

BY ROBIN ROBINSON



The medical science liaison role was born almost 40 years ago, and in this time it has undergone many transformations. Today, as MSLS continue to be an integral component of the communication link between pharma companies and healthcare providers, they also face new opportunities and challenges.

EVOLUTION of SKILLS

New exciting roles await the MSLS of the future

The intent of the first MSL role, created in 1967 by the Upjohn Company, was to create a position within the pharmaceutical company that could interact with academia-based physicians and researchers. In the 1970s, the trend grew, with other companies mostly implementing MSL hiring from within their own sales organizations.

According to attorney Mark DuVal, president of DuVal & Associates, MSLS started out in “fairly purist functions” but over time, the role was altered, and sales and education were brought together in the same function.

In 2002, the Office of Inspector General changed the landscape of the MSL arena by implementing strict regulations requiring a clear separation between R&D and sales and marketing.

“Today, MSLS are completely separate from the sales and marketing departments and are high-level healthcare professionals who can speak in depth to other healthcare professionals on a highly scientific and technical level,” says Robin Winter-Sperry, M.D., president and CEO of Scientific Advantage LLC and MSL Advantage LLC. “MSL is an evolving specialty and is attracting high-level candidates with advanced science degrees.”

The core principal function of the MSL is to provide medical science information on a peer-to-peer basis. The need to deliver that information has increased over the years. While roles are solidifying in terms of compliance and the separation from sales gets clearer, there is still room for expanding duties.


 Joy Morrell, The Therapeutics Institute

MSLs are a talented group of academic individuals who hold very high-level positions, **YET THEY HAVE LITTLE STANDARDIZATION TO GUIDE THEM.**



MSLs always knew what their roles and responsibilities were, **BUT OFTEN THEY WERE FORCED BY THE ORGANIZATION TO MORPH INTO A QUASI-SALES ROLE.**

Mark DuVal, DuVal & Associates

“This trend may help keep MSLs happier in their positions,” says Erin Albert, Pharm.D., president and CEO of Pharm LLC. “MSLs often say they feel as if they are stuck in a career cul-de-sac, but the future holds many more roles that are engaging and intellectually stimulating, which is the primary motivator for MSLs. The wider array of offerings provided to them, the higher likelihood of innovations, and the higher level of MSL job satisfaction, as well as customer satisfaction, make for a win-win career.”

Subject to Business Trends

Over the years, the evolution of the MSL has followed the course of the industry as a whole, responding to tightening regulations and the changing needs of healthcare providers. MSLs can look forward to a multitude of challenges and responsibilities, all dependent on the company, a product's life cycle, the therapeutic category, and the level of specialty the product requires.

“With salesforces being reduced and physician access diminishing, the industry is focusing on resource deployment,” Dr. Winter-Sperry says. “As a resource, MSLs can address many different needs, the most important being to answer healthcare provider questions. This information is critical for improving

patient care and patient outcomes and it is essential for companies to have someone who functions as a field-based medical resource.”

As the commercial pharmaceutical environment enters into another period of change, with an increasing number of hospitals limiting or completely eliminating access to sales representatives, and some states considering legislation that would require licensing of representatives, companies must continue to adjust their business models, says Brian Best, VP of marketing at Medicare Inc.

“All of these adjustments will expand the role of the MSL, who serves as the primary vehicle for dissemination of information about industry-driven, cutting-edge medical advances,” he says. “As traditional channels of communication with customers become less viable, the MSL will continue to enjoy access to decision-makers and key opinion leaders.”

According to Wayne Pines, president, regulatory services and healthcare, at APCO Worldwide, and senior regulatory counselor to Scientific Advantage, as smaller pharma and biotech companies begin to implement MSL programs — a new trend over the past few years — opportunities for MSLs will continue to increase.

“MSLs are going to have increasingly more important responsibilities within drug and device companies and they will become an even more essential resource for healthcare professionals,” Mr. Pines says.

