Meeting Highlight

From Science to CEO

The Scientific Path to Corporate Leadership

By Neil H. Gray

It's not often that one gets to hear and observe three pharmaceutical company CEOs on the same meeting discussion panel, but that's precisely what unfolded as part of Scientific Advantage's Annual Medical Science Liaison Seminar and Leadership Summit held recently at the Bridgewater Marriott in New Jersey.

During the second day of the meeting, P. Roy Vagelos, MD, retired Chairman and CEO of Merck & Company, Ernest Mario, PhD, Chairman of Reliant Pharmaceuticals, and Laurence J. Downey, MD, President and CEO of Solvay Pharmaceuticals shared with their audience some of the drivers that brought them into the pharmaceutical business, challenges and opportunities they faced over their careers, and advice to those medical science liaisons (MSLs) seeking to expand their horizons and responsibilities.

The meeting also provided attendees with helpful overviews and discussions of current regulatory and compliance issues, the importance of linkages between the R&D and MSL teams, and different career avenues MSLs can pursue within the pharmaceutical industry.

The meeting began with a focus on current regulatory and compliance issues, led by Kathryn Gann, PhD, Vice President, Scientific Development at Scientific Advantage, and Wayne Pines, Senior Regulatory Counselor at Scientific Advantage and former Associate Commissioner for Public Affairs at the FDA.

Shifting FDA Focus on Long-Term Effects of Drugs

Pines explained some of the political, scientific, and legal currents that affect the course the FDA steers, and noted that the agency is increasingly interested in the long-term effects of drugs. "Lots of the drugs marketed today reflect only incremental, not breakthrough, changes," commented Pines, "and there is an increasing demand for comparative data, especially as managed care organizations (MCOs) want to reimburse for better drugs, not equivalent drugs." Pines noted that comparative studies will be in keen demand and will strong drivers of future reimbursement.

In 1962, Congress gave the FDA authority over prescription drug advertising. Pines observed that the FDA today has evolved into a very conservative agency, with a broad network of international, state, regional, and district level offices.

FDA User Fees

Curiously, Congress only currently appropriates $1.6B out of an approved FDA budget of $2.0B, but additional sources of funding are helping to close the budgetary gap. The agency's annual drug approval fees are rapidly approaching $400MM, and Pines explained that there is legislation being considered by the Senate that would seek new user approval fees for DTC television broadcast ads, with additional application fees of $40,000 - $60,000 for FDA advisory opinion letters which would be developed within 45 days of receipt (it's currently free for 90 days). These new funds would help DDMAC grow its current staff of 40.

The Seven Fundamental Elements of OIG Compliance

Gann continued the session with coverage of the seven fundamental elements of OIG compliance, which include:

1. Implementing written policies and procedures.
2. Designating a compliance office/committee.
3. Conducting effective training and education.
4. Develop effective means of communication.
5. Conducting internal monitoring and auditing.
6. Enforcing standards through well-publicized disciplinary guidelines.
7. Responding promptly to detected problems and undertaking corrective action.

Gann commented that "the key to consistent field actions is consistent training, with additional updates on new legal opinions and cases."

"The FDA makes no distinction between sales reps and MSLs within the OIG guidelines," added Pines, and it is critical for speakers retained by industry to always have independence. "Nothing should ever be done to undermine this," commented Gann.

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Funding Transparency Long Overdue
When asked for his reaction to the news that Eli Lilly was making transparent its support of medical education initiatives (WSJ May 1, 2007 (B1) article on Eli Lilly lifting the veil of secrecy on funding), Pines remarked "Becoming more transparent on funding is long overdue." Indeed, transparency and openness are becoming organizational necessities that are ever more important within the life sciences industry (as recent Avandia news would suggest).

FDA Scrutiny
Pines suggested that key triggers for FDA scrutiny are whether information provided by companies is false and misleading, and whether it poses a threat to public health. FDA warning letters generally target printed materials that have over-emphasized efficacy, and minimized risk, he noted.

