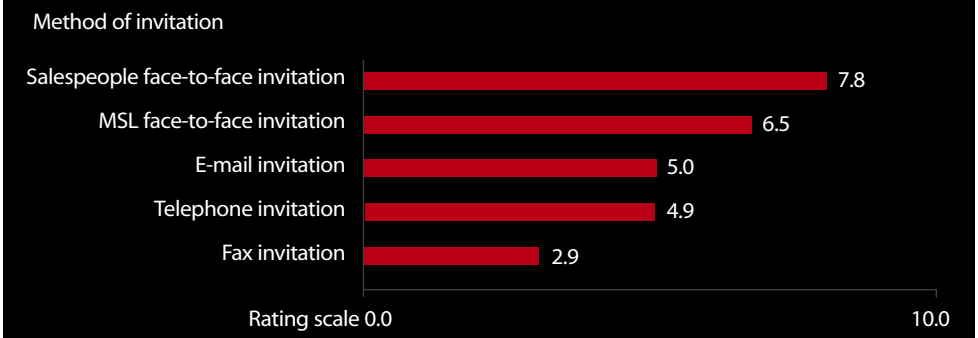
RATING THE BEST DRIVERS OF ATTENDANCE TO SPEAKER EVENTS



Source: Cutting Edge Information, Pharmaceutical Speaker Programs: Measuring ROI and Communicating Value. For more information, visit cuttingedgeinfo.com.

Most Americans Want More **INFO ON NEW BIOTECHNOLOGIES**

Nanotechnology and synthetic biology continue to develop as two of the most exciting areas of scientific discovery, but research has shown that the public is almost completely unaware of the science and its applications. A poll of 1,001 American adults conducted by Peter D. Hart Research Associates and the Project on Emerging Nanotechnologies (PEN) found that 90% think the public should be better informed about the development of cutting-edge technologies.

"Historically, government and industry have done a poor job of informing and engaging the public about scientific developments that could have transformative impacts on society," says David Rejeski, director of PEN. "The poll showed that better communication is needed and could be beneficial in securing the promise of our investments in science."

According to the poll, about 31% of respondents had heard a lot or some about nanotechnology, up from 24% in 2008 and about the same level measured in 2006. By contrast, about 22% had heard a lot or some about synthetic biology, a sharp increase from 9% a year earlier.

"Public awareness of nanotechnology has barely moved in over four years of our project's polling, despite billions of dollars of investment in research and a growing number of nano-enabled products in the marketplace," observes Andrew Maynard, chief science advisor for PEN. "Clearly, the message about this new and important technology is not reaching the public."

The survey showed that the area of application is a decisive factor in shaping public attitudes toward synthetic biology. More than half of the respondents supported research in synthetic biology aimed at the development of more efficient biofuels even after being informed of the potential risks and benefits of this application. But poll respondents harbored concerns about potential risks associated with the development of synthetic biology, including its potential for creating what they perceive as artificial life. Two-thirds of the participants supported regulation of this emerging technology.

For more information, visit nanotechproject.org.

WHAT DO YOU THINK SYNTHETIC BIOLOGY IS?

VOLUNTEERED COMMENTS	% RESPONDENTS
Something man-made, artificial, fake, not natural, not real	29%
Has to do with cloning, genetic manipulation	13%
Has to do with biology, altering the biological makeup	7%
Used in medical research to develop new medicines, treatments	6%
Used to develop better, safer plants, sources of food	6%
Attempt to create life, artificial life	5%
Some kind of material, synthetic material	5%
Don't know; no response	28%

Source: Peter D. Hart Research Associates and the Project on Emerging Nanotechnologies (PEN). For more information, visit nanotechproject.org.

PHARMA REBRANDING OF SPEAKER EVENTS Is Paying Off

Jason Richardson

Many companies have improved their programs by focusing on the core value provided by the events while adhering to the restrictions on the extras, says Jason Richardson.

In response to increased political and regulatory scrutiny, pharmaceutical companies are rebranding their promotional speaker programs as unparalleled opportunities for physicians to learn or remain current on the latest drug developments and to network with colleagues.

