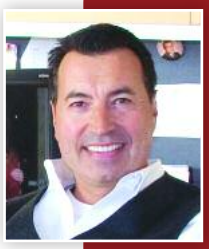
Everyone is WATCHING

PhRMA, DDMAC, OIG, DOJ, FDA— this is more than regulatory alphabet soup; these government agencies and trade groups are charged with making sure the industry toes the line.

The advent and growth of federal and state compliance regulations and the monitoring of those regulations have absolutely been game changers in the life-sciences industry over the last 10 years, says Peter Sandford, executive VP of NXLevel Solutions, a developer of technology-delivered learning applications.

BACK TO THE FUTURE



INDUSTRY HEAL THYSELF: THE PHRMA CODE

MATT GIEGERICH
Chairman and CEO, Ogilvy CommonHealth Worldwide

» **THEN (2001):** The guidelines were the right thing to do. But they were late in coming. The intensity of the scrutiny already was at a fever pitch.

» **NOW:** In some ways, the PhRMA code went too far in that it galvanized a fear-based, risk-averse environment at a time when the industry was — and still is — desperately trying to reinvent its commercial model. In other ways, the PhRMA code did not go far enough, because it did not specifically address the emerging and critical role of new technologies, user-generated content, social network influence, etc. The industry is now forced to anxiously experiment with new approaches under the inconsistent Damocles sword of DDMAC and the FDA.

"Being able to use online technology to procure samples is, I believe, one of this last decade's more significant game changers for the life-sciences industry."

JIM KNIPPER / J. Knipper & Company

"The charge led by the OIG and DOJ in the early 2000s has markedly changed how life-sciences companies interact with, and provide information to, healthcare providers," Mr. Sandford says. "Over the last 10 years public transparency in these relationships has increased, and that trend is likely to continue well in to the future with the disclosure requirements in the Affordable Care Act."

The increase in regulatory oversight in the last decade was the result of many cascading events, but three are often cited as the main sources: abuse of the PhRMA code by marketers, sales forces trying to curry favor with physicians, and the market withdrawal of Vioxx.

"Merck's withdrawal of Vioxx, which ushered in an era of regulatory conservatism and risk aversion that still dominates today, was the biggest game-changing paradigm shift in the life-sciences industry in the past 10 years," says Matt Giegerich, chairman and CEO of Ogilvy CommonHealth Worldwide, a healthcare communications network. "This event — more than any other in the past decade — dramatically altered the tone and trajectory of the pharmaceutical marketplace."

Some say more guidelines are coming, as soon as the agency gets its arms wrapped around the ever-expanding social media phenomenon.

"Patients generate PR by misinformation or perceptions that can — and do — become reality," says Jeanne Male, president and CEO of Emp-Higher Performance Development, a

> "Competition to develop innovative medicines as opposed to 'me betters' will intensify."
>
> **DR. DAVID LACEY** / Amgen

> "The charge led by the OIG and DOJ in the early 2000s has markedly changed how life-sciences companies interact with, and provide information to, healthcare providers."
>
> **PETER SANDFORD** / NXLevel Solutions

> "The FDA and other agencies are taking a long, hard look at how we share consumer and professional messages."
>
> **MARC WEINER** / Ogilvy CommonHealth

consultancy. "We cannot wait for FDA guidance or policies to engage e-patients and to seize social media opportunities. This is far more time sensitive than the DTC days when smart companies proceeded to push the envelope prior to guidance. I see potential for an emerging role: a 2.0 pharmaceutical consultant with the needed competencies and the technical skill set of MSLs along with the customer service/people skills of field or call center representatives to directly engage with patients and healthcare advocates online."

According to Marc Weiner, managing partner at Ogilvy CommonHealth Worldwide, a healthcare communications network, in terms of sheer impact, the federal government will be the biggest market shaper in the next decade.

"Healthcare reform is likely to be the most significant disruptive force," he says. "The FDA and other agencies are taking a long, hard look at how we share consumer and professional messages. When their final guidelines are handed down, we're likely to see significant changes in how brands are allowed to communicate in social and other new-media channels."

But Nancy Lurker, CEO of PDI, a provider of integrated multichannel promotion outsource services, says the biggest game changer is the slow down in the FDA approval of new drugs.

