PHARMA TRAX

SALES, MARKETING, AND R&D TRENDS AFFECTING THE HEALTHCARE INDUSTRY

PHARMACEUTICALS MERGERS AND ACQUISITIONS, 2000 TO 2009

Year	Dollar Total ($ in billions)	Number of Deals
2000	$97.4	41
2001	$27.7	87
2002	$66.1	147
2003	$23.6	173
2004	$95.2	171
2005	$46.6	128
2006	$74.8	138
2007	$71.6	180
2008	$40.7	140
2009	$147.2	140
10 Year Total	$691.0	1,345

Source: DealSearchOnline.com. For more information, visit dealsearchonline.com.

GlaxoWellcome, Pfizer Chalk Up **BIGGEST MERGERS OF PAST DECADE**

The past decade was a boom time for pharmaceutical mergers. According to a recent report from DealSearchOnline.com, a total of 1,345 mergers and acquisitions of pharmaceutical assets and pharmaceutical companies were announced during the 10 years ended Dec. 31, 2009, with disclosed prices totaling more than $694 billion.

GlaxoSmithKline was responsible for the largest of the pharmaceutical mergers and acquisitions this past decade. GlaxoWellcome announced its $74 billion merger with SmithKline Beecham in 2000, resulting in the entity now known as GlaxoSmithKline. Pfizer announced two of the largest pharmaceutical mergers and acquisitions of the decade, including its $68 billion acquisition of Wyeth in 2009 and its $56 billion acquisition of Pharmacia in 2002.

Three of the top 25 pharmaceutical mergers and acquisitions announced in the past decade happened during 2009.

In addition to Pfizer's acquisition of Wyeth, 2009 saw Abbott Laboratories' acquisition of Solvay Pharmaceuticals for $7.6 billion, and Merck's acquisition of Schering-Plough for $41.1 billion.

For more information, visit dealsearchonline.com.

Pharma Takes More **STRATEGIC APPROACH TO DRUG SAFETY**

Some high-profile examples of poor drug safety efforts over the past decade — and even some more recently in 2010 — have prompted the pharma industry to invest more in drug safety.

Beyond changes to investments and added resources, companies are beginning to regard drug safety in more strategic terms, with the understanding that drug safety teams are vital to protecting patients and keeping drugs on the market. According to the recent Cutting Edge Information report, Benchmarking Drug Safety and Pharmacovigilance, many different functions intersect with pharmacovigilance activities at some point in a drug's life cycle.

Overall, the most common department to oversee drug safety groups is clinical development, with many of the ties between the drug safety and clinical teams that existed during a drug's development remaining once a drug reaches the market.

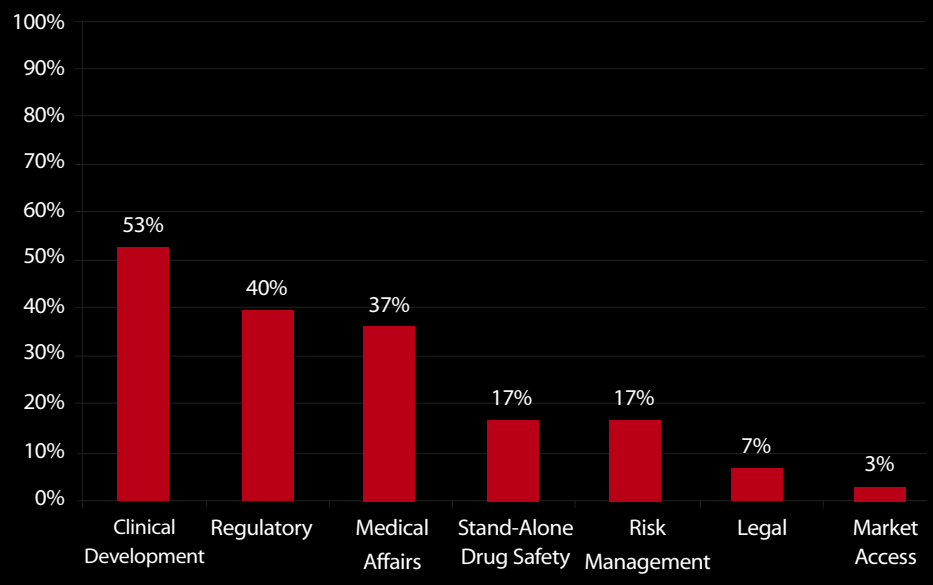
With so many guidances newly released and the landscape of drug safety changing so quickly, many interviewed executives said they are confused from time to time as to the exact reporting requirements for adverse events.

The Food and Drug Administration recently released a preliminary new guidance stating that companies must report everything, but this guidance has not yet been approved. As such, it is unclear whether reporting is required for adverse events that are unrelated to the drug. Even though drug safety groups could use assistance from the FDA in clarifying these changes, historically the industry has been reluctant to contact the FDA for questions.

