PharmaVOICE

THE FORUM FOR THE INDUSTRY EXECUTIVE

Volume 10 • Number 3

PharmaVOICE (ISSN: 1932961X) is published monthly except joint issues in July/Aug. and Nov./Dec., by PharmaLinx LLC, P.O. Box 327, Titusville, NJ 08560. **Periodicals postage paid** at Titusville, NJ 08560 and additional mailing offices.

Postmaster: Send address changes to PharmaVOICE, P.O. Box 292345, Kettering, OH 45429-0345.

PharmaVOICE Coverage and Distribution: Domestic subscriptions are available at $190 for one year (10 issues). Foreign subscriptions: 10 issues US$360. Contact PharmaVOICE at P.O. Box 327, Titusville, NJ 08560. Call us at 609.730.0196 or FAX your order to 609.730.0197.

Contributions: PharmaVOICE is not responsible for unsolicited contributions of any type. Unless otherwise agreed in writing, PharmaVOICE retains all rights on material published in PharmaVOICE for a period of six months after publication and reprint rights after that period expires. E-mail: tgrom@pharmavoice.com.

Change of address: Please allow six weeks for a change of address. Send your new address along with your subscription label to PharmaVOICE, P.O. Box 292345, Kettering, OH 45429-0345. Call us at 800.607.4410 or FAX your change to 937.890.0221. E-mail: mwalsh@pharmavoice.com.

IMPORTANT NOTICE: The post office will not forward copies of this magazine. PharmaVOICE is not responsible for replacing undelivered copies due to lack of or late notification of address change.

Advertising in PharmaVOICE: To advertise in PharmaVOICE please contact our Advertising Department at P.O. Box 327, Titusville, NJ 08560, or telephone us at 609.730.0196. E-mail: lbanket@pharmavoice.com.

Letters

Send your letters to feedback@pharmavoice.com. Please include your name, title, company, and business phone number. Letters chosen for publication may be edited for length and clarity. All submissions become the property of PharmaLinx LLC.

Along the continuum...

As PharmaVOICE enters its 10th year, the basic premise on which we founded the publication, and the company, remains as true today as it did on that February afternoon back in 2001: there is a fundamental need to understand the life-sciences industry from a holistic perspective that cuts across industry silos and provides a horizontal overview of the myriad topics that affect a drug or biologic compound from molecule through market.

There are hundreds, if not thousands, of intersecting points along the drug development continuum. To do our jobs effectively, we contend that it is imperative to understand what happens before, during (directly and tangentially), and certainly after one's interaction with a drug or biologic candidate.

The drug development stakes couldn't be higher, and the chances against success are staggering. According to Tufts CSDD, currently it costs, on average, more than $1 billion and takes more than seven years from the start of a clinical trial to conduct the necessary studies and win approval to market a new drug in the United States.

In 1980, PhRMA's member companies invested $2 billion in research and development of medicines; in 2008, they spent a record $65.2 billion in the research and development of new life-changing medicines and vaccines. According to PhRMA, the sector's R&D focus also provides considerable value to the U.S. economy; PhRMA member companies dedicated roughly 70% of their R&D investment domestically.

According to the most recent study conducted by Archstone Consulting and Dr. Lawton R. Burns, Director, The Wharton Center for Health Management and Economics at The Wharton School, University of Pennsylvania, domestic R&D spending by biopharmaceutical companies was about $65,000 per direct employee in 2006 — about eight times the published estimates of R&D spending per employee in all manufacturing industries between 2000 and 2004. Furthermore, about one-quarter of the more than 686,000 direct employees of the sector were engaged in life, physical, or social sciences research in 2006; the sector also supported 1 million indirect jobs and 1.5 million induced jobs that year.

As of late, the industry has experienced its share of challenges, but there remains an urgent need to safely address unmet medical conditions in dozens of therapeutic categories.

Obviously, it's impossible to capture all of the processes, strategies, and technologies that affect a molecule's progression along the drug development timeline; however, we hope this special issue provides you with some valuable top-level insights that you can use in your pursuit of excellence, efficiency, and successful outcomes.

We thank the more than 60 industry experts who took their time to raise their voices on the myriad topics included in the print as well as digital edition (don't forget to check out pharmavoice.com for exclusive bonus content) ranging from target identification and validation, HIT finding, and lead optimization, to early clinical safety and efficacy; to Phase I through Phase III trials; to registration and launch; and, finally, postlaunch.

We welcome and encourage your feedback on this issue — Raise Your Voice!

Time is of the essence