"This trend, combined with generics increasingly eroding the major blockbusters, has resulted in financial pressures that are having major repercussions throughout the industry," Ms. Lurker says. "If new drugs were being approved more quickly and there was less generic impact, it would be more like business as usual. Spend levels would be up and not down. Instead, we have major layoffs and everyone is focusing on how to substantially revamp the commercial model with serious consideration of outsourcing to relieve financial pressures."

The hyper-vigilance and hyper-conservatism of the FDA on everything from drug approvals to what colors can or cannot be used in promotional materials have turned the life-sciences industry on its side, says Jeff Burkel, chief operating officer at MicroMass, a behavior science-based communications agency. "This has led to the need for new commercial models, fewer drugs being approved, reduced R&D investments by big pharma companies, an urgency to globalize, and generally throttled back progress and innovation. As companies reach out directly to consumers we have also seen radical changes in how drugs are promoted, along with disconnected relationships between physicians and the industry."

Terry Nugent, VP of marketing at Medical Marketing Service, which has developed a methodology that maximizes the value of list data for medical marketers, says the biggest market shaper over the next 10 years will be the success of pharmaceutical research and development. This, he says, will require companies to consider several factors, including the productivity of R&D departments and various governmental policies, principally FDA approval policies and CMS's reimbursement policies.

"To some extent these may become intertwined as comparative effectiveness is implemented," Mr. Nugent says. "Pharmaceutical companies can to some extent control all of these factors, especially R&D productivity, however government policies are less manageable and more subject to the vicissitudes of partisan politics and subsequent election outcomes."

According to David Lacey, M.D., senior VP of discovery research at Amgen, a biotechnology company, regulators and payers will be increasingly focused on meaningful differentiation of new therapies vs. current standards of care obtained through comparative effectiveness studies.

"Competition to develop innovative medicines as opposed to 'me betters' will intensify," he says.

Ms. Male says industry regulation and con-

> "The desire to demonstrate unique value in clinical discovery — as early as Phase I and II — has meant that KOLs are being asked to become much more engaged in shaping future directions of development."
>
> **MICHAEL CURRY** / Curry Rockefeller Group

> "If new drugs were being approved more quickly and there was less generic impact, it would be more like business as usual."
>
> **NANCY LURKER** / PDI

traction have been exponential game changers.

"Despite innovation in key therapeutic areas, for example oncology, the industry has not been able to provide novel compounds or stockholder returns in step with those of a decade ago," she says.

According Mr. Weiner, in terms of sheer impact, the federal government will be the biggest market shaper in the next decade.

"We can make logical predictions about how EMRs will change the market, but we're looking at the tip of the proverbial iceberg," he says. "Healthcare reform is likely to be the most significant disruptive force. The FDA and other agencies are taking a long, hard look at how we share consumer and professional messages. When their final guidelines are handed down, we're likely to see significant changes in how brands are allowed to communicate in social and other new-media channels."

Patient Protection and Technology Regulations

In the future, some experts predict there will be more oversight of IRBs and particularly in relation to human subject projection.

"My belief is that among the biggest market shapers in the next 10 years it will become a requirement to provide documentation of certification of human subject protection training of all clinical research staff," says Lynn Meyer, managing partner of IntegReview Ethical Review Board, an IRB. "I believe this may become a requirement either of sponsors or by means of federal regulation. In my experience over the past 10 years, I consider the biggest game changer in the research industry to be the implementation of accreditation of human research protection programs. Accreditation has resulted in enhanced policies and procedures for protecting study participants not only by IRBs but also sponsors and CROs. Additionally, many sponsors and CROs are now only working with IRBs that have achieved accreditation."

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which took affect in April 2001 (companies had until April 2003 to comply) has become ubiquitous to anybody operating in the clinical space and was intended to extend patient protection.

Not all regulations are considered draconian, and in fact, many new cottage industries, consultancies, and services have been started to help companies manage within the lines.

The FDA's 21 CFR Part 11 is one regulation that has had a positive impact.

"Being able to use online technology to procure samples is, I believe, one of this last decade's more significant game changers for the life-sciences industry," says Jim Knipper, founder and CEO of J. Knipper and Company, a provider of healthcare marketing solutions. "The source of this change can be traced to shifts in government regulations over the last few years. More specifically, approval of Part 11, which led to the subsequent development of e-signatures, made it possible for prescribers to get samples without onsite distribution by a pharmaceutical sales rep or having to submit an actual physical signature. This paperless approach to fulfillment is not only more green and secure while less obtrusive, more importantly e-sampling makes samples and production information more readily available to all who might benefit. This is something that I view as revolutionary and much needed."