Many study participants say their departments have been instructed not to contact the FDA with anything less than a major issue, for fear that questions will increase scrutiny or lead to an audit.

At least one interviewed executive believed the FDA was more receptive to a conversation than it had been in the past and would be less likely to

DEPARTMENTS WITH SOME OVERSIGHT OF DRUG SAFETY GROUPS (OVERALL)



Source: Cutting Edge Information, Benchmarking Drug Safety and Pharmacovigilance. For more information, visit cuttingedgeinfo.com.

hold a reporting concern against a company. But most continued to respect a distant relationship with the FDA.

For more information, visit cuttingedgeinfo.com.

Life-Sciences Companies Advised to **USE SOCIAL MEDIA WITH CARE**

Social media presents a great opportunity for companies to engage their customers and employees on a lateral platform and invite feedback to establish and build relationships.

But social media also comes with significant risk, especially for life-sciences companies, given the amount of state and federal regulatory scrutiny to which their communications are subject.

In a recent white paper on social media monitoring, Huron Consulting Group observes that companies must continually be vigilant for the posting of unauthorized material, material that has not been properly reviewed through the company's social media material review process, or material that could be considered off-label promotion or as potentially requiring adverse event reporting. Companies must also address the potential volume of information shared on various social media sites with the ability to process that information in a continuous and timely manner for state, federal, and international regulatory compliance purposes.

Ultimately, these risks should not be viewed simply as compliance risks but also as business risks, as content posted by dissatisfied customers may reach millions of additional potential customers and sway their opinion of a company or product. Indeed, a search on Twitter for popular drug brand names will reveal tweets from a large number of users, many of which contain adverse event information related to usage of that drug.

The industry as a whole must consider how to respond to such information so that their reputations are not adversely affected.

For more information, visit huronconsultinggroup.com.

GUIDELINE CONSIDERATIONS FOR LIFE-SCIENCES COMPANIES' INTERNAL USE OF SOCIAL MEDIA

1. Institute a committee that will review all materials to be posted on social media Web sites. This committee would likely consist of the same or similar people who currently make up the company's promotional review committee (or equivalent).
2. Establish a dedicated review and approval process for all materials that would be posted to social media sites. This process would likely be the same or similar to the company's existing promotional material review process, with all materials needing to be routed through this process before being posted on any social media sites.
3. Develop clear and consistent guidelines that would be used to evaluate proposed social media pieces before their distribution. These guidelines should tie closely to any guidance provided by the FDA; in the period of time before the provision of that guidance, these guidelines should generally adhere to the company's existing policies related to the publication of promotional materials.
4. Ensure that, where applicable, information is posted to social media sites in a manner such that it is not readily accessible to residents of those countries in that it would be illegal to transmit such information. For instance, information which might be considered direct-to-consumer advertising should not be posted to the local country versions or in the local country languages of social media sites where the local country regulations do not allow for the production of direct-to-consumer advertising.
5. Consider instituting the position of "social media monitor." The person in this position, likely residing within the company's compliance department, would be the centralized clearinghouse for all social media postings and would be responsible for maintaining all social media accounts and granting permission for new accounts.
6. Consider developing enterprisewide training to educate employees on these new policies and instruct them that they must not use personal Twitter, Facebook, or other social media accounts to disseminate confidential company information.

Source: Huron Consulting Group, Social Media Monitoring. For more information, visit huronconsultinggroup.com.

INNOVATIVE R&D APPROACHES May Prove Best Path for Drug Developers

Because patents on dozens of drugs are due to expire within the next few years, paving the way for generics to compete with those products, drug developers are in a race to develop and win market approval for new medicines.

Innovative approaches to drug development, including alliances and partnerships, may prove the best way to increase the rate at which the research-based drug industry brings new products to market, according to a panel of pharmaceutical and biotech industry leaders recently convened by the Tufts Center for the Study of Drug Development.

According to Tufts CSDD, drug development, which starts in discovery and may involve examining many thousands of compounds, takes an average of 15 years to produce a product approved for sale in the United States.

"No one has yet figured out how to reliably identify early on which newly discovered compound will bear fruit," observes Tufts CSDD Director Kenneth Kaitin. "This is spurring companies across the industry to experiment with a growing range of new tools and approaches to weed out unpromising drug candidates earlier, speed development, and reduce development costs."

Industry executives at the Tufts CSDD roundtable noted that while a growing number of drug companies are developing alliances with external service providers, those approaches have not yet emerged into full-fledged partnerships, where both parties share development risks and rewards.

