BY ELISABETH PENA VILLARROEL

# Representing the MASSES

Associations and organizations throughout the life-sciences industry represent their members by advocating for professional development, influencing public policy, and providing educational and mentoring opportunities for career enhancement.

The life-sciences industry's associations represent broad sectors and stakeholders varying from marketing to clinical as well as targeted segments such as businesswomen.

PharmaVOICE reached out to the CEOs, presidents, and chairs of the groups that represent the industry and asked these thought leaders to discuss the trends and challenges affecting their organizations' membership, as well as how their groups can impact change in the coming years.

According to our Forum participants, common themes include the increasing globalization of the industry and issues related to outsourcing and distance education, as well as incorporating technology to better facilitate global cooperation. On the home front, the upcoming presidential election, patent protection concerns, and work toward universal healthcare are topics that are on everyone's mind.

## Overriding Trends

*Although the heads of these industry groups represent diverse segments of the life-sciences industry, the trends that are expected to impact these organizations and their members are similar, ranging from concerns over the political environment to dealing with advances in technology.*

**GREENWOOD.** BIO. Many changes are going to happen over a fairly short time period. Obviously, we are going to have the presidential election this year. Also, we are looking toward 2015, which will be the first year that fewer dollars go into Medicare than go out. That will be a big moment for the country and Congress. Between now and then healthcare costs are going to continue to rise. The portion of healthcare that constitutes products of major manufacturers is increasing. All of these factors create an interest in putting downward pressure on expenses. We have to constantly remind policymakers that this comes at the cost of innovation, which means more will be spent on healthcare because, in the long run, all of our industries reduce the cost of healthcare instead of increasing it.

**ADAMS.** ACRP. Clearly, the election will have a major impact in terms of public policy and the pharmaceutical industry. We have a divided Congress and White House, and if this continues then we would expect the same type of debates on pharmaceutical issues that we have had over the last few years. If the Democrats

## Association Leaders

**THOMAS L. ADAMS** is President, CEO, Secretary-Treasurer, of the Association of Clinical Research Professionals (ACRP), Alexandria, Va. He is active in a number of associations and has served as an officer and director of the American Association of Medical Society Executives. An association executive for most of his career, Mr. Adams served as Executive Director of the American Society of Plastic Surgeons, President of the Medical Group Management Association, and Executive VP of the Wisconsin Medical Society before joining ACRP in January 2001. He sits on the U.S. Secretary of Health and Human Services' Advisory Committee on Human Research Protections. For more information, visit acrpnet.org.

**JONATHAN ANDRUS, MS, CQA, CCDM**, is the incoming 2008 Chair of the Society for Clinical Data Management Inc. (SCDM), Milwaukee, Wis. Mr. Andrus also serves as VP, Clinical Data Management and Regulatory Operations, at Phoenix Data Systems Inc. where he manages regulatory compliance, data management, and training. Before joining PDS, Mr. Andrus managed clinical system validations and Part 11 and HIPAA assessments, and he conducted computer system audits with Taratec Development Corp. His other professional affiliations include the DIA, the American Society for Quality, and the Mid-Atlantic Region Society for Quality Assurance. Mr. Andrus is a frequent speaker on topics related to electronic data capture, quality assurance, and regulatory, and he is an instructor with the Pharmaceutical Training Institute. For more information, visit scdm.org.

**JAY BOLLING** is President of the Healthcare Communication & Marketing Association Inc. (HCMA), Bethlehem, Pa. In addition, he serves as President of Roska Healthcare Advertising. Having overseen healthcare advertising programs for more than 20 years, Mr. Bolling is a recognized thought leader and innovator at the forefront of today's pharmaceutical marketers. For more information, visit thehcma.org.

**BRIAN FAGAN** is Executive Director of The Society of Pharmaceutical and Biotech Trainers (SPBT), Roanoke, Va. Before joining SPBT, he

**Jay Bolling**
**HEALTHCARE COMMUNICATION & MARKETING ASSOCIATION**

**Marketing to allied healthcare professionals is a major area of growth** for the industry, whether those professionals be nurses, nurse practitioners, physician assistants, or pharmacists.

retain control of both houses and gain the White House then the discussions could turn toward drug importation or potentially the government bargaining with pharma companies over prices, which could impact pharma income. This could have a negative impact on research and development in the United States and hasten the outsourcing of clinical trials away from the United States and Europe.

**MUTISYA.** HBA. One trend is progressive healthcare reform with likely accelerated change in the payer structure, more constrained reimbursement schemes, and even greater limitations on physician prescribing practices. Longer term, these changes will impact not only pricing power and sustainable cost structures, but also viable commercialization models and R&D innovation. Related to this is a second trend: growing disincentives for innovation. Specifically, these include increasing attacks on intellectual property rights, a more conservative regulatory environment with additional hurdles for truly novel compounds, and a shorter-term focus from company shareholders and the financial markets. The third trend represents a true opportunity for our industry. Increasingly, we are taking a global, more integrated approach to drug development and commercialization and using more creative partnership and alliance models to overcome hurdles and better address unmet patient needs.

**TAUZIN.** PHRMA. Trends and concerns that we all have in common include the broader question of having an America where everyone is insured and properly covered for the products our manufacturers make. Additionally, we all have in common certain key concerns. One is the strength of IP and patent protection in this country, because to a large extent the United States is where intellectual ideas are born into great medicines and devices and biologic products. If we lose the capacity to have the massive investment that occurs in this country

spent 24 years in the pharmaceutical industry in sales leadership positions. For more information, visit spbt.org.

**RONALD D. FITZMARTIN, PH.D.**, is President of the Board of Directors of the Drug Information Association (DIA), Horsham, Pa. In addition, Dr. Fitzmartin is VP, Informatics and Knowledge Management, at Daiichi Sankyo Pharma Development, the product development arm of the U.S. organization, engaged in clinical development, translational medicine and clinical pharmacology, regulatory affairs and risk management, informatics and knowledge management, biostatistics and data operations, and development research. He has held positions at Daiichi Medical Research, Purdue Pharma, the U.S. Census Bureau, the U.S. Department of the Navy, and the University of Maryland. For more information, visit diahome.org.

