Taren Grom

A Decade of CHANGE

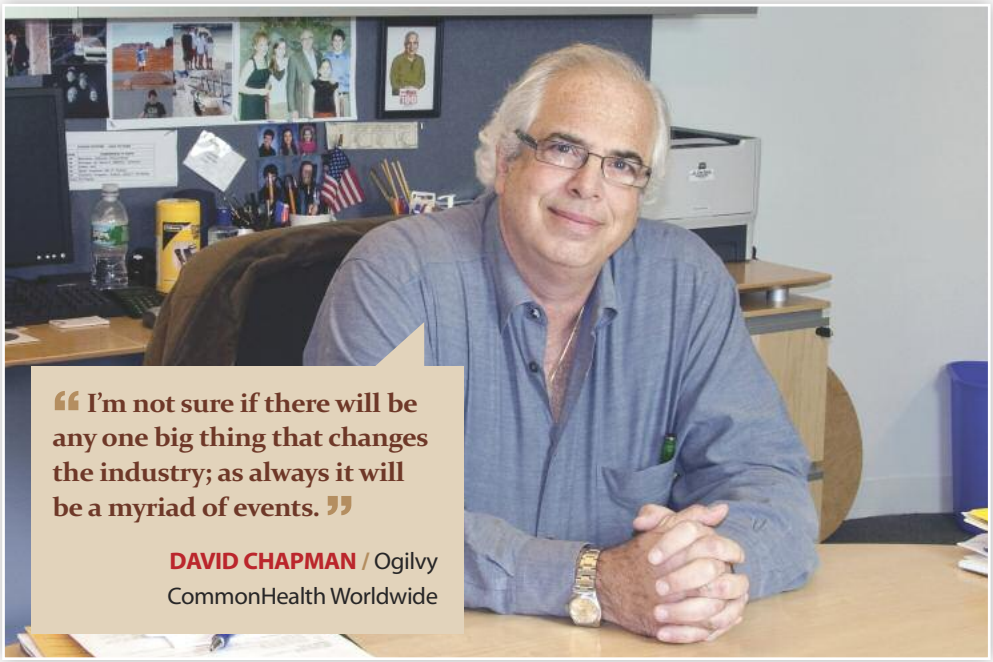
During the past decade there have been tremendous advances in science, innovation, technology, communications, and patient engagement. There have also been some tremendous setbacks, including major drug recalls, intensified regulatory oversight, and let's not forget the infamous "gas-and-go" tactics employed by some members of the field force.

It has been the best of times, it has been the worst of times, to paraphrase Charles Dickens.

All in all, the decade can be defined as one of tremendous change. And one should expect the same pace of radical ups and downs during the next 10 years. As Scott Cotherman, CEO of CAHG, a healthcare agency network, says for those who are change-averse, now would be a good time to explore opportunities outside of the industry.

We are taking a look back in this special report to identify the top 10 game changers that have impacted the industry in the last 10 years. At the same time, we are uncovering what industry thought leaders believe will be the next set of factors to shift the paradigm.

Business as usual is only true if one defines usual as change. What was true yesterday may be completely different tomorrow.



> "I'm not sure if there will be any one big thing that changes the industry; as always it will be a myriad of events."
>
> **DAVID CHAPMAN** / Ogilvy CommonHealth Worldwide

As David Chapman, managing partner of Ogilvy CommonHealth Worldwide, says there are a number of key questions that face the industry — some are new, some are old as the hills: what will healthcare reform bring, how will the patent cliff change medicine, and will genetic markers lead to personalized medicine?

"I'm not sure if there will be any one big thing that changes the industry; as always it will be a myriad of events," Mr. Chapman says.

As Mr. Cotherman notes, some of the major trends to impact the industry and market growth over the last 10 years include the decline in innovative pipelines; increasing regulatory pressures slowing drug approvals; and blockbusters losing patent exclusivity and the resulting shift to generics. In fact, three out of four prescriptions are now generic.

"These market-changing paradigms have affected every part of the supply chain servicing the pharmaceutical industry," he says. "We are now facing the loss of one-third of global sales for branded medicines associated with the top-selling drugs of all time. The effect on all aspects of the marketplace has been remarkable and game changing for everyone."