Pines also counseled the attendees to never state conclusions on whether a drug is safe and effective unless the FDA has said it first. "That's their job," he said. Therefore, disclaimers are a good idea (eg, this drug has not been approved by FDA and is under investigation).

MSL Independence
The panelists reinforced that MSLs must be non-promotional and independent from sales and marketing, as there are stiff penalties for illegal behavior, for both the company and the individual if the Justice Department proves laws have been broken.

Under the False Claims Act, 31 U.S.C. §§ 3729-3733, those who knowingly submit, or cause another person or entity to submit, false claims for payment of government funds are liable for three times the government's damages plus civil penalties of $5,500 to $11,000 per false claim.

Pharma fines under false claims now exceed $4B.

Handling Unsolicited Requests from Physicians
Both Gann and Pines observed that when responding to unsolicited requests (which should always be documented):

- Only address the specific question
- Be balanced and non-promotional
- Clearly state the regulatory status of the product or compound (ie, information is off-label), and if it has approved indications, state the indications

Gann commented that any employee of a company who discusses a specific product with external customers or audiences is subject to the same constraints, and materials handed out by MSLs also are regulated the same way. An exception, however, may be when MSLs recruit investigators.

"It is essential that timely, comprehensive information is available to healthcare providers on today's increasing complex therapeutic agents and devices in order to continue to improve patient outcomes. MSLs serve as a field based medical resource bridging that vital scientific information link between the healthcare industry and healthcare providers."

-- Robin L. Winter-Sperry, MD

The Relationship between R&D and the MSL Team
When examining the potential of the MSL role as a strategically focused position, Michael Daley, PhD, TiGenix cited several potential opportunities and needs of R&D where MSLs can be of significant assistance, including:

1. Improving the number, sources, and efficiency of screening leads
2. Improving efficiency of early screening-out of poor candidates
3. Refining efficiency of clinical enrollment, quality investigators
4. Achieving timely completion of pivotal clinical trials
5. Exploring possible extended use of products (ISTs and KOLs)
6. Identification of new technologies/opportunities for in-licensing
7. Awareness of product potential; minimize time to peak sales
8. Early awareness of adverse events; prudent pharmacovigilance
9. Competitive intelligence

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While many MSL teams perceive their primary stakeholders as being situated outside their respective companies, R&D is a critical internal customer, Daley argued. In fact, Daley commented, "MSLs are R&D's internal customers, but R&D just doesn't know this yet!" Strong working relationships between MSLs and R&D are built on a foundation of mutual sensitivity to scientific space, intellectual property, and confidentiality. Daley further commented that MSLs need to have a strong appreciation for the risks that members of the R&D team must navigate on their route of bringing lead compound candidates closer to commercialization.

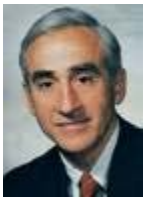
To make partnerships more valuable and mutually inclusive between MSLs and R&D, Daley counseled that MSL teams be proactive, and need to treat internal and external customers similarly.

"It's important to have designated liaisons/contacts within the MSL organization, and to consistently schedule joint meetings among MSLs, R&D, and Medical Affairs," said Daley.

Conversely, Daley noted that R&D plays a key role in training MSLs on new R&D technology platforms and pipeline initiatives, as well as educating MSLs on company policies regarding intellectual property, clinical research, competitive intelligence. Daley also believes that annual meetings among MSLs, R&D, and Medical Affairs can strengthen development of an integrated medical plan, including strategic clinical development.

Science and Corporate Leadership

At a time when corporate leadership across many industrial sectors in the US is uneven, it was both instructive and fascinating to hear the observations and recommendations of three pharma industry CEO heavyweights.



Roy Vagelos, MD, former CEO of Merck and now Chairman of the Board of Theravance, Inc., a biopharmaceutical company based in San Francisco, described how after spending time early in his career as an intern at Merck, he realized that the company was not using biochemistry for discovery, but rather animal models.

Early on, Vagelos appreciated that new (and future) products were key. "During my second year at Merck, I realized how important new products were," said Vagelos. After working in (and finally heading) the research function there, Vagelos argued the importance of Merck's focus on single molecules. Ultimately, he headed R&D with a primary focus that Merck would change the way drugs were developed.