**JAMES C. GREENWOOD** is President and CEO of the Biotechnology Industry Organization (BIO), Washington, D.C. Since his appointment in January 2005, he has markedly enhanced the trade association's capacity — increasing both its staff and budget by almost 50%. He represented Pennsylvania's Eighth District in the U.S. House of Representatives from January 1993 through January 2005. A senior member of the Energy and Commerce Committee, he was widely viewed as a leader on healthcare and the environment. From 2001 to 2004, Mr. Greenwood served as Chairman of the Energy and Commerce Committee Subcommittee on Oversight and Investigation with oversight authority over issues in the committee's vast jurisdiction. Before his election to Congress, Mr. Greenwood served six years in the Pennsylvania General Assembly (1980-1986) and six years in the Pennsylvania Senate (1986-1993). For more information, visit bio.org.

**MARK B. LEAHEY, ESQ.**, is the Executive Director of The Medical Device Manufacturers Association (MDMA), Washington, D.C. His responsibilities include advocating on behalf of the entrepreneurial sector of the medical-device industry to Congress, the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services

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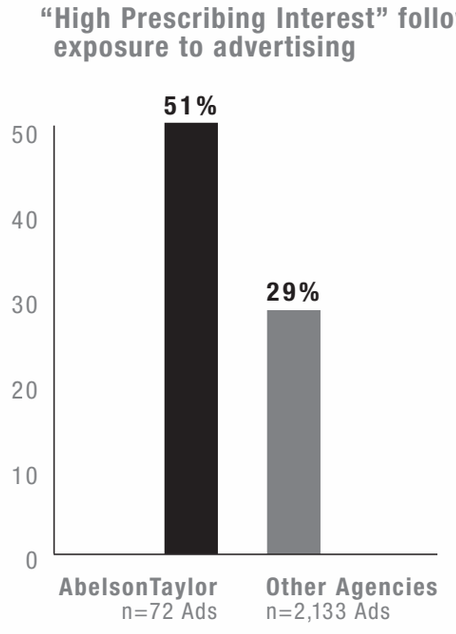


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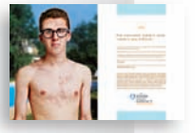

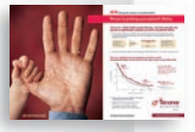


**All of us serve and represent patients**; they stand at the apex of our concerns and the concerns of Congress.

**Billy Tauzin**
**PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA**

behind that discovery and innovation, this country, as well as the world, will suffer.

**PEDDICORD.** ACRO. Obviously, one of the biggest trends is that clinical research and drug development will continue to become increasingly globalized. For ACRO, this means our efforts representing the industry will be similarly globalized. We already have established relationships with U.S. and European regulators and we are beginning to develop contacts and relationships with regulators and policymakers around the world. For instance, we just had initial meetings with the SFDA in China as well as the Ministry of Health in China, and we have had similar conversations with the Drugs Controller General in India.

**FITZMARTIN.** DIA. In drug discovery, pharma has embraced technology as rapidly as it can. In clinical development, dealing with the compliance and validation issues can take longer than the technology cycle. In six months there's going to be new technology. There is an impetus to get out of the siloed mentality and into using more interoperable systems. Platform technologies are certainly in vogue. We could talk about software as a service (SaaS). Years ago, pharma companies didn't share their technologies because of competitive advantage. Back then, companies developed technologies in house. Today, companies have access to the same technologies. When RDE, remote data entry, was first done in the early 1970s, it was very crude but the concept was there. Today, we've renamed it EDC, electronic data capture, and this is being used in about 25% of all clinical trials. Here we are, 34 years later, and some people are still saying, "Paper is better; paper is faster." The use of EDC and technology in clinical research will have a resurgence as the demand for adaptive trials continues and as we look to integrate or harvest data from electronic health records.

**ANDRUS.** SCDM. We are at, or beyond, the midway point of embracing and adopting electronic technology in the clinical-trials space. The trends that are going to impact the sector are the burgeoning new technologies and the potential convergence of electronic and medical health records with EDC.

**FAGAN.** SPBT. Based on our 2007 benchmark study, we know that training departments have developed more formalized development programs for their senior sales management, regional, and district managers. Marketing training also has become an area of focus. In 2005, only 14% of organizations offered training for brand managers. Today, 43% provide that training, another 7% plan to add this offering in the next year. Another trend is more measurement. Today, learning and development departments are armed with better tools to capture post-training data than in the past. For example, new technology on the market is allowing training departments to pool performance data, test results, financial data, and other metrics to create dashboards. Using dashboards, trainers and managers can view an employee's performance on test scores, time to completion, and compliance on policy exams. Finally, another trend is the changing business model. The share-of-voice model will expire. There is much experimentation taking place to determine ways in which the industry can regain trust and bring value to its customers and patient care. Training will change as the systems and models in organizations change.

## Growth Areas: Internal Impact

*Given the trends and challenges expected in the industry over the next few years, industry*

## Association Leaders *(continued from page 9)*

(CMS), and other federal agencies. Mr. Leahey lobbied for a more reasonable user fee for small companies, worked to open access to the hospital marketplace by challenging the exclusionary and anticompetitive nature of large group purchasing organizations (GPOs), as well as ensured that medical-device technology is reimbursed at adequate rates. Before his appointment to executive director in 2002, Mr. Leahey served as the association's Director of Federal Affairs. For more information, visit medicaldevices.org.

**ELIZABETH M. MUTISYA, M.D.**, is the 2008 President of the Healthcare Businesswomen's Association, Fairfield, N.J. Dr. Mutisya, who has held senior roles in the pharmaceutical industry, is currently a consultant at McKinsey & Company. For more information, visit hbanet.org.

**DOUGLAS PEDDICORD, PH.D.**, is Executive Director of The Association of Clinical Research Organizations (ACRO), Washington, D.C. Following a career as a clinical psychologist, he was an American Association for the Advancement of Science (AAAS) Fellow in the U.S. Congress in 1994-1995. Dr. Peddicord speaks frequently on the subject of the particular role of the CRO (along with the sponsor, investigator, IRB, and regulator) in the system that provides for the protection of human research participants, as well as on broader issues relating to the conduct of clinical research, including health information privacy, financial conflicts of interest, and the globalization of clinical trials. For more information, visit acrohealth.org.

**LYNN SHAPIRO SNYDER, ESQ.**, is the Founder and President of the Women Business Leaders of the U.S. Health Care Industry Foundation (WBL). In addition to founding WBL, Ms. Snyder is a senior member in the Washington, D.C., office of the national law firm, Epstein Becker & Green, PC. She serves on the

**Mark Leahey**
**THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION**

**The United States is not the manufacturing economy it was 20 years ago.** America is an innovation economy, and we have to make sure we keep a competitive advantage around the world.