According to Cutting Edge Information, the rebranding is helping to attract physicians who are more interested in learning than in getting a free meal, and is working to improve program ROI and lessen pressures from outside agencies that feel the meetings are payoffs for prescriptions.

The report, Pharmaceutical Speaker Programs: Measuring ROI and Communicating Value, observes that companies have switched their focus from providing physicians with incentives for attending speaker events to making the program content itself the centerpiece for drawing prescribers. Because a range of perks can no longer serve as the attraction, companies must present the most knowledgeable speakers and informative content. Likewise, companies position speaker events as networking opportunities where physicians can communicate with other doctors in their field and communities.

"Pharmaceutical companies know that speaker programs still hold great value as educational and promotional tools," says Jason Richardson, president of Cutting Edge Information.

The report notes that companies must work diligently to get the word out on their events and drive attendance to make programs successful.

For more information, visit cuttingedgeinfo.com.

JAPAN PRESENTS OPPORTUNITIES, CHALLENGES for Generic Manufacturers

According to a recent Thomson Reuters white paper, a combination of major drug patent expiries before 2012, a rapidly aging demographic, wide-ranging government initiatives to reduce healthcare spending, and comparatively high reimbursement prices are making the generic drug sector in Japan increasingly attractive to foreign manufacturers looking for a large, relatively untapped, and receptive market.

Japan is the world's second largest pharmaceutical market, commanding estimated annual sales of $64.5 billion; but only 6.6% of its prescription drug sales are contributed by generic drugs, the report says.

"As Japan's generic market is beginning to expand, market growth rates in established generic markets, such as Europe and the United States, are trending downward, sending generic drug companies seeking opportunities to enter new markets," notes Mark Garlinghouse, senior VP, Asia-Pacific at Thomson Reuters.

Thomson Reuters' white paper, The Japanese generic drug market: opportunities and strategies for success, includes an exploration of the probable impact of the recent change in government in Japan on the generic industry.

The incoming Democratic Party of Japan has signaled that it intends to continue to support the promotion of generic pharmaceuticals; however, in its July 2009 manifesto, the party claimed that even though generics are judged to be equivalent to the brand-name drug, the current tests for equivalence are insufficient, and it will promote the collection of additional information to be used in further evaluation of generics.

For more information, visit go.thomsonreuters.com/jp_generic.

TIPS FOR SUCCESS IN JAPANESE GENERIC MARKET

While the market for generics in Japan offers opportunity, foreign drug companies seeking to enter it face significant challenges. Thomson Reuters offers the following recommendations to those opportunity-seekers:

- Don't go it alone. In-country experience, brand reputation, and personal relationships offered by domestic partners are vital to success.
- Reach out to physicians to promote the value of generic drugs. While public awareness of generic drugs is increasing in Japan, many patients are still reluctant to ask physicians to prescribe generics, and many physicians continue to be suspicious of generic drugs.
- Have a spotless quality record. The Japanese market's focus on quality will make it difficult for those generic companies that have run afoul overseas to make inroads in Japan.

Source: Thomson Reuters, The Japanese generic drug market: opportunities and strategies for success. For more information, visit go.thomsonreuters.com/jp_generic.

BLOCKBUSTERS EXPECTED TO COME OFF PATENT IN JAPAN, 2010-2012

YEAR	ACTIVE INGREDIENT	SPONSOR IN JAPAN
2010	insulin aspart	Novo Nordisk
	risedronate sodium	Ajinomoto
	salmeterol xinofoate	GlaxoSmithKline
	tacrolimus	Astellas Pharma
2011	atorvastatin calcium	Astellas Pharma
	pioglitazone hydrochloride	Takeda
	pramipexole dihydrochloride	Nippon Boehringer Ingelheim
2012	anastrozole	AstraZeneca
	losartan potassium	Banyu Pharmaceutical
	quetiapine fumarate	Astellas Pharma, AstraZeneca
	rabeprazole sodium	Eisai Co Ltd
	raloxifene hydrochloride	Chugai Pharmaceutical Co., Eli Lilly Japan KK
	telmisartan	Nippon Boehringer Ingelheim, Astellas Pharma
	zoledronic acid	Novartis

Source: Thomson Reuters, The Japanese generic drug market: opportunities and strategies for success. For more information, visit go.thomsonreuters.com/jp_generic.

