

U.S. Biochip Market TO REACH \$2.5 **BILLION IN 2012**

U.S. demand for biochip products and services is forecast to grow 9.9% annually, to \$2.5 billion in 2012, led by uses in drug discovery and epidemiological research. According to The Freedonia Group, protein characterization and analysis are expected to provide the fastest-expanding technologies.

The Freedonia report, Biochips, projects that biochips or microarrays will account for about \$1 billion of the \$2.5 billion market by 2012, with the remaining \$1.5 billion divided among related reagents and other consumables, instruments, software, and services. Since drug discovery will remain the leading application for microarray technology over the long term, pharmaceutical companies, biotechnology firms, and major medical universities will continue to form the three largest markets served by the biochip industry.

The report predicts that DNA chips will continue to generate broad use in genomic research. But the shift toward a greater focus on proteomics will create stronger growth opportunities for protein and laboratory biochips. Advances in characterization and analysis methods will expand the range of protein microarrays available for drug screening and optimization and the identification of disease

The market for biochip instruments is projected to grow 6.1% annually through 2012. Based on convenience and efficiency, workstations that combine sample preparation, hybridization, and detection will post the strongest gains in demand among biochip instruments. Software that interfaces with public genomic and proteomic databases will fare particularly well in the marketplace as life-sciences researchers continue to study HGP results.

The report predicts the market for biochip-related services will generate annual growth of more than 11% through 2012. Contract research and out-

	% Annual Grov					
	2002	2007	2012	2002-2007	2007-2012	
Biochip Product & Service Demand	\$684	\$1,570	\$2,520	18.1%	9.9%	
Products	\$477	\$1,110	\$1,740	18.4%	9.4%	
Biochips (Microarrays)	\$222	\$635	\$1,000	23.4%	9.5%	
Reagents & Consumables	\$101	\$231	\$390	18.0%	11.0%	
Instruments	\$115	\$167	\$225	7.7%	6.1%	
Software	\$39	\$77	\$125	14.6%	10.2%	
Services	\$207	\$460	\$780	17.3%	11.1%	

U.S. BIOCHIP PRODUCT & SERVICE DEMAND, 2007 (\$1.6 BILLION)								
Microarrays 40%								
Reagents & Consumables 15%								
Instruments 10%								
Software 5%								
Services 30%								
Source: The Freedonia Group Inc., Biochips. For more information, visit freedoniagroup.com.								

sourcing services, especially in the area of drug discovery, will post the strongest gains as proprietary pharmaceutical companies broaden the pursuit of new blockbuster therapies. Growth opportunities for biochip maintenance and technical support services will also increase favorably, spurred by upward trends in the number of microarray instruments and the continued aging of previously installed systems. For more information, visit freedoniagroup.com.

Medicare **PART D PREMIUMS** Forecast TO RISE DRAMATICALLY in 2009

More than 2 million low-income Medicare beneficiaries may once again face a disruption to their prescription drug coverage amid skyrocketing premium costs and a dramatic reduction in plans available in 2009. This will require them to switch to new Medicare Part D plans or face premiums that they cannot afford and/or limit access to the medicines prescribed by their doctors.

The Low Income Subsidy (LIS) program provides total or partial premium assistance to more than 9 million low-income seniors and individuals with disabilities. These Medicare beneficiaries only receive the full benefit of the subsidy if they enroll in plans with premiums below an amount set annually by Medicare. Because Medicare Part D benefits are administered through private insurance companies, premium costs change from year to year, as do the plans that are fully covered by LIS.

According to a report by the National Senior Citizens Law Center (NSCLC), roughly a quarter of LIS recipients are currently enrolled in plans that were fully covered by LIS in 2008, but are not covered for 2009. More than 1.6 million low income beneficiaries will be automatically reassigned by Medicare to a new plan in 2009, while an additional 620,000 will need to switch plans themselves to avoid a monthly premium. Monthly premium liabilities for beneficiaries who remain in their current plans could range anywhere from 10 cents to \$47.50. Medicare Part D beneficiaries outside the low-income bracket will also face higher premium costs.