*associations are looking to focus and grow not only to prepare for, but to effect change, for their members.*

**FITZMARTIN.** DIA. Eastern and Southern Europe, Japan, India, China, Canada, Latin America, the Middle East, and South Africa present new business opportunities and challenges. Increasing our portfolio of educational offerings within each region remains a priority. In 2007-2008, the strategic planning initiative will focus on the expansion of DIA into India and China. The board of directors approved a business plan for India, and DIA will execute it this year. We are in the process of developing a business plan for DIA in China.

**GREENWOOD.** BIO. In terms of the remainder of this Congress, patent reform legislation is what we are focusing on, and so far what the House has passed and the Senate has under consideration are very infringer friendly and threatening to our industry. In the broader term, we are focused on slaying dragons. Congress is looking at the baby boomers heading into Medicare, and members of Congress see dragons on the horizon. They think written across the chests of the dragons is "hospital costs," "device costs," "doctor costs," and "medicine costs." They think they have to slay these dragons. As these dragons get nearer, they will see the writing actually says "cancer," "cardiovascular disease," and "diabetes." And we, meaning the bio companies, are the ones who are slaying those dragons, so if we can all work together instead of pointing fingers, we will succeed.

**ADAMS.** ACRP. Trying to understand the different needs that the different segments of our membership have is very important. With an umbrella organization such as ACRP, trying to keep our programming relevant for each segment of the membership is a challenge. Likewise, the globalization of the industry, in terms of being able to provide different levels of education in many different locations in a cost-effective and timely manner, is a challenge.

**MUTISYA.** HBA. I want to make sure that we thoroughly understand our members' and stakeholders' needs and adjust our programs and offerings to deliver useful, highly relevant value to enable them to achieve their full potential. We need to leverage our global position to elevate the dialogue about leadership development issues, particularly as they relate to women. Our goal isn't just to describe the problem. We are committed to partnering with healthcare companies and providing data-driven recommendations to help them create or refine effective leadership development and retention initiatives.

**PEDDICORD.** ACRO. Our principal interest is positioning the CRO industry as a positive resource for regulators and policymakers and as a key stakeholder in the drug-development enterprise. The CRO industry is involved in 40% to 50% or more of clinical trials worldwide, so we have emerged as an important stakeholder to which regulators and policymakers can reach out. It is increasingly important for the CRO sector to have a global voice that is reasonably unified or harmonized in dealing with regulators and policymakers. One of our goals is to be an umbrella organization not only for global CROs, but for CROs of all sizes and in all locations so we can coordinate messages about the importance of our industry.

**BOLLING.** HCMA. We are looking at distance learning and will have a very robust Web presence that allows people to gather information and access various learning opportunities on their time. The needs of our constituency are

firm's board and finance committee. She has almost 30 years of experience at the firm advising clients about federal, state, and international health law issues.
For more information,
visit womenleadinghealthcare.org.

**BILLY TAUZIN** is President and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA), Washington, D.C., a post he assumed in January 2005 at which time he immediately took up two of the most important causes of his career: to help ensure patients everywhere continue to have access to medicines, and to ensure that innovative biopharmaceutical research thrives, improving and saving lives everywhere. He knows firsthand what patients face as they search for hope, treatment, and cures having recently battled cancer himself. Mr. Tauzin has a long and distinguished public service career, including 13 terms representing the people of the 3rd Congressional District of Louisiana. He began his public service career in the Louisiana State Legislature where he served in a variety of distinguished posts such as Chairman of the House Natural Resources Committee and Chief Administration Floor Leader. He was chosen twice as one of Louisiana's Ten Best Legislators. He was first elected to the U.S. House in 1980 as a Democrat. Because his conservative views increasingly led him to vote with GOP House members despite his Democratic affiliation, he switched parties in 1995. In September 1995 he was named Deputy Majority Whip; he is the first American to have been part of the leadership of both parties in the House. In an effort to promote a spirit of bipartisan cooperation on Capitol Hill, he cofounded and served as Co-Chairman of the Mainstream Conservative Alliance, better known as Republican Blue Dogs. Until February, 2004, he served as the Chairman of the influential House Committee on Energy and Commerce. For more information,
visit phrma.org.

different from five years ago, and the way our members work is different. We can't assume the way people in biotech work and the challenges they face are the same as those in big pharma. Our goal is to have the depth to bring forth the types of benefits a strong national organization provides and localize this mission in key markets, customize the offerings to the needs of the people in those markets, allow them to gain education locally, and understand what is going on in their areas.

**LEAHEY.** MDMA. Our agenda always focuses on delivering the best product for the patient. That starts with innovation and making sure there are policies in place to make that possible. Top priority for closing out this Congress is patent reform and making sure we move a bill that enhances the quality of the patent and doesn't undermine the patent that was issued to the point where it provides carte blanche for manufacturers in India or China to copy the product and undercut the investment and incentive for innovation. Another focus for us is looking at the cost of healthcare and the short-term cost of the product versus the overall value to the healthcare system and making sure that mes-

## FACE-TO-FACE-TO-FACE LEADERSHIP

*Jim Greenwood, BIO, Billy Tauzin, PhRMA, and Mark Leahey, MDMA, convene to discuss common industry challenges.*

**At the Biotech 2007 conference hosted by the Biotech Council of New Jersey and PA Bio in Philadelphia in October, Taren Grom, Editor of PharmaVOICE, spoke with James C. Greenwood, President and CEO of the Biotechnology Industry Organization (BIO), Mark B. Leahey, Esq., Executive Director of The Medical Device Manufacturers Association (MDMA), and Billy Tauzin, President and CEO of Pharmaceutical Research and Manufacturers of America (PhRMA). This marked the first time the heads of these three industry organizations had attended the same meeting.**

**During the interview, these leaders discussed some of the common misconceptions the general public has about the life-sciences industry and what can be done to change the dialogue to improve the industry's perception by the American public.**

"One of the greatest concerns expressed by Americans is the desire to find a cure for cancer. That is so important to the American public. What they don't understand is that a huge investment in private dollars into the companies that we represent is needed to accomplish this goal. That means that pension funds, day traders, and mutual funds have to invest in our pharmaceutical and biotechnology companies. Those decisions are not based on love of our technologies; they are based on the expectation of a return on investment. It is very easy for Congress and the general public to say we don't want bio companies to make much money, but if we are not profitable, the private investment will move to automobiles, chemicals, or somewhere else and we won't find the cure for Alzheimer's disease or cancer. And until people accept this premise and recognize the value that the industry provides, we are always going to be on the defensive."