R&D FOR IMMUNOTHERAPIES Expands to Alzheimer's, Other Indications

Applications of immunotherapies and vaccines for prevention and treatment of infectious diseases and cancer are well known; but clinical investigation of immunotherapies for other indications, while progressing for many years, has not received the same level of public attention.

The use of immunotherapies for treatment of these diseases is a very promising field. The Insight Pharma Reports study, Immunotherapies and Vaccines for Nontraditional Indications, notes that while performance will vary with the different disease indications, some of these immunotherapies and vaccines have a potentially large market opportunity. For example, the current market for therapies to treat the symptoms of Alzheimer's disease already exceeds $4 billion annually worldwide. This market is likely to grow significantly if more effective therapies that actually treat the disease itself become available.

For more information, visit insightpharmareports.com.

MARKET FOR BIOMARKER ANALYSIS Expected to Boom

The biomarker analysis market has excellent growth potential, and the field of biomarker research will test the frontiers of biomedical research in the coming years, according to analysts at Frost and Sullivan. A biomarker is a characteristic objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.

According to the Frost & Sullivan report, An insight into the active and high growth Biomarker Market, at present there is a huge lag between the time that a biomarker is discovered in the laboratory and when it is actually commercialized.

This is because of the various challenges faced in the biomarker validation and assay development, including the emerging status of its constituent companies, which are mostly startups.

Frost & Sullivan research has shown that the biomarker analysis market is in the early growth phase and is expected to continue in this phase for

SELECTED COMPANIES DEVELOPING IMMUNOTHERAPIES (I.E., MONOCLONAL ANTIBODIES, VACCINES) FOR ALZHEIMER'S DISEASE

COMPANY	PRODUCT/TECHNOLOGY	STATUS	COMMENTS
ESBATech	Antibody fragments	In development	ESBATech is a spin-out of the University of Zurich and is focusing on development of human antibody fragments for therapeutic applications. In February 2008, researchers at ESBATech and the University of Zurich published a paper entitled "Antibody-based approaches in Alzheimer's research: safety, pharmacokinetics, metabolism, and analytical tools." This paper includes a discussion of the potential use of antibody fragments for treatment of Alzheimer's disease.
Genentech (part of Roche) and AC Immune	Anti-Abeta (MABT5102A)	Phase I	Humanized monoclonal antibody that binds to amyloid beta (Abeta); generated using AC Immune's supramolecular antigen technology
GlaxoSmithKline	GSK933776A (933776)	Phase I	Monoclonal antibody
Janssen Alzheimer Immunotherapy (part of J&J) and Pfizer	Bapineuzumab (AAB-001)	Phase III	Humanized monoclonal antibody Phase III (intravenous) Phase II (subcutaneous)

Source: Insight Pharma Reports, Immunotherapies and Vaccines for Nontraditional Indications. For more information, visit insightpharmareports.com.

APPLICATIONS OF BIOMARKERS

Biomarkers have several applications in four main areas: discovery, preclinical, clinical, and diagnostics. Some of the disciplines in which they currently play an active role include:

- Early disease identification. Detection of certain biomarker molecules can help predict the presence of diseases such as cancer, Alzheimer's, and Parkinson's at an early stage.
- Identifying potential drug targets. Currently, researchers use very advanced techniques such as proteomics to find proteins specific to various disorders, which may offer a potential target for drug treatment. Biomarkers help researchers understand the disease process at the protein expression level.
- Predicting the response of patients to medications. Biomarkers can help physicians monitor the response to medication administered to patients suffering from serious ailments and judge the efficacy of a particular drug regimen in terms of cure rate.
- Accelerating clinical trials. Biomarkers play a major role in reducing trial duration by predicting drug efficacy in animal models and human trials by acting as surrogate primary endpoints.
- Personalized medicine. Biomarkers could help physicians prescribe the right medication to the right patient. This could help reduce side effects, as patients would be prescribed a drug after determining the particular pathway that is playing an active role in the progression of disease in the patient in question.

