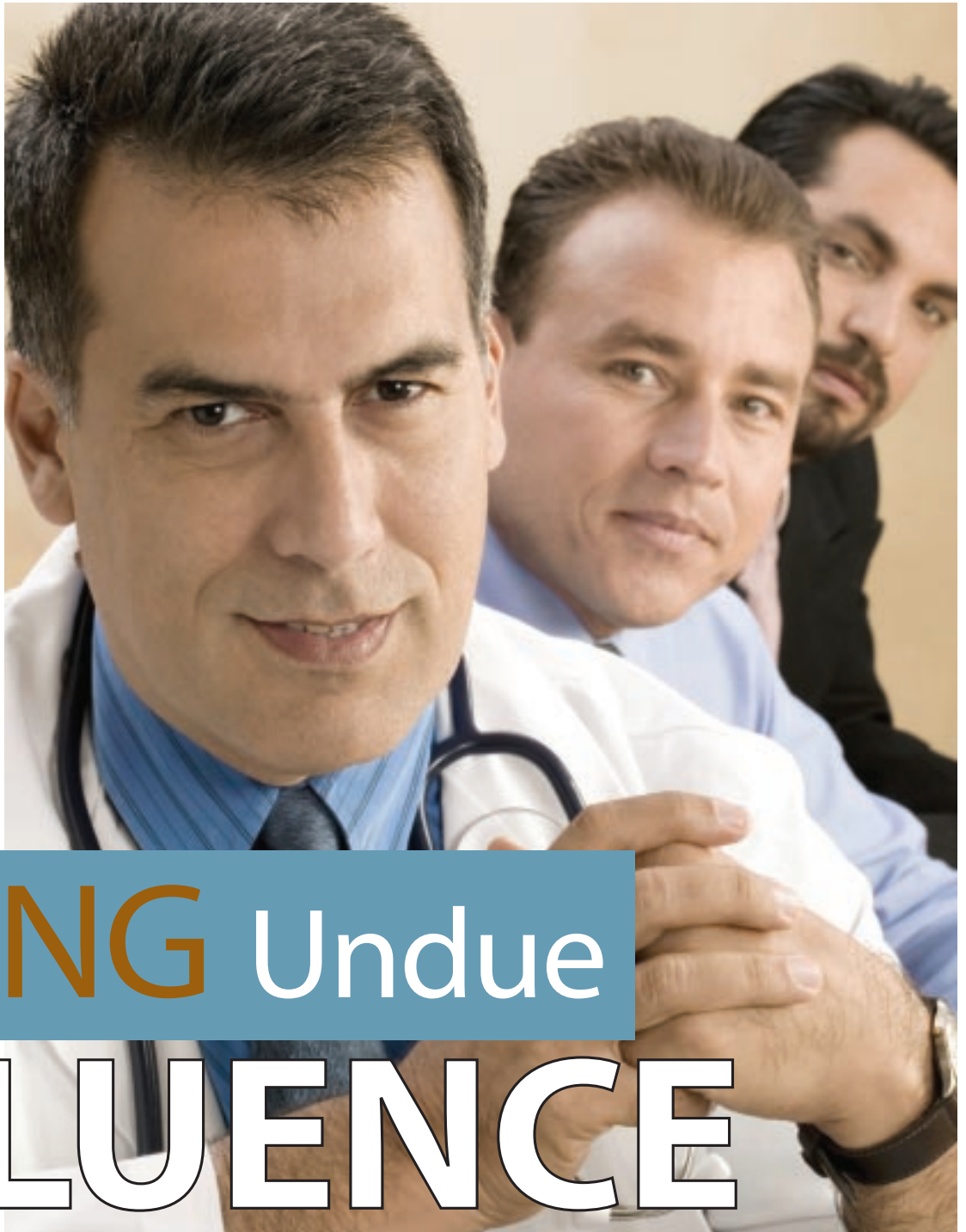


BY AUTUMN KONOPKA

PHARMACEUTICAL  
COMPANIES'  
RELATIONSHIPS WITH  
THOUGHT LEADERS HAVE  
CHANGED IN LIGHT OF  
REGULATIONS THAT AIM TO  
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individuals still are trusted  
advisors who can help  
pharma reach physicians.



# AVOIDING Undue INFLUENCE

**THOUGHT LEADERS — SCIENTIFIC AND CLINICAL EXPERTS — PLAY A PIVOTAL ROLE IN HELPING PHARMA COMPANIES IDENTIFY KEY TOPICS OF INTEREST TO PHYSICIANS.** Depending on their role, these KOLs provide launch and sales support or play a critical role in continuing medical education. They provide solid, evidenced-based education that translates science into practical application and informs their colleagues about new, cutting-edge information.



**Physicians want information from an unbiased source.**

The best source, however, is often the company that developed the drug.