—Jim Greenwood, BIO

"It is important for folks to understand that while some pharmaceutical, biological, or device companies are very profitable, 90% of the products that start at the bench never make it to the bedside and that there is a significant cost associated with development. We would be very fortunate if most of our companies even had portfolios that were 20% successful. There is no guarantee a company will develop a blockbuster. This is important for patients and lawmakers to understand. Development is a long process and it takes many years and a lot of investment to make sure these products go from bench to bedside."

—Mark Leahey, MDMA

"In 1965, the percentage of the healthcare dollar spent on medicine was 10%. It is still 10% today. The percentage of product recalls in the market was 3%. It is still 3% today even with the more complex, difficult medicines; but 3% is too much. We have to get that number down, but the bottom line is that 97% of the medicines that are approved by the FDA do exactly what they were thought to do in terms of efficacy. I have learned as a cancer patient that the drug I took worked differently in my body than in my neighbor's. Patients know this but the American public doesn't necessarily understand. They think when the FDA approves a product it is going to work the same in every body. We are learning how different we are even though we are so much the same. We are learning how disease operates and how side effects might be different in one patient than another. Those are lessons we as Americans have to learn if we are going to support a system that expedites rather than delays new discoveries that are going to save lives."

—Billy Tauzin, PhRMA

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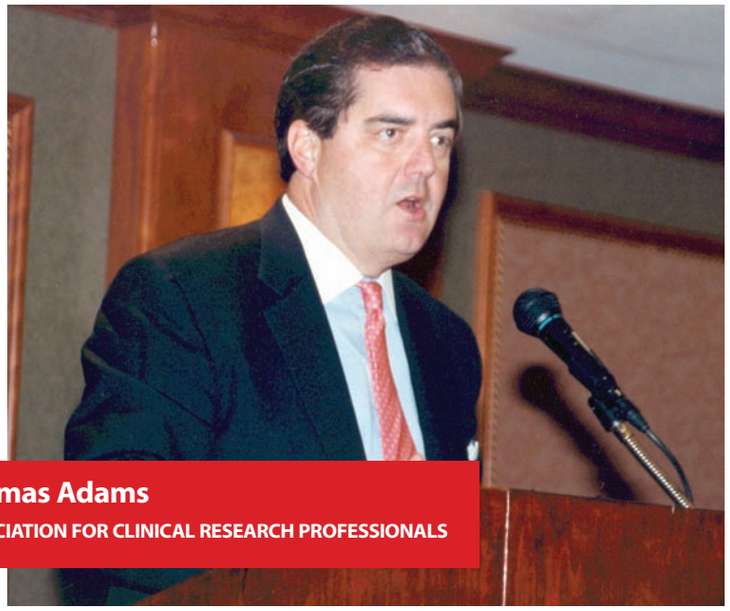

**Thomas Adams**
ASSOCIATION FOR CLINICAL RESEARCH PROFESSIONALS

**We have made a significant commitment** to being responsive to clinical-research teams globally and becoming a truly global organization.

**Lynn Shapiro Snyder**
WOMEN BUSINESS LEADERS OF THE U.S. HEALTH CARE INDUSTRY FOUNDATION

**The greatest challenge facing senior executive women from the healthcare and life-sciences industry** is one of visibility as potential board members to serve in for-profit companies throughout the entire economy.

**Dr. Elizabeth Mutisya**
HEALTHCARE BUSINESSWOMEN'S ASSOCIATION

**The biggest growth areas in healthcare** relate to increasing globalization, demographic changes with respect to rising age and population size, and growing healthcare spend and purchasing power, particularly in emerging markets such as India and China.

sage is understood by people on Capital Hill, patients, and others in the policy realm. The third focus for us is working with the FDA to make sure there is enough oversight to give patients the confidence that the FDA is vigorous in its review but also that reviews are done in a timely manner so millions of patients aren't waiting for these innovative technologies.

**ANDRUS.** SCDM. Providing Web-based educational opportunities and training is a trend for our sector because as the world shrinks and outsourcing becomes more frequent and technology changes are rapidly occurring we need to deliver relevant, time-sensitive products and services. For example, we have a lot of interest across the globe in topics and information that we are sharing. We have to provide opportunities for people to tie into those events and to derive benefits, whether they be Webinars that provide information on project management skills for the clinical data manager or acceptance testing or validation that helps them deal with the continued use and expansion of technology in the clinical trials space.

**SNYDER.** WBL. In the coming year, WBL will continue working to educate all business executives on the fact that women are the No. 1 consumers and a majority of the employees of most healthcare and life-sciences companies. Despite this fact, women are not adequately represented at the corporate board level of these companies. Even outside the healthcare and life-sciences sector, women do not have adequate representation at the board level. Women continue to fill only 14.7% of Fortune 500 board seats. Another goal is educating executives and current board members that having more women represented on corporate boards is not merely a best practice; it has become a financial and governance imperative. Including one woman is not sufficient. Indeed, research shows that three women are required for governance and boardroom dynamics to really change.

**TAUZIN.** PHRMA. We are all conditioned to look at things through the eyes of patients. If it is good for patients, we are for it. We have instituted reforms designed to build up policy objectives around this. The biggest concern is IP protection. Patients need to have the assurance that the pipeline of discovery continues to be filled with great new products and the knowledge that we are working day and night to save lives of patients across America. Protecting the investment model and making sure people understand if we stop investing in the science behind these products, people die and people suffer who don't have to. Secondly, we are focusing on reforming the healthcare system in America; we are going to be big players in that. Thirdly, we have to build a case on the industry's value but we can only do that if we work on the front end and change the healthcare system so that everyone benefits.

**FAGAN.** SPBT. More medical device and diagnostics companies are interested in sharing best practices around training. We think pharma can learn from these companies, which have traditionally invested a lot in training high-caliber salespeople because of the sophis-

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Inspiration to find creative solutions.
And the proactivity to deliver in real-world settings.