The executives agreed that new approaches, such as engaging in collaborative relationships and reducing distinctions between clinical development phases, could help increase R&D efficiency. Using the Phase I, II, and III distinctions between clinical phases is a matter of practice and not a legal requirement; starting human trials earlier may offer a way to save money and time, the panelists said.

Executives also suggested engaging in collaborative relationships similar to the Asian Cancer Research Group being formed by Lilly, Merck, and Pfizer as a way to help accelerate research. They also recommended using the exploratory IND, a relatively new type of pre-Phase I clinical trial that lets sponsors evaluate up to five chemical entities or formulations simultaneously to identify a lead compound.

For more information, visit csdd.tufts.edu.

QUICK FACTS

- The value of the global market for therapeutic vaccines is estimated at $137 million in 2010, but the market entry of new vaccines to treat cancer and nicotine addiction is expected to propel the category to almost $3.1 billion in 2014, for a four-year compound annual growth rate (CAGR) of 117.7%.

Source: BCC Research, Therapeutic Vaccines: The Global Market. For more information, visit bccresearch.com.

- The global market for products used to treat depressive and anxiety disorders is expected to be worth an estimated $29.4 billion in 2009 and increase to $38.5 billion in 2014, to a five-year CAGR of 5.6%. The antidepressants segment has the largest share of the market, with growth projected at a CAGR of 5.5% to more than $21.2 billion in 2014. The antianxiety drugs segment is projected to increase at a CAGR of 5.6% to $17.3 billion in 2014.

Source: BCC Research, Therapies for Depressive and Anxiety Disorders. For more information, visit bccresearch.com.

- The stem cell market is divided into three segments — cell-based treatments, umbilical cord blood banking, and the use of stem cells to evaluate the efficacy and safety of new drugs developed by other methods. Total global sales for this market reached $410 million in 2008 and are expected to jump to $2.68 billion by 2012 and $5.1 billion in 2014.

Source: Business Insights, Advances in the Stem Cell Industry: The future impact of innovation, and an evaluation of the commercial landscape. For more information, visit globalbusinessinsights.com.

- Surveyed psychiatrists say the decrease in the severity of manic symptoms is the attribute that most influences their prescribing decisions in bipolar mania. Clinical data and the opinions of interviewed thought leaders indicate that Lilly's Zyprexa (olanzapine) has advantages in this attribute over AstraZeneca/Astellas' Seroquel (quetiapine), the leading seller in the bipolar disorder drug market.

Source: Decision Resources, DecisionBase 2010 report, Bipolar Mania: Emerging Therapies That Offer a Reduced Risk of Weight Gain and Metabolic Side Effects Will Not Unseat Current Drugs Unless They Offer Efficacy Comparable to Olanzapine. For more information, visit decisionresources.com.

- A therapy that would improve median overall survival over IFL (bolus 5-fluorouracil, generics/leucovorin, generics/irinotecan) plus bevacizumab (Roche/Genentech/Chugai's Avastin), would earn a 60% patient share in stage IV colorectal cancer, according to surveyed U.S. oncologists. In Europe, such an agent would earn a 50% patient share, according to surveyed European oncologists.

Source: Decision Resources, DecisionBase 2010 report, Colorectal Cancer (Stage IV): Blockbuster Opportunity Awaits a Therapy That Would Improve Overall Survival over IFL/Bevacizumab. For more information, visit decisionresources.com.

- Analysts expect that in 2018, a quadruple therapy consisting of a combination of two hepatitis C virus-specific antiviral agents (e.g., an HCV protease inhibitor plus a polymerase inhibitor, or an NS5A inhibitor plus a protease inhibitor), a long-acting interferon, and ribavirin will likely be widely used for the treatment-naive patient population with the hepatitis C virus.

Source: Decision Resources, DecisionBase 2010 report, Hepatitis C Virus (Treatment-Naive Patients): Triple- and Quadruple-Therapy Regimens Vying for Patient Share of a Diminishing Patient Population. For more information, visit decisionresources.com.

- A once-daily formulation of Pfizer's Neurontin would earn a 50% patient share in the treatment of postherpetic neuralgia, according to surveyed U.S. neurologists. In Europe, such an agent would earn a patient share of 40%, according to surveyed European neurologists. Such a drug would likely become the patient-share leader both in the U.S. and Europe's postherpetic neuralgia market in 2013.

Source: Decision Resources, DecisionBase 2010 report, Postherpetic Neuralgia: The Greatest Opportunities Are Improved Safety and Tolerability. For more information, visit decisionresources.com.

- A drug's impact on global symptoms and its effect on positive symptoms are the attributes that most influence surveyed psychiatrists' prescribing decisions in schizophrenia. But clinical data and the opinions of interviewed thought leaders indicate that current and emerging therapies have no advantage over sales leader Lilly's Zyprexa on these attributes. Instead, the commercial success of emerging therapies (both oral and depot formulations) is expected to be dependent upon safety and delivery advantages.