The recent NSCLC report recommends a number of changes to the Medicare Part D system that would reduce annual disruption to lowincome beneficiaries, including:

- Establishing a Medicare-administered Part D plan to provide Part D enrollees the same options and choices they have in other parts of the Medicare program.
- Changing the way that plans eligible for the LIS are identified to reduce the annual changes to eligible plans.
- Requiring plans that are eligible for the LIS also provide high-quality, comprehensive services.
- Improving the reassignment process so that it

also takes a beneficiary's known prescription needs into account when identifying a new plan.

- Expanding communications to better inform all subsidy recipients about likely changes to their current plans and options available to them for the coming year.
- Sharing more information with the public about LIS recipients and the reassignment process.

For more information, visit nsclc.org.

RESEARCHERS URGE TRADITIONAL MEDIA to

Embrace Web 2.0 Tools

From their growing use of discussion boards, blogs, wikis, video, and podcasts, scientists are learning how to employ Web 2.0 and social media tools to good effect. According to a recent BioInformatics survey, online collaborative tools are becoming

increasingly valuable to today's researchers, while reliance on traditional media as an information source is on the wane.

The BioInformatics report, The Brave New World of Scientific Publishing, is based on 1,557 responses from life scientists to a 37-question online survey about how they use the Web for research, collaboration, and networking. The findings reveal that traditional publishing models, while still viable, no longer stand alone as a way to thrive in a community of scientists who want more speed, more control, and easier access to information, as well as the perception that their



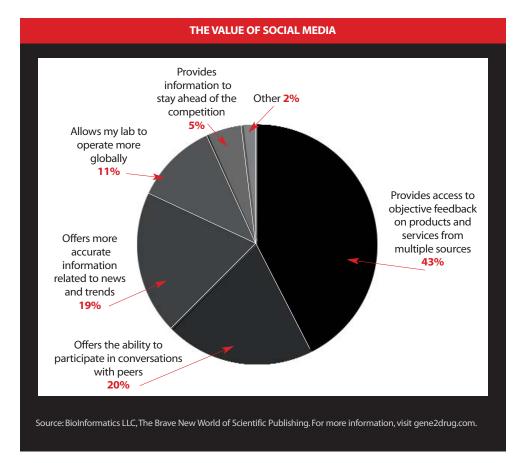
An organization must leverage its existing reputation and influence its online audience, says Tamara Zemlo of BioInformatics.

voices are being heard. Publishers that understand these needs and adapt accordingly are already taking the lead.

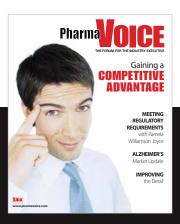
"Our assessment is that publishers are well-placed to deliver social tools in a secure and trusted environment, but they also need to incorporate tools that are more relevant, focused, and easy to use," says Richard Grant, who served as a lead consultant on the BioInformatics report.

For example, one survey respondent called the traditional peer review system "too slow, outdated, becoming obsolete" and advised that articles be published instantaneously on the Web and linked by aggregator sites so they can be reviewed and commented upon online by other scientists.

According to the study, publishers must resist the temptation to view social media as the same type of threat the Web was perceived to be in the mid-to-late 1990s. Publishers have the opportunity to use this latest tool to reinforce the mandate to communicate and collaborate that drives scientific research.



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Among the key findings of the report are:

- Social media usage has increased, but the amount of time spent on these tools has decreased slightly.
- Social media tools continue to broaden scientists' perspective on problems.
- Scientists are becoming more informed about recent Web 2.0 tools for social collaboration, but their use doesn't yet match their awareness.
- The awareness of some new information sources is higher than traditional ones.
- Scientists remain ambivalent about whether services such as Google Scholar are an infringement of copyright laws.
- As their awareness of Web 2.0 social media increases, distinct generational differences in respondents' use of these tools are emerging.

For more information, visit gene2drug.com.