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**LATE PHASE**

ticated nature of their products. Over the last two years, we've added two training directors from device companies to our board. Another growth area for us will be individuals who have training responsibilities are based in the field rather than at the headquarters. Complex regional differences and the changing role of the representative are the reasons for this move.

## Needs and Resources

*To meet the challenges ahead and stay on course, leaders of the industry's organizations and associations are constantly listening to their members so they can provide the resources and solutions needed for success.*

**BOLLING.** HCMA. Distance education and online learning are ways to address the biggest needs of the members in our constituency, which are around career development and training. People are moving from the salesforce and into marketing, and they are moving between companies and between industries — from the service sector to the industry sector. The goal of the organization is to become a focal point, a national clearing center, that allows people to maintain a standardized career development and training program throughout their professional lives, whether they are switching jobs, companies, or industries.

**MUTISYA.** HBA. Our member companies' needs include attracting promising candidates in the ongoing war for talent. A second challenge is identifying high-potential individuals within their own organizations, providing them with appropriate developmental opportunities, and retaining them. Third, many of our member companies wrestle with building a deep leadership bench of capable, gifted individuals with complementary strengths and skills who can meet their evolving needs.

## BACKGROUND ON THE INDUSTRY'S BACKBONE

**The many industry organizations featured in this article represent the life-sciences industry's many varied members and sectors. The following is a brief history of these groups and their missions.**

### ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS (ACRO)

ACRO is the professional organization of companies whose focus is clinical research. Founded in 2002 by leading clinical research organizations (CROs) that provide specialized services integral to the development of drugs, biologics, and medical devices, ACRO, Washington, D.C., provides an active voice for the CRO industry. The association works to provide a heightened awareness of the critical role CROs play in medical product development, and it is an active participant in policy discussions around regulations, legislation, and other policy initiatives that may impact the CRO industry, both in the United States and globally. For more information, visit acrohealth.org.

### ASSOCIATION FOR CLINICAL RESEARCH PROFESSIONALS (ACRP)

ACRP, Washington, D.C., was founded in 1976 to address the distinct educational and networking needs of research nurses and others who support the work of clinical investigations. With its own professional society came the recognition of a new distinctive profession — that of the clinical researcher. More than 25 years later, ACRP is an international association comprised of more than 20,000 individuals dedicated to clinical research and development. ACRP's mission is to provide global leadership to promote integrity and excellence for the clinical research profession. For more information, visit acrpnet.org.

### BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. BIO also produces the annual BIO International Convention, the global event for biotechnology. For more information, visit bio.org.

### DRUG INFORMATION ASSOCIATION (DIA)

The DIA, founded in 1964, has evolved from a founding group of 30 professionals employed in academia and the pharma industry into a multidisciplinary organization with members in more than 80 countries. The professional association is comprised of more than 18,000 members worldwide who are involved in the discovery, development, regulation, surveillance, and marketing of pharmaceuticals or related products. DIA, Horsham, Pa., is committed to the broad dissemination of information among its members, with continuously improved professional practice as the goal. For more information, visit diahome.org.

### HEALTHCARE BUSINESSWOMEN'S ASSOCIATION (HBA)

The HBA, which was recently named one of the Top 100 Leadership Development Programs in the United States, is a global organization dedicated to furthering the advancement of women in the healthcare industry. The HBA was formed in 1977 when five professional women recognized the need for women in healthcare to come together to exchange industry and career information and resources. Today, the HBA empowers its almost 4,000 members to achieve their full potential by providing educational opportunities to develop cutting-edge industry knowledge and leadership skills; recognizing outstanding women in the industry; providing opportunities for networking; creating greater visibility for women in the industry; fostering mentoring relationships, and serving as a conduit for research on career advancement issues. For more information, visit hbanet.org.

### HEALTHCARE COMMUNICATION & MARKETING ASSOCIATION INC. (HCMA)

The Healthcare Marketing & Communications Council Inc. (HMC), Medical Marketing Association Inc. (MMA), and Midwest Healthcare Marketing Association (MHMA) have consolidated their respective resources into one national organization, which is being established to better serve the needs of healthcare marketing, communications, and

**ADAMS.** ACRP. From what we see at our exhibition, certainly human resources is a key issue, and that is true for both CROs and pharmaceutical companies. Clearly, trained researchers and potentially the financing of research and development, depending on what happens politically in the upcoming elections in the United States, are key issues for our sector of the industry.

**FITZMARTIN.** DIA. We should be on the forefront of delivering information to our members when and how they want it. That is why we will continue to improve and explore new technologies that will help to overcome geographic boundaries and time differences and advance education for our members about drug development and clinical research throughout the world.

## Working Together

*Given the commonalities shared by many of the industry's representative organizations, the leaders interviewed by PharmaVOICE share how they work with other presidents and CEOs of the major industry associations to move the industry forward.*

**PEDDICORD.** ACRO. We collaborated with our colleagues at PhRMA and BIO and other industry associations last summer with regard to the export of biological samples out of Russia. There was a period of several weeks where Russian authorities were prohibiting the export of biological samples that were part of clinical trials. ACRO joined with PhRMA and BIO and others to defend and advance the interest of our industry against an action on the part of authorities that had the potential to interfere with good practices. We are developing contacts with several other associations, such as EFPIA and ABPI in Europe, and we are following the emergence of CRO associations in other parts of the world as well. We look to collaborate with those client associations and other

education professionals in the manufacturing and service sectors. The HCMA serves a national constituency and provides a comprehensive offering of educational resources (programs/services) across all career phases; standardized training and accredited programs; networking and mentoring opportunities; and national recognition of excellence in marketing, communications, and education. For more information, visit thehcma.org.

**MEDICAL DEVICE MANUFACTURERS ASSOCIATION (MDMA)**

MDMA was created in 1992 by a group of medical-device company executives who believed that the innovative and entrepreneurial sector of the industry needed a strong and independent voice in the nation's capital. Since its inception, MDMA can claim credit for a number of policy achievements, from the defeat of legislative proposals to foist user fees upon the industry in 1993 and 1994 to the development and passage of the landmark FDA Modernization Act of 1997. MDMA is a national trade association that represents independent manufacturers of medical devices, diagnostic products, and healthcare information systems. For more information, visit medicaldevices.org.

**PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA)**

PhRMA, Washington, D.C., represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies, which are leading the way in the search for new cures, invested an estimated $43 billion in 2006 in discovering and developing new medicines. PhRMA's mission is to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical/biotechnology research companies. For more information, visit phrma.org.