10 Years — 10 Game Changers:

- Agency Business
- Business Models
- Emerging Markets
- Innovation
- Marketing Communications
- Outsourcing
- Patent Expirations/Payer/Reimbursement
- Regulations
- Sales
- Technology

Source: PharmaVOICE

KEY FACTS

Research & Development

» **Time to develop a drug**	10 to 15 years

Development Costs

10 Years of Change	
» **Cost to develop a drug**	
2005	$1.3 billion
2001	$802 million
1987	$318 million
1975	$138 million
» **Cost to develop a biologic**	
2005	$1.2 billion

R&D Spending

Year	PhRMA members	Total industry
2009	$45.8 billion (est.)	$65.3 billion (est.)
2008	$47.4 billion	$63.7 billion
2007	$47.9 billion	$63.2 billion
2006	$43.4 billion	$56.1 billion
2005	$39.9 billion	$51.8 billion
2004	$37.0 billion	$47.6 billion
2000	$26.0 billion	not available

Medicines in Development

2010	2,950 compounds
1999	1,800 compounds

Sales

Generic share of market	
2009	74%
2000	49%

Source: PhRMA. For more information, visit pharma.org.

Over the next 10 years, the fundamental issue will be the extent and effectiveness of efforts to control cost growth while maintaining a flow of innovative therapies to offset the huge losses to generics.

Aging populations in developed markets and expanded healthcare access in the developing world are two unrelenting cost drivers, says Michael Kleinrock, director of thought leadership at IMS Health, a market intelligence company.

> **"As the nation struggles with healthcare reform, the value of certified CME becomes critical."**
>
> **CATHY PAGANO** / The Institute for Continuing Healthcare Education

"The bubble of patent expiries ahead, without further actions, will not drive enough of the savings necessary in many markets to balance the books," Mr. Kleinrock says. "In major markets around the world, we already see constrained access to innovative therapies. The focus on high-ticket items and the need to measure and demonstrate specific value in outcomes and quality reflects both this ongoing budget pressure and a continuously rising bar clinically. These changes impose a series of progressively more-challenging strategic responses from R&D-based pharmaceutical companies, and they pose the challenge to them to innovate their business models and processes, as much if not more, than they innovate around the therapies they develop."

On the commercialization side, Frank Powers, president of the healthcare agency Dudnyk, says there are three main things that will contribute to the evolution of marketing in the life-sciences industry.

"First is the digital explosion," he says. "Even more than today, most healthcare professional communications will be digitally based and will need to be available on-demand. The second is the transformation of the sales force. The sales force of the future will feature highly experienced specialty reps, who orchestrate the brand efforts in a multichannel, digital environment. The typical detail will occur online when the doctor is available. This change will lead to more efficient and productive conversations and the immediate delivery of branded materials. The third game changer will be branded generics. Unprecedented generic competition will shape the marketing landscape. Every major therapeutic area will be affected, and companies will have to change the way they differentiate their brands. Agencies will need to precisely articulate brand positioning and value in a more crowded environment, given that traditional distinctions, such as efficacy data, will be neutralized."

Some trends, such as CME, corporate responsibility, and the epidemic of obesity, just didn't fit neatly into any one category, but are just as noteworthy. From the perspective of funding certified continuing medical education (CME), the paradigm shift has been rad-

Predictions for 2011

» **Partnering:** There will be no major slowdown in big pharma's appetite for biotech partnering. Both big pharma and big biotech will again compete for companies with advanced product pipelines. The deal structures will embrace "shared risk." The days when biotech enjoyed major up-front payments from pharma companies to access their technologies are over. Collaborations with emerging market players in China, India, and Latin America will also increase.

» **Pharma restructuring:** Pharma companies will continue to make job cuts and restructure their businesses ahead of loss of patent protection on major blockbusters.

» **Increased government involvement in healthcare:** The federal government, through Medicare and Medicaid, will continue to play a greater role in the delivery and reimbursement of healthcare. This trend will create an array of new regulatory and compensatory rules, issues, and challenges for healthcare providers.

» **Regulatory environment:** The industry will continue to adjust to a regulatory environment that includes comparative effectiveness research (CER). Payers will be looking at CER as a way to gather the necessary data on whether to reimburse for genomically guided medicines. With PDUFA expiring in 2012, there will be a major battle over drug safety and review issues in Congress in 2011.

» **Science and technology:** The evolving legal battle over the patentability of genes will heat up; uncertainty will continue to swirl around stem cells but regenerative medicine will be hot.

Source: Burrill & Company.
For more information, visit burrillandcompany.com.

Outlook 2011

With dozens of prescription drugs due to lose their patent protection in the next few years, and few likely blockbusters in company pipelines to replace declining revenue, developers are aggressively changing the way they do R&D, according to the Tufts Center for the Study of Drug Development.

Noting that developers are looking to reduce development time, cut costs, and improve operating efficiency, Tufts CSDD Director Kenneth Kaitin said, "The research-based drug industry, in the United States and globally, is not sitting still, but the question remains whether developers can bring enough new drugs to market at the pace needed to remain financially viable."