CHEMOTHERAPY DRUGS TO FEEL STING of Generic Competition

Chemotherapy, or cytotoxic therapy, has been the cornerstone of cancer treatment for many years, representing the second-largest class of oncology drugs. But as the segment matures, generics companies are chasing after the success of several block-buster brands. According to a Datamonitor report, Commercial Insight: Cytotoxic Therapy Cancer Brands, the chemotherapy market will reach a peak of \$16.5 billion by 2013, after which it will decline in the face of generic incursion.

Sales of the 25 cytotoxic therapy cancer brands currently available in the seven major worldwide markets totaled \$10 billion in 2007. Eleven of the 25 brands are approved for use in breast cancer, the incidence of which is estimated to have reached 455,315 in the seven major markets in 2008.

"Even though targeted therapies are becoming more and more popular, cytotoxics remain the backbone of cancer treatment," observes Chandni Surti, Datamonitor oncology analyst. "As the incidence of cancer continues to rise with the aging population, the use of effective cytotoxic therapies is likely to remain strong."

For more information, visit datamonitor.com.

GlaxoSmithKline POISED TO OVERTAKE PFIZER as World's Largest Pharma Company

Growth forecasts indicate that over the next four years, there will be major changes in the global pharmaceutical market and key changes in the list of top 10 pharma companies, with GlaxoSmithKline (GSK) rising to the No. 1 spot.

A recent report from Urch Publishing —Pharma-

TOP 3 CYTOTOXIC AGENTS BY 2007 SALES

PRODUCT	COMPANY	SALES*
Eloxatin	Sanofi-Aventis	\$2 billion
Taxotere	Sanofi-Aventis	\$1.8 billion
Gemzar	Eli Lilly	\$1.2 billion

* Seven major markets: France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States.

Source: Datamonitor, Commercial Insight: Cytotoxic Therapy Cancer Brands. For more information, visit datamonitor.com.

ceutical Market Trends, 2008-2012, Key market forecasts and growth opportunities — projects that by 2012, Pfizer will fall from first to third place on the top 10 pharma list, surpassed by GSK in first place and Roche in the No. 2 slot.

The study forecasts the global pharmaceutical market will grow to \$929 billion in 2012, an equivalent compound annual growth rate (CAGR) of 5.5% over the next four years. Future sales growth will remain limited by high prescription drug copays for insured consumers, the growing availability of generic drugs, and a lack of new blockbuster drugs to replace the leading products scheduled to lose patent protection.

According to the report, the top 10 companies,

Top Pharma
Companies in 2012
GlaxoSmithKline
Roche
Pfizer

as ranked by pharmaceutical sales, generated total sales of \$284 billion in 2007. Pfizer was the No. 1 pharma company, with a market share of 6.2%; GSK was in second posi-

tion, with a 5.4% market share; and Roche was third, with a share of 4.3%.

"Total pharmaceutical sales from these top-10 companies accounted for more than 40% of the total market," notes Steve Seget, author of the report. "But only two of the top 10 pharmaceutical corporations in 2007 are forecast to grow at a rate above the overall pharmaceutical market over the next five years: Roche, with a CAGR of 6.2%; and Novartis, with a CAGR of 6.1%."

The report also concludes that Johnson & Johnson and Merck will suffer stagnant growth in the four-year period to 2012.

Other key findings from the report include:

- The top 100 blockbuster drugs generated total 2007 sales of \$252.5 billion, accounting for 35.5% of the total pharmaceutical market.
- In 2007, the leading therapy areas by sales were CNS, with a 16.5% share, and cardiovascular, with 15.4%.
- The leading blockbuster by increased sales revenue in 2007 was the blood agent product

- Plavix, comarketed by Sanofi-Aventis and Bristol-Myers Squibb.
- Four of the top 10 products in 2007 are forecast to increase sales over the next five years.
- The U.S. retail pharmaceutical market increased to \$206 billion in 2007, but growth rates fell due to loss of patent protection on some blockbusters.
- France, Germany, and the United Kingdom together accounted for almost 50% of all European pharmaceutical sales in 2007.
- There were a total of 61 companies generating pharmaceutical sales in excess of \$1 billion in 2007.