In some companies, MSLs take on responsibilities that include medical education and investigator recruitment. Whatever the duties, Mr. Pines says he believes the MSL function will play an increasingly central role in the pharmaceutical and device industries' outreach and education programs.

While there have been some layoffs of MSLs in the industry recently, these are mostly due to product life-cycle management decisions rather than cost-reduction efforts, Dr. Albert says.

“There has been some downsizing, but most of the reductions are pipeline driven,” she says. “Layoffs were related to drugs not receiving approval. Recruiters are telling me they still have open positions to fill.”

According to Bruce Armon, partner at Saul Ewing, if a company is tightening its R&D spend, there could be some correlation in terms of the MSL function.

“In some respect the MSL function is a microcosm of what is taking place at the company level — expanding when there are growth opportunities and contracting when a company might experience an R&D road block,” he says.

Downsizing may not be all bad news. Cutbacks in larger companies may open up opportunities for MSLs to join small emerging companies where the roles may be more unique. No matter what happens, experts agree that the MSL role is here to stay.

“The need for MSLs will continue to grow,” says Joy Morrell, VP and managing director of

**MSL IS AN EVOLVING
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The Therapeutics Institute. “The demand for a rich scientific exchange between pharma companies, brand executives, thought leaders, and healthcare providers will increase as companies look for ways to optimize patient outcomes.”

To prepare for what Dr. Albert calls the “musical chair” effect in the industry, she suggests MSLs expand their knowledge beyond one therapeutic area so they can adapt to the changing environment.

“My advice to MSLs is to not box themselves into a niche,” she says.

Another factor that may prove to be challenging for tomorrow’s MSL is the shrinking hiring window, which is the opportunity between prelaunch and launch.

“Back in the day, a company might hire MSLs to talk and learn about the therapeutic category and the disease state 18 months to 24 months before the drug was approved,” Dr.

MSL Services, Partnerships, and Roles

SERVICES MSLs PROVIDE

Thought leader development

A link between medical affairs and clinical

Positioning the science for the brand

Scientific resource for the company with managed markets

PARTNERSHIPS FOR THE MSL ROLE

Act as internal stakeholders, for example, to bridge the relationship between commercial and clinical

Establish external relationships with KOL and academic institutions

Collaborate between each other to drive standardization

STRATEGIC ROLES OF THE MSL FUNCTION

Position the accuracy of the science from early to late development

Position the company and the brand for leadership and success, which leads to improved clinical and economic outcomes for patients

Source: Joy Morrell, The Therapeutics Institute, Somerset, N.J. For more information, visit inventivhealth.com.

If MSL leaders don't collaborate on some basic standards for the role, THE ROLE IN THE FUTURE COULD BE TENUOUS.

Dr. Erin Albert, Pharm LLC

Albert says. “Because the FDA is not approving as many compounds and has tightened regulatory requirements, companies are hesitant to invest in MSLs until it appears likely that the drug will be approved.”

The Future Looks Bright

Companies that are not allowing MSLs to expand their role are missing out on the full potential MSLs can bring to the table. According to Dr. Albert, one of those opportunities includes engaging preclinical researchers in meaningful dialogues during preclinical development.

“There is a huge opportunity for MSLs to talk to Ph.D. bench-level researchers who are doing *in vitro* and small animal studies to support the initiatives through investigator-initiated research.”

Another way to expand the MSL role is for MSLs to gain access to executive management.

MSL Metrics and Trends

MSL programs pay their MSLs a base annual salary in the range of \$100,000 to \$150,000.

MSL teams continue to have strong cross-functional interactions with marketing and sales teams.

MSL involvement in preclinical and early clinical development is rare; most MSL activity occurs from Phase II forward.

Most MSL program leadership communicates with executive stakeholders about the status of their field-medical activities on a monthly basis.

Justification of MSL headcount is based on unmet need, numerical justification of unmet need, sales-to-MSL personnel ratio, and other factors.

Source: Medical Science Liaison Institute LLC, Redondo Beach, Calif. For more information, visit mslinstitute.com.



