Throughout the industry, Pharmaceutical & Biotechnology manufacturers are facing increasing pressure from all stakeholders related to the coverage and reimbursement of new and existing therapies. Although the legality of recent healthcare reform in the US has been taken into question, there is no doubt that the government, payers and consumers will continue to pressure the pharmaceutical industry to lower costs, regardless of the outcome of reform. As such, the industry needs to be prepared for every eventuality, by compiling and presenting the most compelling cases for the reimbursement of their products, through precise and thorough evidence development and presentation. During the 4th Annual Pharmaceutical Reimbursement & Market Access Conference, presenters and attendees will have an opportunity to discuss and debate the many challenges and changes that have occurred over the course of the past 12-18 months, and also forecast the future of this dynamic industry. Though the concept of evidence development and dosiers is not a new area for pharmaceutical corporations, today’s environment requires these documents to contain more information than ever before, and requires that data be collected in an extremely rigorous manner. Evidence development and use will be a primary theme of the 2012 annual program, allowing organizations an opportunity to hear from various stakeholders, from government representatives to private payers, on the evidence they feel is most applicable and compelling when making coverage decisions. The increasing relevance and utilization of health technology assessments will also be discussed, providing a global theme to the program content.

As with all Q1 conference programs, the focus of the event will not only include educational program content delivered by experienced executives and multiple stakeholders but will also include formal and informal networking opportunities that are so critical to the success of this industry. Through a carefully blended program including case studies, panel discussions and networking opportunities, the 4th Annual Pharmaceutical Reimbursement & Market Access conference will once again be a must attend program.
PPACA UPDATE: EXAMINING THE CURRENT AND FUTURE IMPACT ON REIMBURSEMENT STRUCTURES

Over the course of the past three years, the Patient Protection and Affordable Care Act (PPACA) has been a considerable topic of concern for the pharmaceutical industry, as it will directly impact and challenge the current reimbursement landscape. Although components of healthcare reform were set to take effect in 2012, the Supreme Court is currently debating the repeal of portions or all of the PPACA or leaving the reform law intact. This session will provide attendees with an update on the current status of the PPACA and will highlight what aspects of healthcare reform will still play a crucial role in causing a shift in reimbursement practices.

Jason B. Caron, Member of the Firm EPSTEINBECKERGREEN

10:30 COFFEE & NETWORKING BREAK

11:00 CLARIFYING IMPLICATIONS OF ACCOUNTABLE CARE ORGANIZATIONS ON REIMBURSEMENT STRATEGIES

Accountable Care Organizations join the greater landscape of cost containment set forth by healthcare reform, with its purpose slated to provide incentives to doctors and hospitals for providing a high level of quality care while reducing cost. ACOs were set to take effect in January of this year, but with the current uncertainty of whether all or sections of the Affordable Care Act will be repealed by the Supreme Court, pharmaceutical executives are anxious to know whether or not ACOs will still play a role in affecting the reimbursement landscape. ACOs will create an environment where pharmacoeconomic data becomes increasingly vital to ensure optimum reimbursement outcomes. Products must demonstrate that they can not only save money through the course of treatment, but they can do it better than a competitive drug.

• Examining the structure of ACOs
• Understanding expectations for interaction with pharmaceutical companies
• Exploring implications of ACOs on the future of reimbursement

H. Scott Sarran MD, MM, Chief Medical Officer, Government Programs BLUE CROSS BLUE SHIELD OF IL

Edward Bambino, Executive Director, Managed Markets EVERETT LABORATORIES

11:45 BIOSIMILARS: IMPACT ON REIMBURSEMENT AND THE MARKET FOR BRANDED BIOLOGICAL PRODUCTS

Reimbursement executives are interested in understanding how biosimilars will affect the marketplace and health plan reimbursement policies and practices. The research-based biopharmaceutical industry wants to remain confident that branded, innovative products will be protected and reimbursed appropriately. In addition, companies are exploring ways to complement their traditional branded product portfolios by evolving and diving into the biosimilar space. Although no biosimilar products have yet been approved in the United States, FDA has now issued several draft guidances clarifying its expectations regarding biosimilars, and approvals are expected soon. Stakeholders have more than half a dozen years of experience with approved biosimilars in Europe.