KOL Oversight

The thought leader is someone to whom others look for guidance and mentorship. The role is critical for advancing new concepts and ideas and for establishing new procedures and techniques.

According to Neil Matheson, CEO of Huntsworth Health, a provider of consulting and communications services, this role is as important today as it was a decade ago because of the rapid advances being made in technology and the ever-evolving understanding of disease processes and therapeutic approaches.

"Establishing thought leader support for

BACK TO THE FUTURE

THOUGHT-FULL RELATIONSHIPS

RICHARD MINOFF
Managing Partner, 1 Global Partners

» **THEN (2001):** Thought leaders often are used to set the stage, change a treatment dynamic, or sometimes to debunk old perceptions, or say 'life has changed; let's move on.

» **NOW:** KOL development, perhaps more than any other marketing strategy, has had to change over the last10 years, and like so many things in our industry that we can view through an uncolored, historical lens, the pendulum has swung far, far to the other, or shall I say the ultra-conservative, side. Actually, while everyone gasped over the changes, albeit in my opinion necessary given so many improprieties, it's obvious that this area had run amok. That said, I strongly believe that there is a shared onus on both the industry, and certainly the KOL/physician community, both of whom drove so many excesses.

> **"It will become a requirement to provide documentation of certification of human subject protection training of all clinical research staff."**
>
> **LYNN MEYER** / IntegReview

new management approaches and for the use of new therapeutic agents or interventions is critical to a new product's success," he says.

The most significant change has been a call for greater transparency regarding the scope of KOL interactions with the industry, particularly among those experts who are investigators in pivotal trials and those who serve in an advisory capacity for industry, says Michael Curry, partner of the Curry Rockefeller Group, a healthcare communications agency.

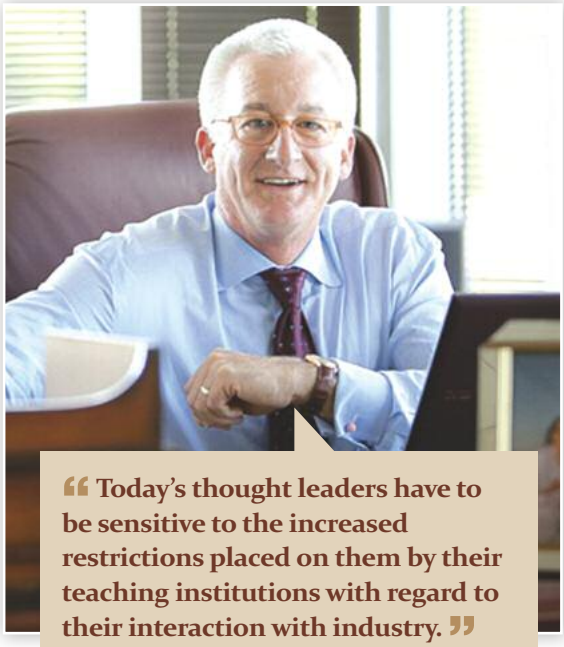
"This means that we have had to work to define more clearly the scope of KOL relationships and to ensure that the essential insights that they provide on clinical and commercial development strategies can satisfy regulatory scrutiny," he says.

Charles Rockefeller, partner at Curry Rockefeller Group, who prefers to use the term KOL engagement, says today's thought leaders have to be sensitive to the increased restrictions placed on them by their teaching institutions with regard to their interaction with industry.

"Given the increased transparency resulting from the current regulatory climate, the institutions have become larger stakeholders in these relationships," Mr. Rockefeller. "More clearly defined engagement, with transparency, is actually good for all parties. The term KOL development I believe applies to those special cases when a company discovers and develops a unique or first-in-class compound, and through the clinical trial process, select investigators naturally become experts in this new approach to treating a disease. In this scenario, a drug company's funding of their clinical development program can actually result in the development of KOLs."

In terms of the abuses that prompted heightened regulatory oversight and more strict guidelines, Richard Minoff, managing partner of 1 Global Partners, a consultancy focused on commercialization, marketing, and life-cycle management, says long gone are the days of weekend junkets to the Caribbean, a week in Vienna, or taking 2,000 physicians to another exotic locale to share information.