“MSLs should be reporting what they are hearing from key opinion leaders,” Dr. Albert says. “MSLs understand the voice of the customer better than anybody else in the company. They are the closest to the academic thought leaders, the movers and shakers of the therapeutic area. This is why they should be talking to managers at the top levels of the company.”

Dr. Albert says more aggressive pharma companies are leveraging MSLs for these types of dialogues, but in some companies, MSLs never even meet the CEO.

“Getting MSLs in front of executive management is critical because it not only bridges the gap but provides another venue for high-level executives to understand the value of the MSL team,” she adds.

Similarly, MSLs need to be involved in dialogues centered around investigator initiated trials. Many companies are leaving the MSL outside discussions involving funding selection, so he or she never gets to justify or explain what the investigator is hoping to accomplish with the trial.

Dr. Albert says often a centralized group reviews the request, which can disappear into a “black hole” for six to 24 months, with no word getting back to the MSL.

“In this situation the academic thought leader may get frustrated for lack of an answer and the MSL who is out of the loop is powerless to provide an answer,” she explains. “If MSLs were included in the approval group as nonvoting members, they could at least contribute by explaining the concept from a research standpoint.”

Another area where the MSL role is growing stronger is in smaller emerging pharma and biotech companies. MSLs, in this case, act as the proverbial front line for the company, not only providing education about the science but introducing the company to thought leaders and the market.

“It’s my diagnosis, but
it’s not just me
living with HIV.”



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Brian Best, Medicare

As traditional channels of communication with customers become less viable, **THE MSL WILL CONTINUE TO ENJOY ACCESS TO DECISION-MAKERS AND KEY OPINION LEADERS.**

“In this case, the MSL has the task of not only making sure the science is translated correctly from the clinical-trial results to health-

care providers, but educating healthcare providers and market influencers about the new company,” Ms. Morrell says. “Essentially,

they are launching the product as they launch the company. This is an important and sometimes new role for the MSL. It is important for the company to support these MSLs with good clinical data as well as the business acumen needed to establish long-term relationships with healthcare providers, thereby lining up the company’s goals and the brand’s direction.”

Some MSLs are being asked to scope out both commercial and scientific opportunities for the company. They are often the first line of inquiry when it’s time to review current trends

Sound Bites from the Field

PHARMAVOICE ASKED INDUSTRY EXPERTS TO PROVIDE THEIR OPINIONS ON HOW THE ROLE OF THE MEDICAL SCIENCE LIAISON (MSL) WILL EVOLVE IN THE INDUSTRY IN THE FUTURE.



STAN BERNARD, M.D., MBA, is President of Bernard Associates LLC, Far Hills, N.J., a healthcare industry management consulting firm. For more information, visit bernardassociatesllc.com.

“The MSL role will expand in breadth and depth reflecting two evolving industry trends. First, there are new, powerful stakeholders beyond traditional physician KOLs. Second, novel, potent technologies are transforming the pharmaceutical landscape. These emerging stakeholders and technologies will determine the adoption and use of pharmaceutical products. Consequently, MSLs will evolve from a physician KOL influencer to a scientific consultant representing companies. They will be responsible for understanding new scientific and medical technologies as they emerge in the marketplace and identifying how they may impact not only KOLs but also other key stakeholders, such as payers, policymakers, and the media. Scientifically trained MSLs will help to translate, communicate, and demonstrate the value of emerging technologies, such as biotechnology, pharmacogenomics, and nanotechnology.”

DAVID BEST, M.D., MBA, is President of The Doctor’s Channel, New York, an educational physician Website. For more information, visit thedoctorschannel.com.

“In 1989, at BMS, I was on the team that



started the first scientifically credentialed MSL group in the industry. There were only two objectives at that time. Objective No. 1 was to increase sales and No. 2 was to enhance the image of commitment on behalf of the pharmaceutical company. Today objective No. 1 has changed to ‘enhance medical education effectiveness.’ One thing that has remained steady is increased physician accessibility. The value the MSL brings to the physician is demonstrated by data that suggest the average call is from 30 to 45 minutes and the ongoing desire of the physician to see the MSL is on average four times per year. MSLs have fulfilled their promise by delivering the medical message at a high scientific level, colleague to colleague, and they will continue to do so in the future.”