**SOCIETY FOR CLINICAL DATA MANAGEMENT INC. (SCDM)**

Founded in 1994, SCDM is a clinical data management society with more than 2,000 domestic and international members. Membership includes professionals from the biotechnology, medical-device, and pharmaceutical industries; the academic, regulatory, and scientific research communities, and third-party organizations that support these groups. SCDM, Milwaukee, Wis., is a nonprofit professional society founded to advance the discipline of clinical data management. The binding interest of all members is quality clinical data management practices. For more information, visit scdm.org.

**SOCIETY OF PHARMACEUTICAL AND BIOTECH TRAINERS (SPBT)**

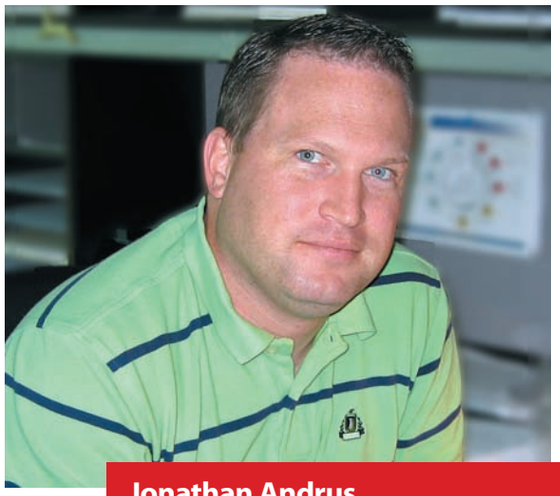
SPBT, Roanoke, Va., was established in 1971 and originally named the National Society of Pharmaceutical Sales Trainers. Today, SPBT has a membership of more than 1,200 training professionals employed by more than 300 companies around the globe. SPBT is a worldwide nonprofit organization aimed at supporting training professionals at pharmaceutical, biotech, medical device, and medical diagnostic companies by providing the resources training professionals need to excel, personally and professionally. For more information, visit spbt.org.

**WOMEN BUSINESS LEADERS OF THE U.S. HEALTH CARE INDUSTRY FOUNDATION (WBL)**

WBL, Washington, D.C., is a nonprofit organization established in 2001 to address the unique needs of women serving in a senior executive or board capacity in the U.S. healthcare industry. The goals of the foundation are to help senior executive women in the healthcare industry improve their businesses and continue to grow professionally. The foundation's objectives include: facilitating networking opportunities for senior executive women and women board members in the healthcare industry; increasing the visibility of senior executive women and women board members in the healthcare industry; expanding the number of senior executive women in the healthcare industry; and expanding the number of senior executive women who serve as members of boards of directors. For more information, visit womenleadinghealthcare.org.

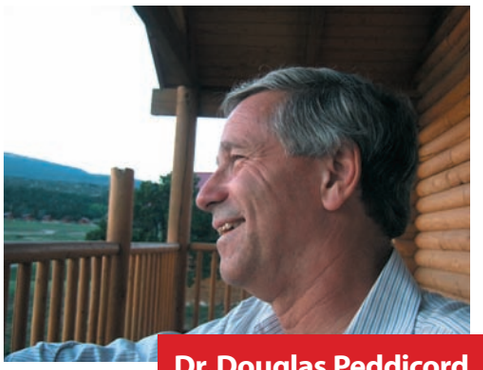
**James Greenwood**
BIOTECHNOLOGY INDUSTRY ORGANIZATION

**The challenge is to achieve the iron rectangle of healthcare:** access, affordability, quality, and innovation. In America, our challenge is to solve the access and affordability issue without sacrificing quality and innovation.



**Jonathan Andrus**
SOCIETY FOR CLINICAL DATA MANAGEMENT

**We are at, or beyond, the midway point** of embracing and adopting of electronic technology in the clinical-trials space.



**Dr. Douglas Peddicord**
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

**One of the biggest trends is** that clinical research and drug development will continue to become increasingly globalized.

CRO associations to work with regulators and policymakers as well as the media.

**GREENWOOD.** BIO. Our ability to function not just as an individual organization, but as a coalition with other industry groups and with other healthcare providers is vital as Congress and the next President become increasingly focused on trying to ratchet down reimbursement. We are going to have to be a very strong coalition.

**BOLLING.** HCMA. We have started to form liaisons with other groups, such as The Coalition for Healthcare Communication, PhRMA, and the Diagnostic Marketing Association (DxMA); we are very interested in collaborating with the different groups in our industry. But I truly think the best way that we can help the industry is by promoting standards and best practices, ensuring that a consistent message is delivered, and providing applicable learning.

**LEAHEY.** MDMA. There is a convergence of devices, biologics, and pharmaceuticals in developing therapies. The challenge that all of our member companies are facing is how to bring the technology to the market. There are certain significant policy changes that are needed, and working together as organizations we have a great opportunity to improve the quality of care for patients.

**ADAMS.** ACRP. We maintain liaisons with various trade groups, and globally we have worked quite closely with the Royal College of Physicians Faculty of Pharmaceutical Medicine in the United Kingdom. It is more a matter of being aware of what is impacting other associations as opposed to working closely together because we all represent very different parts of the industry.