Reflecting on mentors that helped to shape him, Vagelos felt that John Haran, former CEO of Merck, and biochemist Earl Statman were important mentors. Vagelos cited Statman particularly because his chief attribute was to encourage his people to be independent. "When you were ready," commented Vagelos, "he would tell you, 'You're on your own.' And you were."

An Industry in Turmoil

Vagelos believes the industry is currently in free fall when considering its reputation, with many additional challenges brought about by size, which he see as now inhibiting healthy growth.

"In-licensing proliferates," said Vagelos. "Many of the drugs we have today need to be reinvented as they don't go to the basic disease." He also noted that development within R&D is also changing (no longer are studies carried out internally, but rather, out-sourced), manufacturing is also increasingly outsourced to Asia, where it costs 25%-30% of what it costs in the US, and sales forces are bloated and only partially effective.

Classic Sales Rep: An Endangered Species?

"For every 100 sales people sent into the field, only 25% are able to get a 4 minute conversation with an MD," noted Vagelos. "Gifts to MDs will change radically. Major academic centers are beginning to prohibit sale people from meeting with MDs," he commented. It will start at the medical centers, but will permeate the whole system.

That is one reason why MSLs are the way of the future, according to Vagelos. The classic sales rep will disappear. Drugs will be introduced without sales reps at all. According to Vagelos, small companies will be the source of many new products and within 3-4 years, we will have better predictability of side effects and efficacy.

The industry also has to start pricing in terms of value. "Cancer drugs are way out of control pricing wise," remarked Vagelos. "We also need to be sure that drugs can reach all the people who need it. Generics are now embarrassing brand named drug manufacturers relative to price. Loss of credibility is acute. People don't want to believe the results of studies paid for by pharma!"

Qualifications of Today's CEO

Vagelos believes passionately that today's CEOs must focus on talent recruitment and leadership development. Selection and development of people are critical components to a company's

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success. Reflecting on selection criteria for candidates, Vagelos said, "I only pay attention to previous accomplishments, not interviews. Leadership selection takes enormous effort, but it pays off." In depth experience in one select area is more important to Vagelos than broad, multi-functional experience, as is immersion in science.

Case Study: Laurence J. Downey

Laurence J. Downey, MD (Solvay). At age 13, Downey's ambition was to become a local physician. Despite being told that he shouldn't go (as he didn't have a family heritage in the discipline), he attended University of Manchester Medical School. Downey shared that he had a strong drive to prove naysayers wrong, a personal quality that has helped him throughout his career. He did residencies for a family practitioner and then joined a family practice in Lancashire for 6 years, working in the National Health Service. He gravitated to a practice that also had a pharmacy. Meeting with sales reps piqued his business interest.

Downey has been with Solvay since 1980 beginning in a medical marketing role. In 1986 he was asked to move to the US and build a medical affairs department. Subsequently, he was asked to launch two products. "Being associated with a successful project or projects is key to career development," he commented. He then built the medical affairs and MSL groups for Solvay. In 1993 he headed US commercial operations.

MSLs Must Love the Business Too!

When considering career advancement for MSLs, Downey commented, "You have to love the business and be interested in the business side…beyond the science. It's important to work well with marketing, develop your leadership skills, and lead groups of people successfully. Also, be prepared to move geographically. You have to have continuous discussions with others about your career and demonstrate clear leadership potential throughout your career."

Downey concurred with Vagelos that the industry is still highly mistrusted, and that R&D is less productive than it should be, but he differed from Vagelos on candidate qualities. "I like candidates with broad experience." He cautioned attendees to avoid the temptation to hire people "who are clones of yourself. Look for different personalities, people who would challenge you."

Finally, Downey suggested that there is a correlation between the scientific approach to decision making and a company's reputation. "If we had had more of this science directed leadership over the past 20 years, our reputation would be better. We must work on our reputation. We've been caught almost unawares as to the change in power in Washington. We have to get smarter in our R&D area, and better in our development work. Our cost structure has been relatively fat. Other industries would neither endure nor accept our level of costs."