For more information, visit urchpublishing.com.

DEVELOPMENT of Orphan Medicines

With an estimated \$90 billion in prescription medicines set to lose patent protection between 2007 and 2012, pharmaceutical and biotechnology companies are beginning to consider the revenue potential of "niche busters," orphan drugs that tackle serious, rare diseases. Despite relatively small patient populations for such medicines, Frost & Sullivan estimates that the current global market for these niche drugs is around \$26.2 billion.

Big pharma has traditionally bypassed development of orphan drugs because of the small return on the significant investment required to develop and market such products. In 2000, the European Union enacted regulations that encouraged companies to enhance their R&D for developing drugs for rare diseases. This encouragement resulted in the filing of more than 800 applications for orphan drugs, and 30 companies eventually received approval to market more than 40 orphan drugs in the EU.

"Companies that market orphan drugs look for government benefits as well as exclusivity rights to

market the drugs," explains Frost & Sullivan Programme Leader A. Shabeer Hussain. "The regulation on orphan medicinal products approved a 10-year market exclusivity in addition to normal patent protection."

Rare diseases generally lack proper diagnosis and treatment, but the European Organisation for Rare Diseases and other organizations are creating awareness on rare diseases and are also influencing governments to legislate for better quality of life for sufferers.

For more information, visit frost.com.



The European niche buster market is estimated to be around 22% to 24% of the global market, says Shabeer Hussain of Frost & Sullivan.

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Drug approval by the European Medicines Agency (EMEA) does not equate to patient access throughout all EU countries. Coverage, price and reimbursement all must be secured at the country level and, often, at the regional and local levels of individual countries. These processes can delay uptake for years. Once these hurdles have been overcome, utilization controls may limit access even further. Ensuring that the true promise of a pipeline is met requires that marketing and clinical teams work together to weigh clinical promise with real-world considerations. To do this, one must be intimately familiar not only with the current health care systems of different countries, but also how those systems are evolving within a context of complicated macro-economic forces. Specific criteria such as pharmaceutical investment in R&D, improvement over existing standard of care, patient population size, demographics, and need, among other considerations, are important for EU payers.

DATE AND TIME

Wed., Feb. 25, 2009 12 PM - 1 PM ET

GUEST SPEAKERS

Pierre Anhoury, M.D Senior Vice President MattsonJack Europe

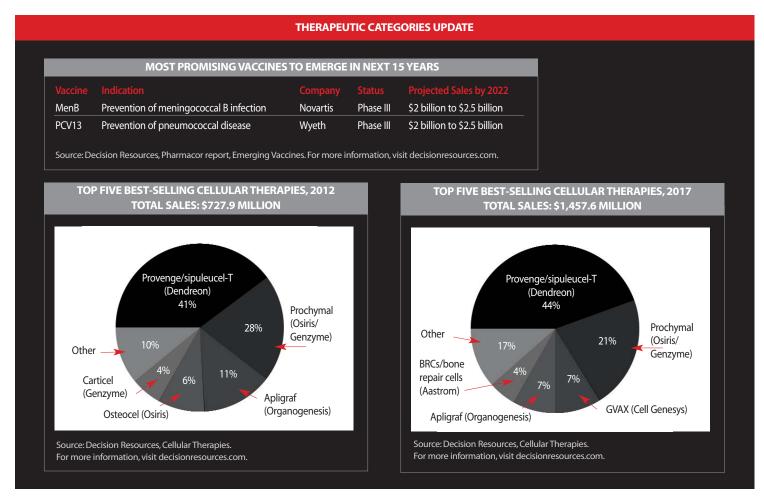
Rhoda Dunn Senior Director Oncology Market Access Europe

Anne-Pierre Pickaert
Consultant
Oncology Market Access Europe

KEY TAKE-AWAYS:

- Identify criteria to better prioritize pipelines and optimally position drugs for success nationally, regionally and locally in terms of price, coverage, reimbursement and healthcare provider update
- Identify emerging marketing opportunities for market growth and corporate differentiation
- Enhance sales forecasts through greater understanding of budget drivers and cycles
- Better target sales force efforts





Will Big Pharma EMBRACE ITS ORPHANS?

