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# Executive Summit: Emerging Strategic and Financial Issues in the Pharmaceutical Industry

**December 6, 2011**
**Yale Club in New York City**
**12:00 Noon to 5:00 P.M.**

**Co-Sponsored by**
**Pharmaceutical Executive Magazine and Young & Partners**

## Preliminary Agenda

12:00 P.M. **Luncheon and Speakers**

**The Impact of the Global Fiscal Crisis on Pharma**
William Looney, Editor-in-Chief, *Pharmaceutical Executive*

**The Current and Future State of the Pharmaceutical Industry**
Peter Young, President, *Young & Partners*

1:00 P.M. **The Pharmaceutical Market: Trends, Issues and Outlook**
Doug Long, Vice President, *IMS Health Inc*.

1:40 P.M. **Achieving Success in the China Market**
Helen Chen, Partner and Head of China Life Sciences, *L.E.K. Consulting*

2:10 P.M. **Pharma M&A: Driving Factors in the Market**
Douglas E. Giordano, Senior Vice President, Worldwide Business Development, *Pfizer Inc*
Peter Young, President, *Young & Partners*

3:00 P.M. **European Biotech: The Symphogen Case Study**
Kirsten Drejer Ph.D., CEO, S*ymphogen*

3:30 P.M. **Biotech Deal Making – M&A, Licensing and Partnering Trends**
Randolph Guggenheimer III, Managing Director, *Young & Partners*

4:00 P.M. **New Developments in Drug Patent Laws**
David Barr, Partner, *Kaye Scholer LLP*

4:30 P.M. **Speaker Roundtable**
Moderator: Peter Young, President, *Young & Partners*
Participants: Executive Summit Speakers

5:00 P.M. **Concluding Comments**

## The Impact of the Global Fiscal Crisis on Pharma

**WILLIAM LOONEY**
**EDITOR-IN-CHIEF, PHARMACEUTICAL EXECUTIVE MAGAZINE**

The innovation premium is the premium the industry has relied on to fund new and innovative drugs. This premium is currently under a lot of pressure.

Biotech IPOs have slumped significantly from almost $10 billion in the second quarter to about $3 billion in the third quarter. Part of this has been driven by an increase in volatility of the financial markets caused by the debt crisis. This makes it harder to price an IPO effectively.

The public sector is a key driver of industry revenues. In the United States, the public sector now accounts for more than 50% of all healthcare spending. Expansionary fiscal policies are very important. We have an underlying issue of 1% real growth in the economy, as forecasted by the OECD. This growth will not be robust enough to revive anything in the government ledgers that will prevent them from having to make painful choices about spending. Few major market countries are immune to this issue and the high revenue potential emerging markets have their own set of problems.

At the beginning of the recession, most European governments said that health was so important and such a social priority that they would keep it out of the discussions about deficit reduction. Now that has changed; drug prices and healthcare are definitely on the table for cuts. When a country such as Portugal decides to reduce its own prices, it creates a trigger effect in many other markets.

The global fiscal crisis is a manageable short-term issue for the pharma industry. Global companies are cash rich and can spread risk. I refer to Big Pharma as the "lender of first resort"- when countries have to do something about their healthcare systems to lower the costs, it is usually the drug industry that comes in to make the first contribution, for a variety of political reasons. Smaller and local-based companies will take the biggest hit, along with the biotech industry start-ups, which are seeing fewer financing options. But in terms of fundamentals, we will see a long-term shift in the industry. This will involve commoditization of the product portfolio, global price transparency, and eroding support for pro-science industrial policies. The pharma industry needs to engage on health system and financing reform, which can be achieved through partnering on private-pay options. The drug value must link to public health outcomes.

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## The Current and Future State of the Pharmaceutical Industry

**PETER YOUNG**
**PRESIDENT, YOUNG & PARTNERS**

The traditional model used by pharmaceutical companies worked for many years. However, a multitude of changes have occurred that have disrupted that business model. Now pharma companies are struggling to devise strategies to survive the new business environment. These strategies include modified R&D approaches, biotech acquisitions/licensing/partnering, diversification, large scale mergers, exiting the pharma industry, geographic expansion, regional consolidation, and the pursuit of biologics.

Granted, there are a number of positive business trends in the industry. The aging populations in the developed countries favor growth in healthcare and pharmaceutical demand. Lifestyle and aging related drug therapies are showing tremendous growth potential relative to other drug markets. There are new technologies to accelerate drug discovery and development and a move to specialty indications. The drug industry appears to be a net winner under the 2010 US Health Care Reform bill that was passed.