Ernest Mario, a Horatio Algier Story

Ernest Mario, Chairman, Reliant Pharmaceuticals and recent recipient of the Remington Honor Medal, shared warm and personal reflections of his life and career with attendees, which has touches of Horatio Algier.

"I am a pharmacist and I always will be a pharmacist," said Mario. "I am also an Eagle Scout."

The son of first generation Americans, Mario conceded that in life a pretty good dose of luck is helpful. After attending pharmacy school, he taught for a year and then got his PhD in chemistry. Subsequently he went to Strassenberg Laboratories where he earned $12,000 annually and entered the pharmaceutical business.

Mario held important positions at several pharmaceutical before becoming CEO of Glaxo worldwide. After Glaxo, Mario launched Alza and later sold it to J&J for $100MM, which he used to start ApothoGem. That venture failed, but Mario ended up at Reliant Pharmaceuticals where he currently serves as Chairman.

MSLs are Best for Reaching MDs

According to Mario, we will see a continued blurring of the lines across biotech and big pharma. He agrees with Vagelos that the way we market products through sales reps doesn't work, and blockbusters are a thing of the past. From his vantage, specialized niche products, served by MSLs, are the future. "The MSL is the way to reach the MD," he said.

Reflecting on the importance of mentors to one's career, Mario noted, "Mentors connote student-teacher relationships. I would not tolerate relationships that weren't trusting. I tied my career to people who I felt were fast trackers. They taught me to share the sunshine, and when things did not go well, to take the heat personally. I want people around me who are hungry to do what I do."

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And conveniently, Mario was somewhat between the positions offered by his CEO colleagues on whether strong expertise in one area or broad expertise in many serves you best during your career. “Nobody lives long enough to be an expert in all the pieces…but you do need to be an expert in something. You can’t be a mile wide and a quarter inch deep.”

Pharma Marketing News

Pharma Marketing Blog

A "Must Read" Blog for Insiders. -- Wall Street Journal

Recent Posts to Pharma Marketing Blog

PhRMA Intern and the No-Strings-Attached CME Proof!

While reading her copy of the *New York Times* recently, PhRMA Intern noticed an op-ed piece by Daniel Carlat, a professor at Tufts Medical School and editor in chief of The Carlat Psychiatry Report. The piece was entitled "Diagnosis: Conflict of Interest."

PhRMA Intern remembered that Ken told her during orientation that PhRMA's Code on Interactions with Health Care Professionals assures that there are "no strings attached" to pharmaceutical company sponsored CME.

But, can she prove it?

Find out by reading **This Post to Pharma Marketing Blog**

Can an In-home Electronic Pillbox Solve Our Medication Error Problem?

Do seniors really need a $200 per month machine that looks like a bread maker -- and which is somewhat bigger than a bread box -- to dispense pills?

Will an in-home electronic pillbox solve this country's medication error problem?

Maybe the only two entities that think so are the company that invented the machine and the FDA.

For more on this and why I think this contraption won't fly, see **This Post to Pharma Marketing Blog**

The Drug Industry Needs Constructive Criticism, Not Pugilistic Put Downs

It's interesting that although almost 60% of blog readers feel that Pharma Marketing Blog is somewhat or very critical of the industry (see **Pharma Blogosphere Survey Summary**), two-thirds of our readers are themselves on the "other side of the fence"; ie, somewhat or very supportive of the industry! And 40% are employed within the industry.

I interpret this to mean that industry insiders and supporters want to learn from constructive criticism, which I hope is what I am providing.

Constructive criticism may be a great unmet need that most of the mainstream trade publications like Pharmaceutical Executive Magazine, MM&M, DTC Perspectives are NOT satisfying.

For my solution on how these publications can meet this need, and to see some results from a recent Pharma Marketing Blog reader survey, see **This Post to Pharma Marketing Blog**

Fard Johnmar Interviews John Mack on Bloggers and the Pharmaceutical Industry

In this **video interview**, Mack touches upon the credibility of pharma blogs, the effect of journalist bloggers, and the role that blogs can play in informing the industry.

View the Video Here