Source: Frost & Sullivan, An insight into the active and high growth Biomarker Market. For more information, visit frost.com.

at least the next four to five years, during which time many new biomarker panels are expected to be approved by the regulatory authorities for mainstream testing during preclinical and clinical drug development. By 2015, the biomarker analysis market is expected to complete its late-growth stage and attain maturity, the report says.

Feedback has indicated that while the United States is the current leader in the biomarker market, some of the world-class biomarker companies are found in Europe, and that the western European region is not far behind the United States in terms of market size and growth rate. Asian countries including Japan are almost on par with Europe, and South Korea is also testing the frontiers of biomarker research and development.

For more information, visit frost.com.

PHARMA COLLABORATION WITH PATIENT ADVOCACY GROUPS Can Boost Education Efforts

Patient and professional advocacy groups are trusted resources for consumers seeking information on new and novel therapies and are an integral part of educating the marketplace on new medicines.

For pharmaceutical companies that are bringing new therapies to market, collaborating with advocacy groups is fundamental as a way to educate the public on treatment options and is especially critical for socially sensitive conditions or therapies.

Respondents to a recent study from Best Practices, Collaborating with Patient Advocacy Groups to Educate the Marketplace, note that the management of relationships with advocacy groups benefits from clarity of the relationship, ownership, role, and responsibility, as well as standardized processes.

According to the study, pharma companies should assess the landscape of advocacy and community-interest groups to understand the broad spectrum of players, special interests, and possible collaborators. Different groups may prove to be more valuable collaborators at different stages of the product and disease life cycle, study respondents observed.

The report also advises pharmaceutical companies to develop an expertise structure to support rapid response to external special interest groups — both positive and negative — and allow rapid resolution of issues and ongoing intelligence gathering.

Other recommendations include centralization of information management and response; staying informed through rapid global updates on hostile group activities; and responding locally to attacks to avoid global issue spread.

For more information, visit best-in-class.com.

SEE DIGITAL EDITION FOR BONUS CONTENT WWW.PHARMAVOICE.COM

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Keynote Speakers

SUNDAY, APRIL 25, 2010

Thomas Gorrie, PhD

PRESIDENT, T.M. GORRIE AND ASSOCIATES

Social Responsibility and the Pharmaceutical Industry in the 21st Century — A Global Perspective

Dr. Gorrie recently retired from a 35-year career with Johnson & Johnson, with his final post being Vice President of Government Affairs and Policy.

He presently provides advice and consulting services to firms worldwide on business, government affairs, and management topics.

MONDAY, APRIL 26, 2010

Joshua Sharfstein, MD *(invited)*

PRINCIPAL DEPUTY COMMISSIONER OF THE U.S. FOOD AND DRUG ADMINISTRATION

Dr. Sharfstein was appointed by President Barack Obama to this position earlier this year, and had previously served as the Commissioner of Health for the City of Baltimore and on the staff of the Government Reform Committee of the U.S. House of Representatives for Congressman Henry A. Waxman.

Special Event

SATURDAY, APRIL 24, 2010

Eva Mozes-Kor

An Afternoon with Eva

ACRP is very pleased to announce that Eva Mozes-Kor is returning for a special presentation.

As a keynote speaker, she mesmerized participants at our 2009 conference by recounting her childhood experience of surviving the genetic experiments of Dr. Josef Mengele in the World War II Nazi concentration camp at Auschwitz.

Eva poignantly reminds us of the need for obtaining proper consent from research participants and the need to remain vigilant on matters of human subject protection.

She remains very active traveling worldwide to discuss her personal, yet controversial, decision to forgive the Nazis for the torture they inflicted on her and her twin sister, Miriam, in order to live her life with grace, compassion, and purpose.

Eva will retell her story of courage and survival, and provide an update on her petition to have samples of substances that were used in the Nazi experiments opened to modern scientific inquiry.