**DR. GARY SCHWEBACH**  
G & S Research Inc.

The relationship between pharma companies and thought leaders is changing in light of regulations that aim to address conflicts of interest, and industry experts say there is a need for strategic planning when reaching out to these experts.

Relationships with thought leaders are migrating more toward partnerships as opposed to providing brand recognition in the field, says Jim Melton, CEO of PMPN.

“Because these relationships are highly regulated, developing these people as trusted advisors requires companies to let them say what they think,” he says.

Thought leaders have a message to convey, says Lawrence Sherman, CEO of Physicians Academy for Clinical and Management Excellence.

“When a thought leader truly speaks his



**Continuing medical education should always be about the same thing:** identifying a gap between ideal and actual clinician knowledge levels on a disease state, securing funding, and providing education to close or narrow that gap.

**MARSHA MEYER**  
CME LLC



**Pharmaceutical companies are rethinking the selection criteria** for who is an advocate and what defines an advocate.

**MARIO NACINOVICH JR.**  
Fission Communications

opinion leaders (KOLs) by offering them inappropriate opportunities that do not match their expertise or interests.

A common mistake, he says, is to send a KOL to the podium when, for example, that individual may be more interested working on research or publications.

“Some leaders will speak even though they are uncomfortable with the medium because it’s one way they gain entry into the relationships, into funding, and then possibly into the research,” he explains.

Mr. Buckwell says it is surprising to see how many brand teams, even those with an extensive history in a category, have little idea who the thought leaders are or what their practice profiles are.

He says a key challenge is the continued need to drive an appreciation of thought-leader development as a rigorous discipline requiring careful planning and adequate tools. The key aspect of the culture shift required is to move thought-leader relationships from being regarded as a “personal asset” to being regarded as a “company asset,” which needs to be managed like any other highly valuable resource.

## Thought Leaders AND MEDICAL EDUCATION

Most experts agree that thought leaders play a pivotal role in CME by helping pharma companies identify key topics of interest and by pushing education providers to offer compelling, relevant content.

In fact, many thought leaders are forming educational foundations, says Heidi L. Liston, Pharm.D., senior VP and general manager of DiMedix LLC.

"These individuals may sit on pharma advisory boards and therefore have the opportunity to take their learnings from those advisory boards and propose CME programs," she says. "Commonly, these are top-level experts and individuals with whom pharma wants to maintain relationships."

Dr. Liston says for some pharma companies, this is not perceived to be a conflict of interest but rather an innovative means to build relationships with top experts through the CME medium.

"Still, other pharma companies, especially in light of the intense scrutiny on CME, view supporting this type of relationship as posing an increased risk for noncompliance," Dr. Liston says.

Mr. Buckwell says there has been a decrease in advisory boards, which used to be a mainstay of thought-leader development.

"In today's regulatory environment, advisory boards are rigorously scrutinized with respect to number and purpose," he says. "We have responded to this new reality by developing a model that incorporates thought leaders at the regional and national level for content development. This serves a dual purpose of not only developing content that is more readily adopted by an audience because of its peer-to-peer nature, but also maintaining a portfolio of ongoing face-to-face contact that is crucial."

When the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) introduced compliance regulations for pharmaceutical manufacturers in 2003, one of the key elements of that program was the insistence that pharmaceutical marketing efforts be completely firewalled from



**When a thought leader truly speaks his own mind, a group of physicians often responds very well.**

**LAWRENCE SHERMAN**  
Physicians Academy for Clinical and Management Excellence



accredited medical-education programs. The purpose of the separation is to promote fair, balanced continuing medical education that does not reflect the bias of any pharmaceutical sponsor.

"CME educates healthcare providers about advances and standards of practice in the diagnosis and management of a disease state; promotional education focuses learning toward a given product or brand," Dr. Liston explains. "In today's environment, fair and balanced CME supported by pharma is a new reality because of firewalls between marketing and medical affairs."

According to Marsha Meyer, senior VP of clinical information at CME LLC, physicians and other clinicians require a lifelong learning approach to continuing medical education.

"Opposed to a series of independent courses, they want education that caters to their particular knowledge levels and schedules," she says. "Continuing medical education should always be about the same thing: identifying a gap between ideal and actual clinician knowledge levels about a disease state, securing funding, and providing education to close or narrow that gap."

But since the firewalls went up — and because thought-leader management programs generally straddle the marketing and clinical side — thought leaders may be viewed with skepticism by their colleagues, suggests Robert Nauman, principal of BioPharma Advisors Network.