• Key relevant points from the recent FDA guidances for biosimilars
• Lessons from Europe on factors likely to drive biosimilar uptake in the US
• Preliminary thoughts on pricing, reimbursement and uptake in the US

Erika Lietzan, Partner COVINGTON & BURLING
PIECES OF THE PUZZLE TO MAKE REIMBURSEMENT DECISIONS

4:30 PRACTICING PERSUASION TO INFLUENCE PRIVATE PAYER DECISIONS

Corporate market access elements, including understanding of insights relating to payer, economy and healthcare and consumer behavior into all aspects and stages of research. Working with clinical and research teams during early stages of product development presents difficulties as accurately forecasting the reimbursement landscape in the future is a complicated endeavor. Reimbursement executives can ensure that clinical and research teams collect appropriate data, including building health economic markers into early phase studies that will be useful for reimbursement purposes in the future.

Manasee Shah, MPH, Manager, Market Access XCENDA

3:30 COFFEE & NETWORKING BREAK

TRACK 1 – PRIMARY CARE

4:00 PANEL DISCUSSION: A HOLISTIC APPROACH TO EVIDENCE DEVELOPMENT FOR REIMBURSEMENT & MARKET ACCESS

As pharmaceutical companies make investment decisions related to evidence development, a key consideration is the determination of what data will be the most effective in supporting reimbursement decisions and how to garner this data most efficiently. Executives look to payer trends in reimbursement decisions. There is no doubt there is a much greater need for evidence development to demonstrate value, as safety and efficacy are no longer the only two factors considered in the reimbursement decision-making process. Pharmaceutical companies are interested in hearing how drug manufacturers are positioning their value proposition to include health economics and clinical trial data to effectively showcase the comprehensive value of a drug.

MODERATOR:
Zeba Khan, PhD, CELGENE CORPORATION

PANELISTS:
Dean Hakanson, NOVARTIS
Kasem Akhras, TAKEDA

4:45 PANEL DISCUSSION: HOW PRIVATE Payers TRIANGULATE THE PIECES OF THE PUZZLE TO MAKE REIMBURSEMENT DECISIONS

Pharmaceutical companies experience difficulties and challenges when understanding and evaluating the potential response of a private payer regarding reimbursement decisions for any specific therapy. Reimbursement executives continuously seek greater clarity from private payers on what types of evidence will maximize reimbursement outcomes, whether it is clinical trial data, economic models or observational study. Managing payer expectations will provide reimbursement executives with a foundation for a product’s commercial success, and this session will allow attendees to engage in a meaningful dialogue with representatives from several private payers who will provide concrete examples dealing with the reimbursement decision-making process.

Burton VanderLaan, PRIORITY HEALTH
H. Scott Saran MD, MM, BLUE CROSS BLUE SHIELD OF ILLINOIS
Kenneth LaPensee, THE MEDICINES COMPANY

5:30 DAY ONE CONFERENCE CONCLUSION

TRACK 2 – SPECIALTY PHARMACEUTICALS

4:00 PANEL DISCUSSION: BRIDGING THE EVIDENCE GAP FOR SPECIALTY DRUGS THROUGH A COMPREHENSIVE VALUE PROPOSITION

The reimbursement and market access landscape for orphan drugs differs greatly from primary care, specifically regarding gaps created by a lack of data to support evidence of product effectiveness and value. Reimbursement teams look to develop a comprehensive value story for payers that emphasizes benefits beyond long-term budget impact and cost-effectiveness, as orphan drugs can be expensive for payers in the short-term. Opening the doors of communication early with payers and utilizing partners such as advocacy groups and key opinion leaders provides pharmaceutical companies with a roadmap for reimbursement success by framing the value proposal through incorporation and understanding of insights regarding improvements in quality of life and patient reported outcomes.