Her one-hour talk will be followed by an interactive Q&A session with the audience lead by ACRP Immediate Past Chair David Vulcano.

An Afternoon with Eva continues in the Exhibit Hall with a book signing of her autobiography, *Surviving the Angel of Death: The Story of a Mengele Twin in Auschwitz.*

Learn more at www.acrp2010.org

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QUICK FACTS

- Over the last decade, pharmaceutical companies have increasingly turned to drug-delivery technologies to enhance drug efficacy, expand the life cycle of their products, and boost their revenues. The global market for advanced drug delivery systems is projected to increase to $139 billion in 2009, up from $134.3 billion in 2008, and is estimated to reach $196.4 billion in 2014, for a compound annual growth rate (CAGR) of 7.2% in the 5-year period.

Source: BCC Research, Advanced Drug Delivery Systems: New Developments, New Technologies. For more information, visit bccresearch.com.

- The global market for gastrointestinal drugs will be worth an estimated $31 billion in 2009. That is expected to exceed $32 billion in 2014 for a modest 5-year CAGR of 0.7%. The prescription gastrointestinal drug segment is expected to be worth nearly $27 billion in 2014, for a five-year CAGR of 0.5%, while the over-the-counter sector is projected to grow at a CAGR of 1.7% to reach $5.2 billion by 2014.

Source: BCC Research, Gastrointestinal Pharmaceuticals: Technologies and Global Markets. For more information, visit bccresearch.com.

- The aging U.S. population is having a major impact on the pain management market as the baby-boom generation reaches the vulnerable state in which chronic diseases are common. Another driver influencing market growth is that chronic pain conditions are notoriously difficult to diagnose and treat. The global market for pain management pharmaceuticals and devices amounted to $19.1 billion in 2008 and is expected to increase to $32.8 billion in 2013, for a CAGR of 11.5% for the 5-year period.

Source: BCC Research, The Global Market for Pain Management Drugs and Devices. For more information, visit bccresearch.com.

- The current overall clinical development and FDA regulatory success rate for drug delivery-enabled products is estimated at 24%, a decline from 2008's estimate of 26%. The average time for clinical development and regulatory product approval was 5.8 years, an increase of 0.1 year.

Source: Bionumbers, Parameters of Performance series report: DD09 - Drug Delivery Product Success Rates, Development Times, Costs, and Marketing Exclusivity. For more information, visit bionumbers.com.

- Because biosimilar insulins are relatively easy to develop and manufacture, a number of competing long-acting biosimilar insulins are expected to enter the market between now and 2018. These biosimilar insulins and insulin analogs stand to erode $6.1 billion in brand sales in the United States, France, Germany, Italy, Spain, and the United Kingdom by 2018, saving healthcare systems $3.8 billion in the process.

Source: Decision Resources, Biosimilars: ESAs, Insulins, and Human Growth Hormones. For more information, visit decisionresources.com.

- The high cost of Avastin, used to treat breast, colorectal, and lung cancers, remains a barrier to treatment for nearly one-fifth of eligible cancer patients, according to surveyed oncologists. Largely because of its price tag, most surveyed managed care organizations' pharmacy directors place significant restrictions on the reimbursement and use of Avastin.

Source: Decision Resources, Physician & Payer forum report: Is Avastin Unassailable? Will Its Dominance in Breast, Colorectal, and Lung Cancers Be Challenged by Drugs with Validated Biomarkers? For more information, visit decisionresources.com.

- Sales of the TNF-alpha inhibitor drug class are expected to triple by 2018 for the treatment of ulcerative colitis, from $426 million in 2008 to about $1.1 billion in 2018 in the major markets. This growth will be driven by the anticipated launch of two TNF-alpha inhibitors for moderate to severe ulcerative colitis: Abbott/Eisai's Humira, expected to receive approval in 2010; and Centocor Ortho Biotech/Janssen/Mitsubishi Tanabe Pharma/Schering-Plough's Simponi, expected to be approved in 2012.

Source: Decision Resources, Pharmacor report on Ulcerative Colitis. For more information, visit decisionresources.com.