JANE CHIN, PH.D., is President of Medical Science Liaison Institute, Redondo Beach, Calif., which advances the role of field-based MSLs in the biopharmaceutical industry. For more information, visit mslinstitute.com.

“MSLs have traditionally focused on developing thought leaders as part of their role in representing the scientific face of their organizations. I expect that MSL teams will become internal consulting units within healthcare organizations and support their internal stakeholders as much as they support external stakeholders. In other words, a future sustainable MSL role should truly embody the liaison concept to bridge the industry with

interfacing constituents beyond clinical and commercial functions. For any MSL team to succeed as an internal consulting unit, the individuals must be able to anticipate organizational needs and understand the value chain to create a differentiation-drive competitive advantage. This requires MSL teams of the future to clearly define objectives, monitor progress, and appropriately measure the outcomes of their activities.”



BETH PRICE is Executive VP of Science Oriented Solutions (SOS), Kennesaw, Ga., which focuses on medical affairs outsourcing, most notably, the provision of credentialed, trained, and managed field-based MSLs. For more information, visit medicalaffairs.com.

“As companies continue to develop more complex products, MSLs have, by necessity, become increasingly more specialized. This specialization will continue into the future, not only in terms of product and disease state, but also specific to the stakeholder mix, where peer-to-peer communications will require a targeted scientific approach. For example, the need to educate primary investigators and their site personnel is critical to recruiting appropriate patient types and advancing a company’s clinical program. To address this need, a new breed of MSLs, called clinical trial liaisons, has evolved, targeting these specialty healthcare providers and providing them with site specific support and resources.”



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Dr. Robin Winter-Sperry, Scientific Advantage

THE NEED FOR FIELD-BASED MSLS HAS GROWN OVER THE YEARS with the increasing complexity of therapeutic agents. Device and biotech companies also are embracing the role and launching their own teams.

in medicine, for example, evidence-based medicine, patient therapy and treatment, and identifying unmet patient needs, Dr. Winter-Sperry says. There are also commercial applications, as MSLs can research new areas for development and therapeutic agent acquisitions.

A similar role that is expected to grow in the industry is that of the clinical trial liaison, or CTL. CTLs assist with the completion of clinical trials by helping support patient-recruitment initiatives and developing successful sites and investigators.

"I continue to see an increasing role for MSLs in the conduct of Phase II and Phase III clinical studies, where a high-touch equals high-output model can drastically improve the cost-effectiveness of clinical research," Mr. Best says. "The MSL or clinical trial liaison can improve study start up timelines, facilitate increased enrollment of appropriate patients, and help build relationships that will successfully transition the product from clinical studies to commercialization."

A CTL position could be a next step for an MSL who is looking for a different type of opportunity, Dr. Albert says. The role is more project management based than therapeutically related, but could be an appropriate move for an MSL with the right skills. CTLs can help speed a drug's approval, which can mean substantial savings as well as increased revenue.

CTLs are on-call 24 hours a day. They are charged with responding immediately to physicians' inquiries about patient suitability for trials.

"This role is most important in helping companies reach patient enrollment deadlines and milestones that can drive the overall success of a clinical trial," Ms. Morrell says. "The ability to develop products today that help patients reach better outcomes and improve



There are many people entering the growing medical science liaison field. BEING AN MSL IS A VERY EXCITING CAREER RIGHT NOW.

Wayne Pines, APCO

quality of life can be greatly influenced by using a CTL at the point of care who helps facilitate recognition of who meets the inclusion criteria and would be willing to participate in the clinical trial."

The Need for Standards

One of the biggest challenges for the MSL of today is the lack of standardization throughout the field. The role of the MSL differs greatly from company to company and the incongruity creates confusion and frustration among both MSLs and the healthcare providers they service.