However, there have also been trends that are negatively affecting the industry as well. The business model of the large ethical drug companies has been under attack. The negative publicity and hesitancy from the FDA has resulted in lengthy and more costly clinical trials. The R&D costs required to launch a new drug is extremely high (about $1.1 billion per drug) and it is taking an average of over 12 years to bring a new drug to market. Patents have also continued to expire in large numbers.

The pharma industry performance was positive in the first half of 2011. Unfortunately, the global stock market prices declined dramatically in the third quarter of 2011. As a result, for the first nine months of 2011, the Y&P U.S. Pharma index only increased by 2.5%, the Y&P Generic index decreased by 16.8% and the Y&P European Pharma index decreased 0.9%. During the first three quarters of 2011, 28 M&A deals worth $55.7 billion were completed, versus 40 deals worth $34.8 billion for all of 2010. Non-bank debt issuance was $20.7 billion, and the equity issuance was $1.6 billion for the first three quarters, indicating a slight decrease in activity on an annualized basis.

The business outlook for pharma companies is mixed, as pharma companies struggle to realign themselves to a new business model that will work. Young & Partners expects M&A activity will continue to be high as pharma companies merge or acquire to achieve scale and to enhance their product pipelines. The need to fill the shrinking drug pipeline will continue to fuel mergers and acquisitions, in-licensing arrangements, and the formation of partnerships and joint ventures.

## The Pharmaceutical Market: Trends, Issues, and Outlook

**DOUG LONG**
**VICE PRESIDENT, IMS HEALTH**

Growth remains at historically low levels due to a number of big negatives and the absence of positives. Brand volume growth is slowing faster than "normal." There are changing promotional dynamics, changes in sales forces both from expiry/launch shifts, and changes in the commercial model. Brand price growth has been at historically high levels, but is offset by rising rebates. Patient visit trends continue to be negative with patients rationalizing to fewer visits per month through impact on overall demand. Brand growth remains anemic, with a 10% decline in scripts through June 2011, as generics take a greater share of volume.

Growth contributions of launches are deteriorating because there are fewer new launches and they are not doing as well. A shift in the power of stakeholders is decreasing the influence of prescribers and stakeholders have expanded criteria by which they assess new products. Less than 1% of the thousands of launches IMS has studied are excellent. Even with a good product in hand, launch success is not a forgone conclusion. The right value proposition is essential, but also increasingly expensive to achieve.

The strongest impact of patent expiries and entry of lower-cost generics is expected in 2012-2013. Expiries in 2010 were largely exclusive; potential exclusivities are expected to trend down through 2015.

Personal promotion to physicians has become increasingly difficult. Brand growth is driven by price. Generics now have new opportunities and less price deflation. Spending due to brand pricing is trending upward, but is being offset by rebates. Payment type is continuing its shift towards Medicare Part D and Medicaid. The debate in the US on healthcare reform was broadly centered on core issues of access, affordability and quality. The most certain impacts of the healthcare reform are negative in the short term, but more positive or uncertain in the longer term. About 25-30 million people will get coverage under the reform, but questions remain about how they will use it.

Recent policy changes driven by macroeconomic factors will have longer-term impacts. The global pharma market will pass the $1 trillion dollar mark in sales by 2013. Pharmerging markets and generics are the only drivers of growth. By 2015, China will replace Japan as the second largest market.

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## Achieving Success in the China Market: Recognizing and Overcoming Infrastructure Challenges

**HELEN CHEN**
**PARTNER AND HEAD OF CHINA LIFE SCIENCES, L.E.K. CONSULTING**

China is expected to be a major value driver of the global pharma market, accounting for a quarter of global value growth in 2015. The underlying drivers of China's healthcare and device markets are the aging population, continuing urbanization and increasing affordability. Many "western" diseases now are also rapidly increasing in China, further driving up the demand for healthcare. The Chinese government has significantly improved medical insurance coverage, though a substantial amount of spending is carried by the patient out-of-pocket.

China's 2009 health reform initiatives and the new "12th Five-Year Plan" are designed to dramatically improve healthcare across regions. The plan focuses on "inclusive growth," with initiatives targeting 7% GDP growth, consumption over investments and exports, a narrowing of the income gap, increasing social safety nets and energy efficiency. There are three key themes regarding healthcare initiatives in the plan: increased coverage and quality of services, innovation, and an industry restructuring and upgrading.

