It's more important than ever that strong patient protections are in place and stringent ethical standards are observed around the world.

ACRO's Chair

JEFFREY MCMULLEN

Addresses Global Drug Development Challenges

During his reign as ACRO Chair in 2007, CRO veteran Jeffrey McMullen's goal is to elevate the public's perception around drug development and elevate the organization's role as a leader around patient safety, regulatory issues in the United States and abroad, and the development of research best practices.

CAREER Highlights

Jeffrey P. McMullen has been a director of PharmaNet Development Group Inc., Princeton, N.J., since June 2005 and CEO since December 2005 and President since March 2006. Mr. McMullen cofounded PharmaNet Inc. in 1996. Before becoming President and CEO of PharmaNet Inc. in 2004, Mr. McMullen held the positions of President and Chief Operating Officer in 2003, Executive VP and Chief Operating Officer in 2001, and Senior VP, Business Development, in 1996.

For more information, visit pharmanet.com.

In December 2006, Jeffrey McMullen, president and CEO of PharmaNet Development Group, was elected chair of the Association of Clinical Research Organizations (ACRO), Washington, D.C. (For more information about ACRO, visit acrohealth.org.) He is joined on the board by David Spaight, president of MDS Pharma Services, who is serving as chair-elect of the association. ACRO, which is celebrating its fifth anniversary, represents the clinical outsourcing industry to regulators, biopharmaceutical clients, policy makers, and the public in the United States and worldwide.

With more than 30 years in the drug development industry, including international experience in Europe, Japan, South America, and Asia, Mr. McMullen is well-versed in addressing global issues related to clinical studies. His professional experience also includes 13 years with major drug development services companies as VP of business development and director of clinical research, and nine years at Sterling Drug, which is now a part of Sanofi-Aventis, in the clinical, regulatory, and drug metabolism areas.

According to Mr. McMullen, CROs have a concentrated focus, one that is concerned with the design, conduct, and administration of clinical trials and testing a medicine or medical device to determine if it performs as intended.

"All of a CRO's talents, all of its skills, are focused in testing products safely and gathering the data necessary to reach accurate scientific conclusions about their performance and side effects," he says.

In an exclusive interview with PharmaVOICE, Mr. McMullen discusses his plans to maintain ACRO's mission to educate stakeholders on the benefits of clinical outsourcing and the expertise CROs provide in the conduct of safe and effective clinical studies.

ACRO Industry Collaborations

April 2007 — ACRO joins The Coalition for a Stronger FDA, which brings together a diverse group of patient groups, nonprofit organizations, consumer advocates, public health organizations, and innovative companies to work together to increase public support for the FDA. The Coalition is designed to be a multi-year effort to make sure the FDA has sufficient resources to protect patients and consumers and maintain and build public confidence and trust in the FDA. For more information, visit fda-coalition.org.

March 2007 — ACRO joins the Biomarkers Consortium, a major public/private biomedical research partnership created to accelerate the delivery of successful new technologies, medicines, and therapies for the prevention, early detection, diagnosis, and treatment of diseases. For more information, visit fnih.org.

ELEVATING PUBLIC PERCEPTION

PV: If there was just one thing you could accomplish in your tenure as ACRO chair what would that be?

MCMULLEN: The one goal would be to elevate the public's perception of the drug-development industry — CROs, pharmaceutical companies, and all of those dedicated to the advancement of human health. Frequently, the availability of therapeutics that are used to treat our children, parents, spouses, and friends is taken for granted as the result of an incomplete understanding of the long, complex process of progressing a drug from discovery to the patient.

ACRO's ROLE

PV: What is the most critical role that ACRO plays in the industry and how can CRO leaders work to advance that goal?

MCMULLEN: ACRO plays several important roles in the drug-development industry: as an organization we communicate the value of outsourcing to study sponsors, health policymakers, and the public at large; we clearly explain what CROs do and how they do it; and we are advocates for patient safety and the rights of human participants in all aspects of clinical research. We also collaborate with constituents and regulatory agencies globally to explore new models for more efficient research and development and additional opportunities for the industry. We work closely with the U.S. FDA, EMEA, European Commission, PhRMA, BIO, academic medicine, and patient groups on many of the important issues confronting the industry today.

As an example, ACRO recently joined a biomedical research partnership, The Biomarkers Consortium, which was created to accelerate the delivery of successful new technologies, medicines, and therapies for the prevention, early detection, diagnosis, and treatment of diseases. (For more information on ACRO's activities, please see the box on this page.)

LEADING THROUGH EXPERIENCE

PV: What do you believe you bring to the role of ACRO Chair?

MCMULLEN: Through my 30-plus years of experience in the pharmaceutical and CRO industry, I have developed extensive personal relationships with industry leaders and can apply consensus-building, communication, and leadership skills that will help support ACRO's charter and mission. As chairman, I will seek the wisdom and expertise of my colleagues on the ACRO board and the members of our various committees to advance the interests of the organization and focus on key initiatives.

ACRO continues to provide its members with opportunities to collaborate with industry leaders on global initiatives to streamline the regulatory process in ways that ensure the integrity of data and the openness of the clinical-trial process. In emerging markets, the association looks to share its members' expertise on regulatory practices with officials responsible for creating the mechanisms through which effective clinical trials are conducted.

ACRO is committed to leading discussions with biopharmaceutical leaders and other stakeholders around patient safety, regulatory issues, and research best practices, and we will continue to speak on behalf of CROs about the value of clinical outsourcing. ✦

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