Leaders in the field believe MSLs need to advocate for themselves by creating a coalition that will set standards for the profession and solidify the role, bringing more consistency to operating procedures.

"Standardization is key and until this happens the industry is putting itself at risk," Dr.

Albert says. "Academic customers are perplexed by the varying responsibilities of their MSLs."

Dr. Albert explains that an MSL from one company may be able to help the healthcare provider conduct investigator initiated trials and provide CME support, whereas an MSL from another company might not be able to assist the

healthcare provider with any of those services.

"Thought leaders are frustrated, and if MSL leaders don't get together and collaborate to set some basic standards there could be trouble in the future," she says.

Ms. Morrell agrees, adding MSLs could benefit by creating their own organization and influencing the direction of their role and responsibilities.

"MSLs are a talented group of academic individuals who hold high-level positions, yet they have little standardization to guide them," she says.

This lack of standards extends even further. Determining where the line is to be drawn between sales and science in the field is clearly understood these days, but internally this distinction can still be blurry. Even though it has been more than five years since the OIG required the separation of sales and MSLs, Mr. DuVal says some companies still put political pressure on their MSLs.

"There are still some vestiges of indirect internal political or financial pressure being placed on MSLs, whether it be through performance reviews, sales-related bonuses, reporting structures, or myriad other ways," he says. "Companies may have eliminated the connection to sales on paper, but in reality, in some cases, it still exists. The big challenge is getting sales and marketing to disengage from thinking

**A CTL POSITION
COULD BE A NEXT
STEP FOR AN MSL
WHO IS LOOKING FOR
A DIFFERENT TYPE OF
OPPORTUNITY.**

The MSL function is in part dictated by the evolution of research and products being developed, **BUT AS LONG AS THEY INVOLVE SOPHISTICATED SCIENCE, MSLs WILL ALWAYS HAVE AN IMPORTANT ROLE IN SHARING KNOWLEDGE AND INFORMATION.**

Bruce Armon, Saul Ewing

they have control over the MSL function,” Mr. DuVal says. “Companies need to create a Chinese wall around the MSL function so these experts can operate in a pure medical and scientific capacity.”

Another internal challenge is how to effectively delineate the lines of authority and accountability for the MSL team. In larger pharma companies, the lines are more clearly drawn, with the teams residing under medical affairs, but a smaller institution might require an MSL to wear more hats and take on more responsibilities, which may blur the lines of accountability.

Dr. Winter-Sperry says because the industry has limited resources, strategically companies must do more with less, which can be challenging for MSLs.

“There used to be room for broader strokes, and more time to get to the end result, but those days are gone,” she says. “Every company is facing the challenge of doing more with limited resources, which means that an MSL’s activities need to be laser focused and that the strategy is appropriately on point.”

MSLS HAVE LITTLE STANDARDIZATION TO GUIDE THEM.

Mr. Armon notes that opportunities and challenges facing the industry are often the same for MSLs. External challenges include the practice of outsourcing, physician access, and compliance. Internal hurdles include creating a clear expectation of roles and responsibilities, compliance, and retaining qualified staff.

“More companies are turning to third-party vendors to acquire skilled and experienced MSLs to help with discrete projects,” he says.

Ms. Morrell adds that the outsourcing trend is growing because the industry has come a long way in being willing to share science information with staff from the outside.

“Allowing a nonemployee to be involved in the positioning of the science in the marketplace is a huge step in the industry,” she says.

Another challenge is the diminishing access to key opinion leaders (KOLs).

“Times are changing and it might become more difficult if a KOL’s employer, for example an academic medical center, suddenly changes its policies to prevent relationships between the



institution and faculty members and a pharma company,” Ms. Morrell says. “This practice would greatly impede the degree of regular and routine access allowed to an MSL for knowledge and information gathering.” ♦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoiced.com.



To access a FREE Podcast featuring Dr. Robin Winter-Sperry go to pharmavoiced.com/podcasts.

Experts on this topic

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