China's generic pharma market is fragmented; there are thousands of generic makers in the market, the quality standard is relatively low, and physicians prefer medicines with brands in order to minimize potential risks. Big Pharma companies have used their sales force clout and physical investments to drive their success to date and have become household names in China. Interestingly, the major revenue generators for Big Pharma are mostly off-patent drugs that were launched years ago.

As the healthcare infrastructure in China changes, county-level hospitals and community primary care facilities are the new investment areas, rather than the traditional large hospitals. Even in well-understood diseases, it is highly likely that a large portion of patients are missed in China. Given the size of the China market, however, there is no one formula to success—both Western and Chinese companies are expanding beyond their traditional strongholds.

## Pharma M&A: Driving Factors in the Market

**DOUG GIORDANO**
**SENIOR VICE PRESIDENT, WORLDWIDE BUSINESS DEVELOPMENT, PFIZER**

The industry is currently facing both many challenges and many opportunities. The challenges facing pharmaceutical companies trying to succeed in high-risk innovation include: pricing and reimbursement pressures, increased regulatory and drug development hurdles, and unprecedented losses of exclusivity on major primary care blockbusters. Unless a new drug entity has superior clinical advantages or is first in class, it will likely be subject to 6-12 months of limited formulary coverage by health plans. However, there is strong growth in emerging markets and a major demographics shift, including the aging population of the developed world.

The key question is how do we address this shift to remain successful? There are various M&A approaches that can be used as part of the solution to the changes in the industry, including: infrastructure/capabilities, break ups, geographic expansion (emerging markets), diversification, product/pipeline, and transformation. The business development strategies both in the US and Europe are a focus on diversification and product/pipeline.

Pfizer has eight diverse businesses that are supported by focused research organizations: primary care, specialty care, oncology, established products, emerging markets, animal health, consumer healthcare, and nutrition. Pfizer's structure enables accountability, flexibility, and focus with its four strategic imperatives: fix our innovative core, maximize our capital allocation, be respected in society, and make Pfizer a great place to work. Fixing the innovative core involves both product/pipelines and technology/platforms. The maximization of capital allocation will come from portfolio enhancement, leveraging global capabilities and unlocking value.

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## Pharmaceutical M&A: Driving Factors in the Market

**PETER YOUNG**
**PRESIDENT, YOUNG & PARTNERS**

The total dollar value of deals was low for most of the 1990s, but escalated in 2000 and has been healthy since. In the first three quarters of 2011, the total dollar volume surpassed the total dollar volume of deals in all of 2010. 28 M&A deals worth $55.7 billion were completed, versus 40 deals worth $34.8 billion for all of 2010. Since 2000, deal volume has been in the $40 billion to $50 billion range except for a couple of mega-merger years.

There has been no historical pattern with regard to cross-border activity, but recently cross-border deals have dominated. The deal volume in the US reached a record in 2007, but slowed dramatically in 2009 and 2010. Volume has surged in the first three quarters of 2011. European M&A volume has been volatile. After a major drop-off in 2008, volume has gradually picked up. Asian M&A activity has typically been low, but Japanese consolidation and emerging Asian company activity has increased activity modestly. Activity in the rest of the world has been chronically modest. This is a reflection of the historical concentration of pharma in the West and Japan.

M&A EBIT valuation multiples have been quite high relative to other industries. However, there has been a gradual decline over time and the range of multiples is narrowing.

Young & Partners expects M&A activity will continue to be high as pharma companies merge or acquire to achieve scale and to enhance their product pipelines. M&A activity in emerging markets will continue to grow as companies look to these markets for growth. The need to fill the shrinking drug pipeline will continue to fuel mergers and acquisition, in-licensing arrangements, and the formation of partnerships and joint ventures. However, a portion of that activity will be directed toward the biotech industry versus pharma companies.

## European Biotech: The Symphogen Case Study

**KIRSTEN DREJER, PhD.**
**CEO, SYMPHOGEN**

What I learned from drug discovery at NovoNordisk when I was there was that if one is able to mimic the way nature works, one might be able to come up with really good drugs that are both effective and safe. So after departing from NovoNordisk, we developed Symphogen with the goal of finding a technology that could try to mimic the natural immune response. We also wanted to have immune system diversity by being able to make recombinant antibody mixtures.

Over the years we have developed three platforms: one to clone the antibodies (simplex™), one to figure out how to identify the correct antibodies for the mixture (symselect™), and a sympress™ technology we have developed to manufacture the mixture. We have also brought two products into the clinic. The pipeline we have developed so far consists of three segments: oncology, hematology (lead drug with an orphan drug indication), and infectious diseases.