Source: Decision Resources, DecisionBase 2010 report, Schizophrenia: Emerging Atypical Depot Formulations Must Meet Psychiatrists' High Expectations to Be Successful in a Generically Threatened Market. For more information, visit decisionresources.com.

- The irritable bowel syndrome drug market is expected to more than triple from $459 million in 2008 to $1.52 billion in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. The primary driver of market growth will be the launches of several novel first-in-class therapies including Salix's Xifaxan, Ironwood/Forest/Almirall/Astellas' linaclotide, Tioga/Ono's asimadoline and Lexicon/Symphony Icon's LX-1031, beginning in the U.S. in 2011.

Source: Decision Resources, Pharmacor 2010 findings on Irritable Bowel Syndrome. For more information, visit decisionresources.com.

- The multiple myeloma drug market is projected to more than double from $2.1 billion in 2008 to $5.3 billion in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Growth will be driven by increased use of Celgene's Revlimid in the first-line setting and the launches of several premium-priced emerging therapies.

Source: Decision Resources, Pharmacor 2010 findings on Multiple Myeloma. For more information, visit decisionresources.com.

- The ovarian cancer drug market is anticipated to more than triple from $449 million in 2008 to just under $1.5 billion in 2018 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. Growth will be driven by the approval and rapid uptake of Roche/Genentech/Chugai's Avastin, which is expected to launch for the additional indication of ovarian cancer in the United States and Europe in 2011, and in Japan in 2013.

Source: Decision Resources, Pharmacor 2010 findings on Ovarian Cancer. For more information, visit decisionresources.com.

- Surveyed gastroenterologists estimate that, assuming no new data on adverse events emerge, they will treat fewer Crohn's disease patients with Centocor Ortho Biotech/Merck/Mitsubishi Tanabe's Remicade by the end of 2010, while the percentage of biologics-treated patients receiving Abbott/Eisai's Humira will increase to 36%. Surveyed gastroenterologists also indicate that the percentage of patients treated with a biologic who receive UCB/Otsuka's Cimzia will rise from 9% to 12% within the next year.

Source: Decision Resources, Physician & Payer Forum report, The Expanding Biologics Landscape in CD and UC: Clinician and Payer Perspective on the Role of Premium-Priced Biologics in CD and UC Treatment. For more information, visit decisionresources.com.

- Automated reminder and follow-up calls for HPV vaccinations increase adherence rates from 5% to more than 20%. The leader in HPV vaccination compliance is the Scotland National Health Service, with rates as high as 92% for

the first dose and 87.8% for the second dose. By contrast, HPV vaccination rates in the state of Mississippi are as low as 15.8%.
Source: iReminder, HPV Vaccination Compliance white paper. For more information, visit ireminder.com.

- Although the $4.1 billion market for anesthesia drugs is considered mature, an increase in surgeries as a result of an aging population are expected to help drive annual growth of up to 4.8% through 2014, and new therapeutic applications in categories such as depression could drive additional sales over the long term.

Source: Kalorama Information, The World Anesthesia Drug Market. For more information, visit kaloramainformation.com.

- In situ hybridization (ISH) tests, which are probes for specific DNA sequences performed on portions of tumor tissue, have become one of the fastest-growing market segments in laboratory medicine, showing 8% sales growth per year. The world market for all ISH tests was estimated at $670 million in 2009, and with new enhancements the technology is expected to continue to drive revenues for Abbott, Genzyme, Invitrogen, and other test makers.

Source: Kalorama Information, The Worldwide Market for Cancer Diagnostics. For more information, visit kaloramainformation.com.

- The in-vitro diagnostics (IVD) market in BRIC nations (Brazil, Russia, India, and China) is expected to be worth $7.3 billion by 2014, for a five-year CAGR of 19%. Market growth is expected to be driven mainly by the increasing healthcare budgets of BRIC economies, along with the increasing number of private corporate hospitals and the rising income levels backed by a huge, untapped population bases.

Source: MarketsandMarkets, In-Vitro Diagnostics (IVD) Market in BRIC (2010-2014). For more information, visit marketsandmarkets.com.

- Assuming biosimilar compounds become permitted under U.S. law by 2012, the value of the biosimilars market segment is expected to account for 2.6% of the biologicals market by 2016. Even with the approval of such legislation, the value of the biosimilars market segment is likely to continue to be dominated by European sales revenue in 2012, and this is likely to account for about 0.6% of the fast-growing biologicals market. But by 2016 the United States is expected to overtake Europe as the leading source of revenue from such products.

Source: Urch Publishing, Biosimilars: A Growing Market - An overview of developments, companies & commercial opportunities. For more information, visit urchpublishing.com.