Jason B. Caron, EPSTEINBECKERGREEN
Michael S. Paas, GfK BRIDGEHEAD
Wesley Winn, THROMBOGENICS

4:45 PRIVATE PAYER PERSPECTIVE ON SPECIALTY PHARMACEUTICALS

As the pharmaceutical industry moves towards a heavier focus on specialty pharmaceuticals, the private payer’s perspective on these types of drugs plays a crucial role in evidence development and implementation of reimbursement strategy. As specialty drugs can be an expensive proposition for payers in the short-term, reimbursement executives seek to develop a greater comprehension of how payers evaluate specialty pharmaceuticals. This session will provide attendees with an understanding of a payer’s decision making process based on insights provided by multiple outlets including health economics and outcomes research results, quality of life data and long-term budget impact for payers and patients.

Beckie Fenrick, Sr. Director, Pharmacy Care Models & Affordability Solutions BLUE CROSS BLUE SHIELD OF FLORIDA

5:30 DAY ONE CONFERENCE CONCLUSION

KEY SPEAKER SPOTLIGHT:

Zeba Khan, PhD
Vice President, Strategic Market Access & Policy
CELGENE CORPORATION

Dr. Zeba Khan is Vice President of Strategic Market Access & Policy at Celgene Corporation based in Summit, New Jersey, where she leads the development and implementation of pricing, health economics, outcomes research, and market access strategies and policies for all therapeutic areas from early development through life cycle management.

Prior to joining Celgene Corporation, Dr. Khan held various positions at Novartis including Global Head of Pricing and Health Economics, CVM in Basel Switzerland and Executive Director, Head of Pricing Strategy and Policy in East Hanover, New Jersey, USA. Prior to joining Novartis, she held various leadership roles in Healthcare Management and Health Economics and Outcomes Research at GlaxoSmithKline in Research Triangle Park, NC, USA. Prior to joining the pharmaceutical industry, Dr. Khan was a clinical pharmacist at the University of Utah Health Sciences Center in Salt Lake City, Utah, USA.

Dr. Khan served on the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Board of Directors and has been an active member of ISPOR since 1996 serving on many committees including Chair of the ISPOR Short Course Committee and the Student Network Faculty Advisor.
DAY TWO / TUESDAY, AUGUST 28 / PHARMACEUTICAL REIMBURSEMENT & MARKET ACCESS

7:30 REGISTRATION & CONTINENTAL BREAKFAST

7:50 OPENING REMARKS

8:00 LESSONS LEARNED: POSITIONING A PRODUCT FOR REIMBURSEMENT SUCCESS IN A COST-CONSCIOUS EUROPEAN ENVIRONMENT

Increasingly, austerity measures and budget pressures within Europe have caused a difficulty in navigating pricing and reimbursement processes across the continent. Pharmaceutical companies seek strategies that can position their products for reimbursement success despite a heavily cost-conscious atmosphere; many organizations are still finding tremendous success, as the need for highly effective products has not diminished. This session will provide attendees with an example that showcases a success story and pitfalls experienced by another drug manufacturer in recent years.

• Impact of healthcare reform in European countries on reimbursement
• Creating effective pricing strategies
• Developing a value message that resonates with payers

Michael S. Paas, Senior Vice President, Market Access
GIK BRIDGEHEAD

8:45 PANEL DISCUSSION: THE IMPLEMENTATION AND ACCEPTANCE OF COMPARATIVE EFFECTIVENESS RESEARCH

Healthcare reform and the billions of dollars in funding filtered through AHRQ for comparative effectiveness research has resulted in an increased need for pharmaceutical companies to truly consider this type of important research. Now that reimbursement executives have a firm grasp on its definition, focus is placed on how CER will be implemented by pharmaceutical companies and evaluated by payers. Understanding the role that CER plays in formulary decisions is crucial to shaping evidence management and development.