Our lead drug is Sym004/EFGR mAB mixture, which compared to approved EGFR mAbs: induces more rapid, effective EGFR internalization and degradation by cross-linking receptors, has superior growth inhibition of cancer cells in vitro and in vivo, and has a broader expected target patient population.

As CEO, I have had to figure out how to finance a successful biotech company. So I looked at successful biotech companies worth more than $1 billion. What I discovered is that these companies have been around 20-25 years and took $700 million to $1 billion in accumulated deficit to get to the $1 billion level. I also noticed that the European biotech companies seem relatively small when compared with biotech companies from the US. Over the last few years, there has been a stream of pipeline failures and commercial disappointments in European biotech. It is possible to achieve success in European biotech, but the obstacles are greater than in the U.S.

In the near future there will be an abbreviated pathway for off-patent biologics, biosimilars will compete on price following the small molecule generic model, and marginal differentiation for "premium" branded new entrants will not be sufficient. The future calls for Proof of Relevance, PoR™, rather than just Proof of Concept.

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## Biotech Deal Making: M&A, Licensing, and Partnering Trends

**RANDY GUGGENHEIMER III**
**MANAGING DIRECTOR, YOUNG & PARTNERS**

From a buyer's perspective, pharmaceutical and large biotech companies are facing patent expirations and pipeline gaps and are looking for products that are late-stage with significant patent protection. Acquirers often wish to mitigate their risk, either by licensing the product or by structuring the acquisition so that the seller shares in the risk. Sellers often are looking to sell or license their products to pharmaceutical or large biotech companies because they do not have the financial wherewithal or development capabilities to continue to advance their products in the clinic past a certain stage. As a result, sellers have become more willing to license their products or sell in earnout deals. Earnout deals have become common in biotech M&A transactions. The payouts on these deals look more like partnering/licensing transactions with milestones for approval or the achievement of specific sales levels. These structures allow acquirers to mitigate their risk and allow sellers to potentially realize significantly high valuations upon success.

Biotech M&A activity continues to be surprisingly modest. Two recent examples that I would like to highlight are the acquisition of BioVex by Amgen and the acquisition of Pharmasset by Gilead.

BioVex was a privately-held, venture-funded biotech company with lead product candidate OncoVEX (GM-CSF), a novel-oncolytic vaccine in Phase 3 trials to treat metastatic melanoma and head and neck cancer. Amgen is a leader in cancer supportive drugs, but has a more limited presence in cancer treatments. The OncoVEX melanoma data suggests that in addition to its direct effect of cancer cells it also triggers a positive immune response. The earnout structure allowed for some mitigation of the risk for Amgen.

Pharmasset is a publicly-traded biotech company and is the current leader in the next generation of HCV (Hepatitis C) products, which offer the promise of curing the disease. Gilead has products under development for HCV which could be combined with Pharmasset's drugs to create the first all-oral regimen. What is less clear is the rationale for the high price that is being paid.

Although the number of licensing deals has fallen somewhat over the last couple of years, the average value of deals has risen. This reflects intense competition among large pharma and large biotech for products addressing the most attractive targets and indications.

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## New Developments in Drug Patent Laws

**DAVID BARR**
**PARTNER, KAYE SCHOLER LLP**

On September 16, 2011 the "America Invents Act" was enacted. This Act was passed "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." This continues the recent efforts to harmonize the US Patent Law with the rest of the world.

Effective for applications and patents containing a claim with an effective filing date of March 16, 2013 or later, US patents will be award to the first person to file a patent application, rather than the first person to invent (previous law). One exception is that an inventor can rely on the date of his own public disclosure of the invention if made within one year prior to filing his patent application. However, a public disclosure prior to filing may result in forfeiture of patent rights in countries which do not have a grace period. This eliminates "interference" proceedings in the PTO to resolve who was the first to invent. It also creates PTO "derivation" proceedings to resolve disputes as to whether one person derived an invention from another.

Under AIA, a patent is barred if the invention "was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention" anywhere in the world. This means prior art includes subject matter described by another inventor in a US patent or published US patent application as of its earliest filing date, even if first filed in a foreign country.

Effective with court actions commenced on or after September 16, 2011, multiple defendants cannot be joined in a single patent action unless the right to relief is joint, several or in the alternative, and the common questions of fact common to all defendants will arise.

The Supreme Court is currently dealing with *Mayo v. Prometheus Labs*, regarding a patent that covers the discovery that measuring the level of certain metabolites present in the blood after administration of a thiopurine drug to treat immune-mediated gastrointestinal disorders can be used to adjust the dosage to increase efficacy and reduce toxicity.