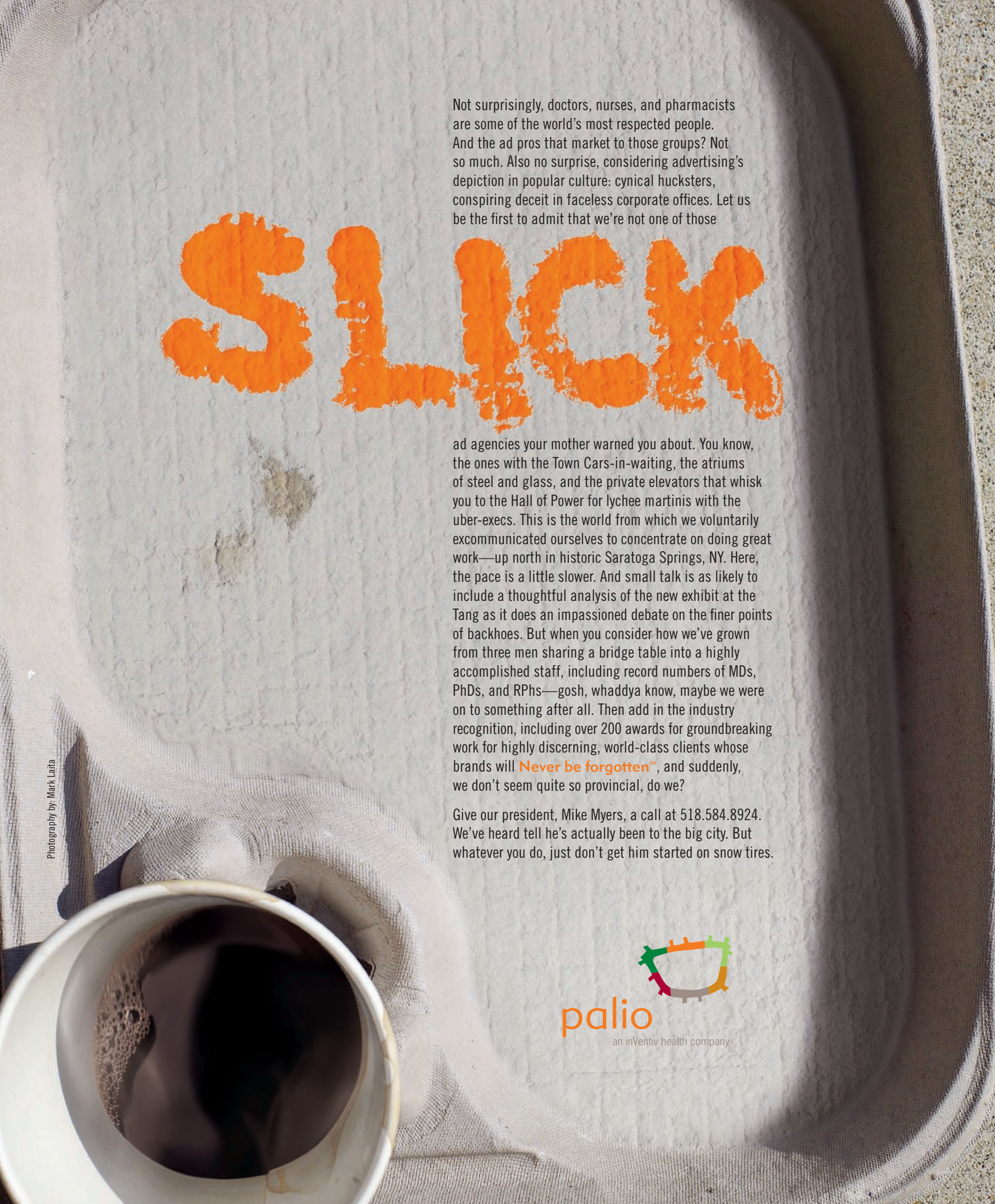
**ANDRUS.** SCDM. We are working with other industry groups, and we have had for a number of years a committee within the society called external relations. We continue to expand our relationship with CDSIC. We are supporters of the CDASH initiative both in human capital by providing resources and also through financial capital. We also have a relationship with DIA; we recently did a joint Webinar on project management and are partnering more from a marketing perspective, and sharing services and products. We have people in our organization who focus just on our relationships with PhRMA, the FDA, the International Network of Clinical Data Management Associations (INCDMA), and others to make sure what we are doing is aligned with what they are doing. We also strive to work together and come together in cross association activities to provide benefit to their members as well as ours.

## Specific Challenges

*When looking at the big picture, the industry's groups share similar challenges, but when it comes to the agendas for these associations and their member companies, the challenges are more specific and diverse.*

**LEAHEY.** MDMA. In telling the industry's story, those who have been patients or who have loved ones who are patients and have seen the miracles our products provide understand our message. For those who aren't part of the system, explaining the positive impact that our medicines and devices have on the quality of care is not something that we can easily put on a bumper sticker. This is a challenge. As more people are impacted by a personal issue and see the real miracles that occur because of pharmaceuticals and medical devices, the more the dialogue will become a true back and forth.

**TAUZIN.** PHRMA. The simplest route to solving our image problem is getting people insured in America, and this is our biggest challenge. Generally, people get angry at pharmaceutical companies because they are uninsured, are paying full price for medicines, or are paying higher and higher copays. If everyone in the country were eventually covered with a good insurance program there would be less angst and anger toward the companies that discover these new products and medicines and there would be a much better environment to tell the stories about the miracles of these products.



Not surprisingly, doctors, nurses, and pharmacists are some of the world's most respected people. And the ad pros that market to those groups? Not so much. Also no surprise, considering advertising's depiction in popular culture: cynical hucksters, conspiring deceit in faceless corporate offices. Let us be the first to admit that we're not one of those

# SLICK

ad agencies your mother warned you about. You know, the ones with the Town Cars-in-waiting, the atriums of steel and glass, and the private elevators that whisk you to the Hall of Power for lychee martinis with the uber-execs. This is the world from which we voluntarily excommunicated ourselves to concentrate on doing great work—up north in historic Saratoga Springs, NY. Here, the pace is a little slower. And small talk is as likely to include a thoughtful analysis of the new exhibit at the Tang as it does an impassioned debate on the finer points of backhoes. But when you consider how we've grown from three men sharing a bridge table into a highly accomplished staff, including record numbers of MDs, PhDs, and RPhs—gosh, whaddya know, maybe we were on to something after all. Then add in the industry recognition, including over 200 awards for groundbreaking work for highly discerning, world-class clients whose brands will **Never be forgotten**℠, and suddenly, we don't seem quite so provincial, do we?

Give our president, Mike Myers, a call at 518.584.8924. We've heard tell he's actually been to the big city. But whatever you do, just don't get him started on snow tires.

