\_

JOB TITLE: \_\_\_\_\_ COMPANY: \_\_\_\_\_

COUNTRY: \_\_\_\_\_

E-MAIL ADDRESS: \_\_\_\_\_

E-MAIL FORMAT PREFERENCE: \_\_\_ HTML \_\_\_ TEXT \_\_\_ NONE

 I also wish to join the PHARMA-MKTING list to participate in 2-way peer-to-peer discussions.

SUBSCRIPTION OPTION: \_\_\_ FULL DISCUSSION \_\_\_ "LURK &amp; LEARN" (DIGEST MODE)

BLACK=OPTIONAL INFORMATION (For our internal use only. We don't sell or rent mailing lists/labels)

ADDRESS: \_\_\_\_\_

CITY: \_\_\_\_\_ STATE/PROV: \_\_\_\_\_ POSTAL CODE: \_\_\_\_\_

PHONE: \_\_\_\_\_ FAX: \_\_\_\_\_

Mail or fax to: VirSci, PO Box 760, Newtown, PA 18940, 215-504-5739 (Fax)