"That's not to say that there wasn't a worthwhile education exchange or significant and very honest debate and dialogue, not always in the meeting sponsor's favor, but the visage of impropriety in an industry that needs to be above board given its impact on human life,



> "Today's thought leaders have to be sensitive to the increased restrictions placed on them by their teaching institutions with regard to their interaction with industry."
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> **CHARLES ROCKEFELLER**
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> "The hyper-vigilance and hyper-conservatism of the FDA on everything from drug approvals to what colors can or cannot be used in promotional materials have turned the life-sciences industry on its side."
>
> **JEFF BURKEL** / MicroMass

was obviously there," he says. "So now we live in an age where total transparency and full disclosure must be the norm for not just clients, brand agencies, public relations companies, medical education companies, digital and publication shops, but KOLs, physicians, and academic institutions. This is certainly not a bad thing as everyone involved in KOL and related work must seek to re-establish the high integrity needed in the healthcare field.

"As healthcare delivery has continued to move toward a more evidence-based and outcomes-driven field, and one in which individual physician choice is less the norm, whether this is being driven by health plans, access to health, or other issues, the role of the KOL has and will continue to diminish," Mr. Minoff says. "However, KOLs can still fill an important role in the future, such as evolving to create a better dialogue among their colleagues on diagnosis and treatment; becoming real patient advocates for high-quality care and service delivery; and to better assess the role and intersection of drugs, devices, and diagnostics as we move forward toward the hope offered by personalized medicine."

From Mr. Curry's perspective, there is a much greater reliance on developing KOL relationships to gain critical insights regarding unmet clinical needs.

"The desire to demonstrate unique value in clinical discovery — as early as Phase I and II — has meant that KOLs are being asked to become much more engaged in shaping future directions of development," he says. "This trend shows no sign of abating."

Mr. Rockefeller agrees, particularly when it comes to the specialty and sub-specialty therapeutic areas, where he and his colleagues view the opinion leader relationship becoming more vital than ever.

"There will always be cynics of whatever the pharmaceutical industry does," he says. "Developing and nurturing a mutually respectful and transparent relationship that helps communicate scientific information to the clinical community is an important part of delivering responsible patient care."

In this decade of change, the impact of social networking must be brought into the discussion, says Julia Ralston, president and CEO of MedErgy HealthGroup, a medical communications agency. "The motivation of top thought leaders is much the same, and they will continue to be the most powerful and trusted influencers in medicine. Indeed, if we overlay the overwhelming influence of evidence-based medicine in the current environment, expert relationships are arguably more important than before. However, we now call them experts rather than thought leaders, and we have more holistic reasons to engage them based on improving patient care and access to appropriate therapies."

According to Ms. Ralston, the basis for engagement must also be much stronger, targeted and on point, and ideally the basis for the relationship should be of value to both sides over the long term.

"In a sense, this represents a more disciplined approach to involving top thought leaders rather than a radical change," she says. "However, more dramatic is the change that social networking has fueled in the healthcare community in terms of what we call practice leaders or other tiers and types of experts. Networks of physicians seeking advice from others in any scale of online community is clearly now a large component of the medical community's influence paradigm."

Mr. Weiner says today's electronic opinion leaders (EOLs) are now shaping healthcare conversations.

"We've witnessed a gradual but significant shift in how patients and professionals get their health information," he says. "Traditionally, information trickled down from KOLs, who were recognized by their peer communities. When KOLs spoke, the market listened. Now, we've seen thought leadership move online and become decentralized. Web 2.0 technology put content creation into the hands of a new generation of influencers. Bloggers — with their zero-barrier publishing model — changed the concept of opinion sharing." PV

BACK TO THE FUTURE

THOUGHT-FULL RELATIONSHIPS

NEIL MATHESON
CEO, Huntsworth Health

» **THEN (2001):** Thought leaders are used effectively to educate colleagues about the epidemiology, pathophysiology, diagnosis, and management of disease.

» **NOW:** The ways in which thought leaders are engaged and their leadership support is developed have changed dramatically in the last 10 years because of the increased concern over relationships between physicians and healthcare product manufacturers and the subsequent increase in regulatory scrutiny and resultant legislation. Relationships are now founded in a scientific, clinical, or medical environment focused on improving the practice of medicine rather than on marketing a specific intervention or product. This subtle but important change also dictates the ways in which thought leaders and industry interact and the financial remuneration that may be appropriate to support those professional interactions.

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