Photography by: Mark Laita

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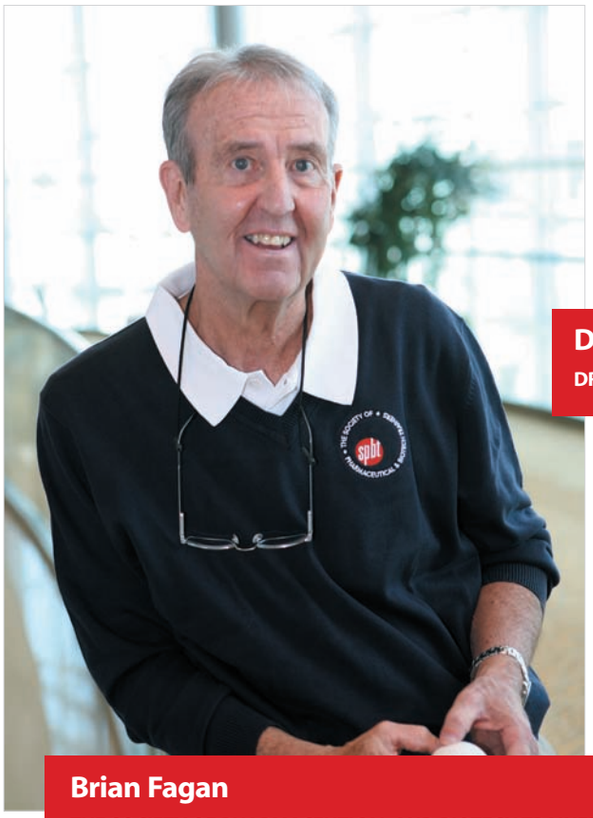
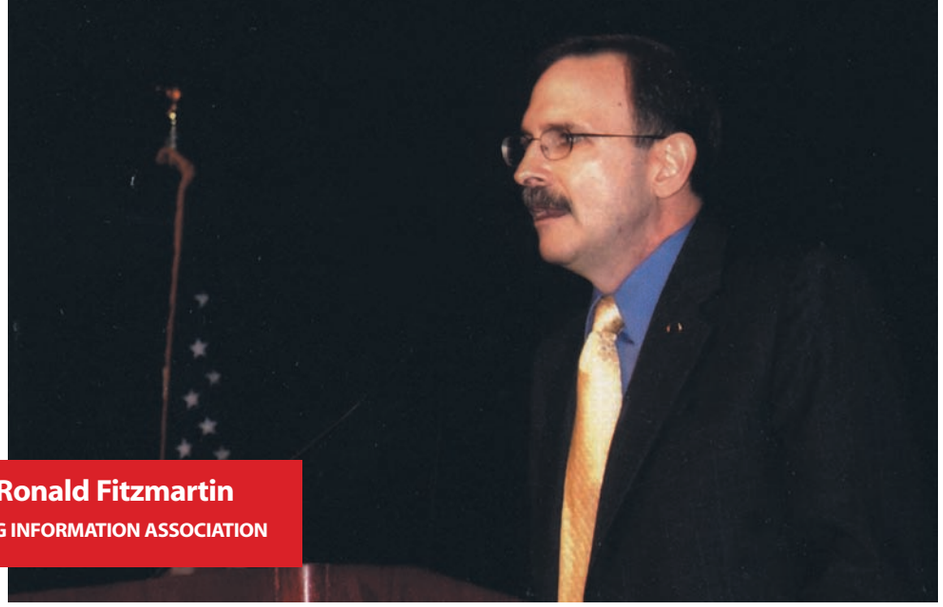


**Brian Fagan**
THE SOCIETY OF PHARMACEUTICAL AND BIOTECH TRAINERS



**Dr. Ronald Fitzmartin**
DRUG INFORMATION ASSOCIATION

**We can help move the industry forward by** helping the communities we serve to view our member organizations strategically in a way that uses the association as an asset for services and resources that they cannot provide individually.

**MUTISYA.** HBA. We are a growing organization of almost 4,000 members across a wide geography and in a number of different sectors of the healthcare industry. One challenge is to ensure that our offerings continue to be highly valuable and relevant to our increasingly diverse membership. No less important, I want to make sure that our members remain actively engaged in the association and continue to feel that they are a central part of a tightly knit community of like-minded professional women and men. About 40% of our members are active, dedicated volunteers, a ratio that is significantly higher than the average membership association. There is tremendous value derived from being an active volunteer, for example, broadening one's leadership skills set and developing a deeper, more meaningful set of professional connections.

**FAGAN.** SPBT. As a nonprofit organization, we need to focus on a few core areas and execute them well. We need to define our customers and stay relevant to those customers by understanding the trends that affect the training community and provide services and resources that bring value to our membership. Since the marketplace is more complex, the expertise that our members need is constantly changing. Our benchmark data reveal that the majority of companies are actually increasing their trainer headcount, even as salesforces are shrinking. Another challenge is related to technology. Just like our member companies, we struggle to identify the best places to use it to meet our objectives. Our challenge at SPBT, because of the sheer volume of information related to training and healthcare, will be to filter that information in a way that brings value to our community.

**One of our primary objectives focuses on** the continual innovation of our educational offerings and increasing educational opportunities in all markets.

**SNYDER.** WBL. The key challenge in moving forward is whether corporate boards will embrace gender diversity as a priority in new board member selection. WBL also works to establish the inclusion of a healthcare industry expert — male or female — as a best practice for corporate boards and to debunk the myth that the most appropriate board member always is a sitting CEO. The healthcare and life-sciences industry is a source of many divisional presidents and other C-suite executives who could be excellent board members. WBL makes these issues known to board members through publications and outreach programs, reaching out to media, corporate executives, and board search firm personnel. Additionally, WBL publishes a report identifying key trends among senior executive women who are part of our network, trends that may make these women excellent potential board candidates.

**ANDRUS.** SCDM. A challenge is trying to continue to invoke the support and volunteerism of more members of the society to get more people involved. Also, we are working to ensure that our product portfolio and the services that we provide to our members remain fresh and current and that the resources that are needed are available. We can't just take our products and stick them on a shelf; we have to constantly look for ways to improve them, make them relevant, make them current, and make them in a way that helps provide the resources that clinical data managers need to be successful.

**FITZMARTIN.** DIA. The pharmaceutical industry continues to globalize. This is a challenging, yet promising, new development. As a neutral, international organization serving multiple constituents, the DIA deals with unique challenges every day. As we look to expand globally and serve individual communities, we have developed multiple task forces aimed at working to understand specific areas of growth. Because the DIA has such a diverse membership, we are able to interact with a global audience to determine common interests so that we are able to provide the right information, at the right place, at the right time.

**GREENWOOD.** BIO. It is easy to make the industry, the drug companies, and hospitals scapegoats for the rising cost of healthcare, but about 75% of chronic diseases result from the choices people make. If we really want to make an extraordinary difference in the cost of healthcare, our challenge is to tell people they have to look at their tobacco consumption, their alcohol consumption, their diet, their exercise, and so on. That is where most of the savings lie. ✦

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

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