- TNF-alpha inhibitors are expected to continue to dominate first- and second-line biologic therapy for the treatment of rheumatoid arthritis in the United States through 2011. But third-line TNF-alpha inhibitor drugs could lose patient share to Roche's emerging IL-6 inhibitor Actemra upon its launch in 2010.

Source: Decision Resources, Treatment Algorithms in Rheumatoid Arthritis. For more information, visit decisionresources.com.

- The U.S. market for diabetes drugs, devices, and monitoring systems is projected to triple in value over the next several years, surpassing $55 billion by 2016. The market for insulin is expected to grow by more than 18% in 2009.

Source: iData Research, U.S. Market for Diabetes Monitoring, Treatment and Drug Delivery 2010. For more information, visit idataresearch.net.

- Drug resistance is a key public health problem and a problem for makers of branded antibacterial products. Traditional antibiotics — quinolones, cephalosporins, and penicillin — have seen their market share shrink due to loss of effectiveness and heavy generic competition. Growth is flat and in some cases declining; the total world market for antibacterial drugs, which represents almost half of the anti-infectives market, is estimated at $24.5 billion for 2009.

Source: Kalorama Information, Worldwide Market for Anti-Infectives (Antifungals, Antibacterials and Antivirals). For more information, visit kaloramainformation.com.

- The worldwide market for vaccines against the H1N1 influenza strain is expanding rapidly due to the prevailing H1N1 pandemic and subsequent huge demand for effective vaccines against it. The global H1N1 influenza vaccine market is estimated to grow at 222.4% CAGR over the next two years, hitting $7,028 billion by 2011.

Source: MarketsandMarkets, Global H1N1 2009 Influenza Vaccine. For more information, visit marketsandmarkets.com.

- The overall healthcare information technology market is expected to reach $53.8 billion by 2014, growing at a CAGR of 16.1%, driven mainly by tremendous demand for general applications such as EMRs, EHRs, computerized physician order entry systems (CPOEs), and nonclinical systems.

Source: MarketsandMarkets, Global Healthcare Information Technology (2009-2014). For more information, visit marketsandmarkets.com.

- Primary care plays a large role in psychotropic drug prescribing, with general practitioners writing about 50% of all prescriptions. Of the 472 million prescriptions written for psychotropic medications from August 2006 through July 2007, general practitioners prescribed 62% of antidepressants, 52% of stimulants, 37% of antipsychotics, and 22% of antimania medications.

Source: Thomson Reuters and the Federal Substance Abuse and Mental Health Services Administration. For more information, visit thomsonreuters.com or samhsa.gov.

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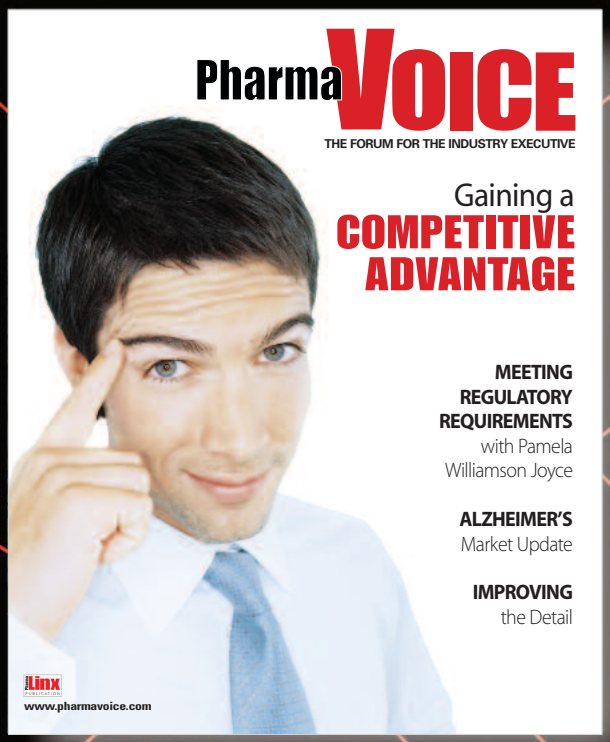

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