**MSLs form a critical education and communication link between the industry and the healthcare providers.**

**DR. ROBIN WINTER-SPERRY**  
Scientific Advantage LLC



"The question that plagues pharma today is whether a thought leader will be seen as an advocate of that company's product and, if so, lose credibility in the minds of his or her peers," Mr. Nauman explains. "My fear is clinicians will have to make a choice whether to practice medicine or be a thought leader to avoid regulatory issues."

It's important that pharmaceutical companies sales and marketing departments, as well as medical affairs, adhere to the firewall provisions and don't overstep regulatory boundaries.

"I've done a tremendous amount of work with physicians at the community level talking about medical education, and there's an inherent skepticism of anything that comes from a company," says Gary Schwebach, Ph.D., founding principal of G & S Research Inc. "Pharmaceutical companies have to figure out what topics practitioners need to know about and fund CME that addresses those topics."

In 2004, the accredited CME industry was valued at more than \$2 billion, according to



Developing thought leaders as trusted advisors **requires companies to let them say what they think.**

**JIM MELTON**  
PMPN

the Accreditation Council for Continuing Medical Education's (ACCME) annual report for that year. More than half of the industry's funding came from commercial supporters, primarily pharmaceutical firms.

"Physicians want information from an unbiased source; the best source for this information, however, is often the company that developed the drug," Dr. Schwebach says. "The challenge is to provide this company-based knowledge to the community in a way that is acceptable to regulators and community physicians."

### Finding a Place **FOR THE MSL**

Another vehicle through which pharmaceutical companies seek to provide fair, balanced education to physicians and thought leaders is the medical science liaison (MSL) function. MSLs are most often individuals with scientific degrees — M.D.s, Ph.D.s, and Pharm.D.s — who serve as the educational interface between the pharmaceutical companies and the healthcare providers.

Best Practices LLC recently conducted a study to uncover what best practices are being used by pharmaceutical companies to identify and recruit thought leaders. Field-based med-



**My fear is clinicians will have to make choices about practicing medicine** in their community and being considered a thought leader working with industry.

**ROBERT NAUMAN**  
BioPharma Advisors Network



**The CME provider should supply commercial supporters with solid information** on the outcomes of the educational activity.

**DEBORAH WOOD**  
Deborah Wood Associates  
and CME Enterprise

A current trend, however, has the formal MSL programs emerging from under the marketing umbrella to establish groups independent of marketing's influence.

A recent report by Medical Science Liaison Institute and Cutting Edge Research found that 60% of participating pharmaceutical companies structure their field-based MSL programs under medical affairs to further accentuate the function's scientific emphasis. Companies do this to create an unbiased resource to help opinion leaders expand research within their specialty or therapeutic area.

"MSLs form that critical education and communication link between the pharmaceutical industry and the healthcare providers," says Robin L. Winter-Sperry, M.D., president and CEO of Scientific Advantage LLC. "They are the source, in most cases, for high-quality, fair, and balanced information about a company's products and scientific endeavors."

Nevertheless, many in the CME world see little room for MSLs in accredited education programs.

"MSLs do not have a role in CME," adds Deborah Wood, president and CEO of Deborah Wood Associates and its subsidiary, CME Enterprise. "The only exception would be for the CME provider to request, in writing, MSLs to assist in the distribution of brochures or flyers announcing a program."

"In our experience, CME activities have



**The underlying problem is a basic lack of understanding of the term ‘thought-leader development.’** It is not a tactic but an approach that realistically should link almost every aspect of the brand portfolio, from R&D to sales.

**CHARLIE BUCKWELL**  
Complete Medical Group

been developed as part of a joint effort between an assembled board of subject matter experts, program managers, and faculty drawn from academia; this structure seems to provide the kind of checks and balances that would disadvantage a single, medical-science liaison,” says Charles Isaac, CEO of Skychaser Communications Inc.

On the other hand, Dr. Winter-Sperry says medical science liaisons can be an invaluable resource for educational programming by providing third-party medical education providers with necessary information about a company and its products, as needed.

“In a highly complex and rapidly evolving

medical community as we have in this country — with all the great resources and all the wonderful things that the pharmaceutical industry is doing — one of the best ways to make sure that physicians really know what’s going on is through continuing education and resources such as medical liaisons,” Dr. Winter-Sperry says. “We all want to make sure that everybody’s as educated as possible and that it is done professionally, within compliance and ethical standards.” ♦

PharmaVOICE welcomes comments about this article. E-mail us at [feedback@pharmavoice.com](mailto:feedback@pharmavoice.com).

## Experts on this topic

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**G & S RESEARCH, INC.**

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G & S Research provides global, primary market research services and consultation to the pharmaceutical and health science industries. For more information on G & S Research and its services, visit the G & S Research website at [www.gs-research.com](http://www.gs-research.com) or contact Jenny Brown, marketing communications manager, at 317-819-4339 or [jbrown@gs-research.com](mailto:jbrown@gs-research.com).