• Integrating CER into product development and reimbursement strategy
• Examples of payer response to CER
• Future role of CER in the reimbursement landscape

Jennifer Graff, NATIONAL PHARMACEUTICAL COUNCIL
Ted Buckley, PhD, SHIRE
Kevin Mayo, ENDOPHARMACEUTICALS
Amanda Bruno, PhD, MPH, XCENDA

9:30 COFFEE & NETWORKING BREAK

10:00 ANALYZING TRENDS IN PHARMACY BENEFIT MANAGEMENT DESIGN AND THE IMPACT ON REIMBURSEMENT

Payers are increasingly raising expectations for their Pharmacy Benefit Management organizations, including requiring cost-saving measures. On the other hand, PBMs continue to exert their influence with healthcare payers. With this dynamic relationship between payer and PBM come changes in formulary design and decision making. Reimbursement executives from the pharmaceutical industry must understand formulary design trends and the ongoing impact on reimbursement of their products. Key trends within PBMs include a focus on value-based plan design, restricted formularies and new pricing methodologies.

• Evolving PBM demands and expectations on pharmaceutical products
• Impact of trends on reimbursement, including shift to 4 & 5-tier plan designs
• Adjusting reimbursement strategy based on PBM design trends

Jeff Haas, Divisional Vice President, Managed Health Care
ABBOTT LABORATORIES

10:45 CASE STUDY: IMPACT OF MEDCO HEALTH SOLUTIONS INC & EXPRESS SCRIPTS INC MERGER ON THE PHARMACEUTICAL INDUSTRY

In April, Express Scripts Inc. acquired Medco Health Solutions Inc. creating the largest pharmacy benefit management company in the country, with about 30% market share. The Federal Trade Commission approved the merger as it will ultimately benefit the consumer by lowering the cost of therapies. This session will outline the changing reimbursement landscape as a result of the merger.

Everett Neville, Vice President & Chief Trade Relations Officer
EXPRESS SCRIPTS

11:30 BREAKOUT SESSIONS: AN EXCHANGE OF IDEAS

Conference attendees will identify topics prior to the conference that they wish to discuss further in smaller groups. From there, volunteer moderators selected from attendees and speakers will lead each discussion. All attendees, speakers and sponsors are encouraged to become active participants allowing for richer exchange of ideas, peer-to-peer learning and open discussion.

12:15 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS

1:30 FUTURE MANAGEMENT OF MEDICAL-BENEFIT DRUGS AND THE IMPLICATIONS FOR REIMBURSEMENT PRACTICES

The pharmaceutical industry has witnessed an emerging trend where payers are moving specialty pharmacy products such as biologics and injectables to a pharmacy benefit structure, rather than medical benefit. This shift in categorization can be attributed to factors such as budget concerns and a smoother process for patients to obtain prior authorization. Moving a complex drug that is typically administered in a doctor’s office to a pharmacy benefit creates considerable challenges for patients, physicians and pharmaceutical companies regarding reimbursement structures, confusion surrounding costs and safety concerns.

• Implications of this trend on reimbursement
• Adjusting reimbursement strategy to overcome move to pharmacy benefit
• Effects of tighter management of medical-benefit drugs

Bill Soucie, Vice President, Managed Markets
IPSEN BIOPHARMACEUTICALS, INC.

2:15 COMMUNICATING EFFECTIVELY WITH PHYSICIAN OFFICES TO OVERCOME REIMBURSEMENT CHALLENGES

Educating physicians and their offices on coverage within payer policies and overcoming inaccurate perceptions of a particular product’s coverage and reimbursement structure is an ongoing challenge for market access teams. Pharmaceutical executives must work to find and implement strategies for effective communication in a language that is easily understood and meaningful to physicians. This session will provide attendees with a concrete example of how a pharmaceutical company’s market access team overcame the hurdle of policy versus perception.

• Developing framework for comprehensive communication
• Education regarding payer policies and reimbursement structure
• Proven impact on market access

Kent Rogers, Vice President, Managed Markets
ACORDA THERAPEUTICS

3:00 CLOSING REMARKS & CONFERENCE CONCLUSION

ATTENDEE PROFILE:

Executives that will find this program of greatest relevance are those currently working to increase the coverage and reimbursement of pharmaceutical and biotechnology therapies through the concise development of evidence and dossiers to support product claims. Job titles of those executives that will find this program to be most applicable to their job functions include:

• Reimbursement
• Market Access

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

• Pricing & Reimbursement Consultants
• Market Access Consultants
• Health Economics Experts
• Outcomes Research
• Dossier Development
• Global Reimbursement Experts

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