The industry is considering "niche busters" — orphan drugs that tackle rare diseases — as potential sources of revenue.

Orphan drugs are intended for the prevention and treatment of very serious rare diseases such as chronic myeloid leukemia, pulmonary arterial hypertension, Gaucher disease, and adrenal cortical carcinoma. Frost & Sullivan (pharma.frost.com) estimates that the current global market for "niche busters" is around \$26.2 billion.

"There are currently 6,000 to 8,000 known rare diseases, but treatment is available for only 200 to 300 of them," says Frost & Sullivan Programe Leader A. Shabeer Hussain. "As many as 80% of rare diseases are of genetic origin and 20% result due to cancer, infections, and other mutations. Rare diseases often affect children under the age of 5."

The term orphan drug was originally coined because the pharmaceutical industry took little or no interest in discovery, development, and marketing of drugs for rare diseases. This was mainly because of the small population of patients they affect, making it difficult for companies to gain a return on their investment.

Oncology MARKET LEADERS

According to a Datamonitor report, Sanofi-Aventis leads the chemotherapy category, marketing four out of the 25 cytotoxic therapy cancer brands: Eloxatin; Taxotere; Gliadel; and TS-1, codeveloped with Taiho. Taken together, Eloxatin and Taxotere are approved for use in the four major cancer types, making them the top two sellers, with combined sales of \$3.8 billion in 2007.

But Eloxatin lost patent protection in 2007 in the European Union, and Taxotere's U.S. and EU patents will expire in 2010. These events likely will have a significant impact on Sanofi-Aventis' future performance in the broader oncology market.

Higher generic erosion rates occur in the United States compared with the remaining major markets, implying a greater dent in brand sales. The impact of generics is expected to reduce cytotoxic therapy brands' overall U.S. market share from 56% in 2007 to 31% in 2017.

As established chemotherapeutics prepare to stave off generic competitors, a new generation of cytotoxic agents is vying for its own piece of the market. Two of these brands — Eisai/Johnson & Johnson's Dacogen and Celgene/Nippon Shinyaku's Vidaza — are antimetabolite cytotoxic

agents approved in the United States for myelodysplastic syndromes (MDS), a type of blood cancer that can progress to leukemia.

Following its launch in 2006, Dacogen has become a major competitive threat to Vidaza, which was launched earlier in 2004. Datamonitor forecasts Dacogen sales growth will be in line with Vidaza over the forecast period of 2007 to 2017. Both brands are seeking EU approval for use in MDS, and Datamonitor forecasts their launch to occur around the same time in 2009.

The increase in sales forecast for Dacogen (\$1.3 billion) and Vidaza (\$1.2 billion) will help boost sales of the total cytotoxic therapy cancer brand market to \$14.9 billion in 2017.

2009 MEDICARE PART D PREMIUMS TO RISE DRAMATICALLY —

More than 2 Million Low- Income Beneficiaries at Risk

Trends show that plan choice under the Medi-

AN EXAMINATION OF TWO OF THE PLANS WITH THE HIGHEST MEDICARE PART D ENROLLMENT NATIONALLY, AARP MEDICARE RX SAVER AND HUMANA STANDARD, REVEALS THE TREND TOWARD HIGHER PREMIUMS FOR LOW-INCOME BENEFICIARIES WHO DO NOT SWITCH TO A PLAN COVERED BY THE LOW-INCOME SUBSIDY.