He made his comments in connection with the release of the Tufts Center's Outlook 2011 report on pharmaceutical and biopharmaceutical trends.

According to Tufts CSDD, the cost of developing a new drug is higher than ever — about $1.3 billion. While it's difficult to predict which drugs could become so-called blockbusters, yielding annual revenue of at least $1 billion, Mr. Kaitin said the ability to create such products is expected to become increasingly daunting in the next few years.

Actions that will help improve R&D productivity, according to Tufts CSDD, include greater reliance on translational science to help identify the right disease targets for new molecules; greater use of partnering with external service providers to share risks, reduce cycle times, lower costs, and improve resource management; and greater use of sophisticated portfolio management techniques.

Among near-term trends highlighted in the Tufts CSDD Outlook 2011 are the following:

» **The FDA will exercise its new activism** to confront a serious public health problem reaching critical mass: shortages of antibiotics, emergency drugs, anesthetic agents, drugs for cognitive disorders, and newer and better pain medications.

» Although more than half of all FDA-regulated clinical trials in 2010 were conducted outside the United States, **sponsors will seek to decrease the number of countries hosting development** activity in an effort to reduce global logistical and regulatory complexity.

» The pharmaceutical and biotechnology industries will continue to **dedicate resources to develop monoclonal antibodies** (mAbs), as annual global sales of these products currently approach $40 billion.

» Among private payers in the United States, **risk-sharing agreements** to manage uncertain outcomes and costs — where pharmaceutical companies and payers agree to share the risk regarding a newly approved product's cost effectiveness in clinical practice — will become more common.

Source: The Tufts Center for the Study of Drug Development. For more information, visit csdd.tufts.edu.

ical. Many CME companies have actually gone out of business or have had to retool their offerings as a result.

"Whereas pharmaceutical companies once sponsored promotional activities alongside CME as part of their marketing strategies, the current practice is to have completely separated — and fire-walled — departments that review and approve grant requests," says Cathy Pagano, president of The Institute for Continuing Healthcare Education. "Currently, on-label and regulated promotional education is left to the marketing departments, and certified education is supported by a highly rigorous grant selection process. Careful consideration is taken to justify the educational needs for such funding, while maintaining a strict hands-off policy in terms of influencing content in any way."

As the nation struggles with healthcare reform, the value of certified CME becomes critical.

"To accurately measure the impact of CME on patient and population health, comprehensive and thorough outcome analysis is paramount," Ms. Pagano says. "There is a need for education more than ever, and the industry will have to take on a more active role in improving healthcare by continuing to support CME. Effective education requires innovation, and innovation needs financial support."

Peter Sandford, executive VP of NXLevel Solutions, a developer of technology-delivered learning applications, predicts that the biggest market shaper in the next 10 years will be the continued shift to a values-based approach to every aspect of business, including sales and marketing, research and development, and management in all areas.

"With the advent of new corporate responsibility legislation, the market landscape will no doubt be altered as more companies recognize the need to make ethics and personal conduct the foundation from which day-to-day business is conducted," he says.

Jay Bolling, president and CEO of Roska Healthcare Advertising, a full-service agency, says while patent expirations, healthcare reform, and the increasing number of Medicare patients will make waves in healthcare in the next 10 years, the growing epidemic of obesity is the brewing tsunami.

"Illnesses associated with obesity are heading off the charts," he says. "Currently, 25.8 million American children and adults — fully 8.3% of the population — have diabetes and 79 million prediabetic Americans are teetering on the brink. The alarming rise in cardiovascular, renal, and neuropathic disorders follows the same dangerous pattern as diabetes. Expect hospitalization and emergency room costs to swell, the need for patient lifestyle management to skyrocket, and demand for patient-relationship marketing to play a far more critical role in drug marketing."

All of these themes, as well as other game changers, will be explored in this special report that not only celebrates PharmaVOICE's 10th anniversary but a decade of unprecedented thought leadership — more than 10,000 industry executives have been featured in our pages. We thank all of those who have contributed to making our vision come to life — a forum in which thought leaders from all sectors of the life-sciences can come together and exchange ideas and bring forth new perspectives, all in the hopes of moving the industry forward and improving the lives of those in need of healthcare solutions — communications, pills, or services.

We also thank all of our partners whose support over the last decade has made PharmaVOICE and its other communication channels possible. We continuously strive to provide all of our stakeholders — thought leaders, readers, contributors, and advertisers — with cutting-edge content in a multichannel format. In closing, we hope you enjoy this "back to the future" approach to recounting the market changers that got us to where we are today and that will take us to where we are going tomorrow. PV

If we missed a trend you think will impact the industry in the next 10 years, send an e-mail to feedback@pharmavoice.com and let us know what will shift your paradigm and why.

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