HUMANA STANDARD CHOOSER PREMIUM LIABILITY IN 2008 VS. 2009

	New Jersey	Colorado	Ohio	Nevada	Texas	California	Florida	New York
2008 Monthly Premium	\$34.50	\$29.70	\$33.60	\$28.90	\$26.10	\$23.00	\$22.00	\$29.50
2008 Chooser Premium	\$3.30	\$5.10	\$6.80	\$12.30	\$1.10	\$3.20	\$2.80	\$5.30
2009 Monthly Premium	\$38.90	\$40.90	\$42.70	\$41.40	\$38.80	\$40.90	\$38.90	\$55.20
2009 Chooser Premium	\$7.90	\$10.70	\$14.30	\$21.20	\$13.40	\$16.00	\$17.40	\$27.50
08 vs. 09 Chooser Premium	\$4.60	\$5.60	\$7.50	\$8.90	\$12.30	\$12.80	\$14.60	\$22.20
% Change in Chooser Premium	139%	110%	110%	72%	1,118%	400%	521%	419%

Source: Musical Chairs: An Analysis of the Part D Annual Reassignment Process, published by The National Senior Citizens Law Center. For more information, visit nsclc.org.

AARP MEDICARE RX CHOOSER PREMIUM LIABILITY IN 2008 VS. 2009

					New						
State	Missouri	Idaho	Utah	Arkansas	Mexico	Louisiana	New York	Arizona	California	Florida	Nevada
2008 Monthly Premium	\$29.70	\$34.90	\$34.90	\$29.90	\$21.00	\$27.30	\$25.40	\$20.60	\$21.00	\$21.70	\$21.40
2008 Chooser Premium	\$3.00	\$1.40	\$1.40	\$2.20	\$1.70	\$2.70	\$1.20	\$4.70	\$1.20	\$2.50	\$4.80
2009 Monthly Premium	\$36.30	\$40.00	\$40.00	\$30.40	\$24.80	\$34.90	\$33.80	\$26.50	\$33.50	\$31.60	\$33.30
2009 Chooser Premium	\$3.10	\$2.50	\$2.50	\$3.50	\$4.30	\$7.40	\$6.10	\$10.30	\$8.60	\$10.10	\$13.10
08 vs. 09 Chooser Premium	\$0.10	\$1.10	\$1.10	\$1.30	\$2.60	\$4.70	\$4.90	\$5.60	\$7.40	\$7.60	\$8.30
% Change in Chooser Premium	3%	79%	79%	59%	153%	174%	408%	119%	617%	304%	173%

Source: The National Senior Citizens Law Center, Musical Chairs: An Analysis of the Part D Annual Reassignment Process. For more information, visit nsclc.org.

care Part D program is shrinking, particularly for those who benefit from the Low Income Subsidy (LIS) that assists with premium, deductible, and copay costs.

The National Senior Citizen Law Center (NSCLC) report notes that of the 765 LIS plans offered across all states in 2008, 400 did not return as LIS plans in 2009.

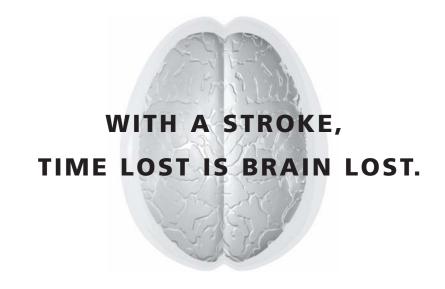
Between 2008 and 2009, the number of LIS plans offered decreased in all but one state (Wisconsin saw no change), with Maine and New Hampshire experiencing the largest decrease (13).

Between 2008 and 2009, each state lost at least 25% of its LIS plans, with Arizona (5 of 7), Maine (13 of 18), New Hampshire (13 of 18), Florida (7 of 8), and Nevada (4 of 5) losing the highest proportion of plans.

With fewer and fewer plans to choose from, it becomes less likely that subsidy recipients will find plans they can afford that cover the medications they need.

The disruption beneficiaries face this year is not new. Last year, more than 2.5 million LIS recipients were affected by plan changes.

The sheer number of beneficiaries affected each year means that many beneficiaries who needed to change plans last year need to once again change plans this year.



Learn the warning signs at **StrokeAssociation.org** or **1-888-4-STROKE**.



American Stroke Association

