CONSUMERS TALK BACK

Countering DTC Criticism

Challenging many of the assumptions of both academic and public-policy critics of DTC, CommonHealth filed a research report with the FDA based on analysis of 440 transcripts of actual provider-patient interactions in community-practice settings recorded between 2001 and 2005.

The report examined the nature of patient-medication requests, references to DTC in the dialogue, and the overall nature of the risk-benefit discussion in three therapeutic categories: allergy, dyslipidemia, and hypertension.

The CommonHealth study uncovered that **DTC does not have the negative impact on the actual dialogue** that many people allege.

THE STUDY FOUND:

- Patient-initiated prescription drug requests are not driven by DTC advertising.
- DTC advertising is rarely referenced by patients (0.6% of visits) and never as "I saw/heard this ad and want this prescription drug."
- DTC advertising does not harm the balance of risk-vs-benefit discussions in observed visits, regardless of DTC spend in the given category.

In addition to these findings, the analysis showed that overall risk-benefit discussions were very brief, and the patient was not engaged in meaningful dialogue about treatment preferences, in part related to the time constraints of the office visit itself.

Editor's Note: Please see the September VIEW on Marketing for more information on this topic.

SOURCE: COMMONHEALTH, PARSIPPANY, NJ

MARKET REPORT

Branded Pharmaceuticals Sales Going Down And Taking the Industry With Them

By 2009, **$80 billion of revenue-producing drugs** will have lost patent protection.

Visiongain analysts suggest that the global pharmaceutical market has entered a period of change that could signify the start of an industrywide economic downturn.

The global pharmaceutical market is currently valued at $550 billion. By 2009, at least $80 billion in revenue from the current leading 200 drugs will be exposed to generic competition because of patent loss. Generic competition is expected to take at least 50% of the market, and the consequent loss of income for the branded companies is significant.

In 2005, the global generic market was valued at $45 billion, an increase of almost 15% on the year before. Visiongain forecasts similar growth over the next five years, as many of the most successful blockbuster drugs of recent years lose patent protection in key markets.

SOURCE: VISIONGAIN, LONDON

VIRAL MARKETING

Marketers Would be Wise to Put Their Money Where Somebody Else's Mouth Is

According to eMarketer, the combination of e-mail and word-of-mouth affords marketers a potentially vast, and very powerful, new marketing tool.

The ubiquity of e-mail, among marketers and Internet users, has created a take-it-for-granted attitude that detracts from its actual power. But with 90% of Internet users — and more than 55% of all Americans — e-mail has access to an audience with critical mass, and it is becoming a primary delivery vehicle for word-of-mouth marketing.

"The fundamental purpose of e-mail marketing is to enhance a company's relationship with its customers and to draw in new prospects," says David Hallerman, eMarketer senior analyst and author of the new report, E-Mail & Word-of-Mouth: Connect with Your Best Customers. "That might mean direct-response sales messages, CPG coupons, building brand awareness, weekly or monthly e-newsletters, service messages about packages shipped, and funds available in bank accounts, all of which can drive traffic to a company or brand Website."

More and more marketers today are joining the conversation with consumers — another way to say word-of-mouth — through e-mail to blend in with marketing today's trend of consumer-generated content, such as blogs, social networks, video, and related media.

SOURCE: EMARKETER, NEW YORK

U.S. E-Mail Users as a Percent of Internet Users and Total U.S. Population* 2003-2010

	E-mail users % of Internet Users	E-Mail users % of Total Population
2003	88.1%	52.0%
2004	88.5%	53.6%
2005	89.1%	55.1%
2006	89.7%	56.4%
2007	90.4%	57.8%
2008	91.1%	59.0%
2009	91.8%	60.1%
2010	92.2%	61.0%

Note: eMarketer defines an e-mail user as a person 3 years old and older who sends an e-mail at least once per month;
* Internet users and total population is 3 years old and older

Source: eMarketer, July 2006

Most Important Things that U.S. Marketers Need to Generate a Word-of-Mouth Marketing Campaign

Have satisfied customers	53.3%
Have great products or services	27.5%
Have a great brand	13.3%
Have an advertising agency or public-relations firm	1.7%
Have the lowest price	0.0%
Don't know/not sure	4.2%

Source: Osterman Research.
Commissioned by BoldMouth, May 2006

Editor's Note: See related article on page 68, Patient Power: Why Your Daughter's Website Can Drive Scripts.

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FDA POLICY UPDATE

Clinical Trials and Monitoring

The FDA has a series of policy and regulatory developments to strengthen its oversight and protection of patients in clinical trials as well as the integrity of resulting data in an effort to modernize its approach to bioresearch monitoring. The new effort is part of an HHS-wide initiative to employ recent advances in basic science, including genomics and molecular analysis.

"As clinical trials continue to evolve, in particular becoming increasingly large, decentralized, and global, the FDA's approach to bioresearch monitoring must also evolve and modernize," says Janet Woodcock, FDA deputy commissioner for operations.

Highlights of what has been completed to date include:

- Draft Guidance; Process for Handling Referrals to FDA Under 21 CFR50.54; Additional Safeguards for Children in Clinical Investigations, published in May 2006
- Guidance for Industry — Using a Centralized IRB Process in Multicenter Clinical Trials, published in March 2006
- Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees, published in March 2006
- Information Sheet Guidances for IRBs, Clinical Investigators, and Sponsors, published in January 2006

Projects in progress:

- Modernizing adverse event reporting to institutional review boards (IRBs) to accommodate major trend toward multicenter trials (March 2005, held Part 15 Hearing – Adverse Event Reporting to IRBs, currently working on draft guidance)
- Published proposed rule: Institutional Review Board – Registration Requirements, FDA reviewing comments
- Finalizing rule: Foreign Clinical Studies not Conducted Under an IN (21 CFR 312.120)

SOURCE: FDA, ROCKVILLE, MD

PhRMA UPDATE

Medicines Save Lives, Reduce Overall Healthcare Costs

"We are in the midst of a real healthcare revolution," says Billy Tauzin, PhRMA President and CEO. "Prescription medicines play a vital part in helping Americans stay healthy, fight disease, and live longer, more productive lives. Better yet, medicines now being developed will do even more to help patients and doctors treat conditions such as diabetes, cancer, AIDS, and Alzheimer's disease, to name just a few."

New medicines generated 40% of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000

AIDS death rates in the United States dropped about 70% since the mid-1990s with the development of a new wave of medicines to treat HIV/AIDS

Available cancer medicines have tripled since 1971 and these new drugs account for 50% to 60% of the increases in six-year cancer survival rates since 1975

Cancer death rates decreased in 2003 — for the first time in 70 years

SOURCE: PHRMA, WASHINGTON, D.C.

LOGGING ON AND PLUGGING IN

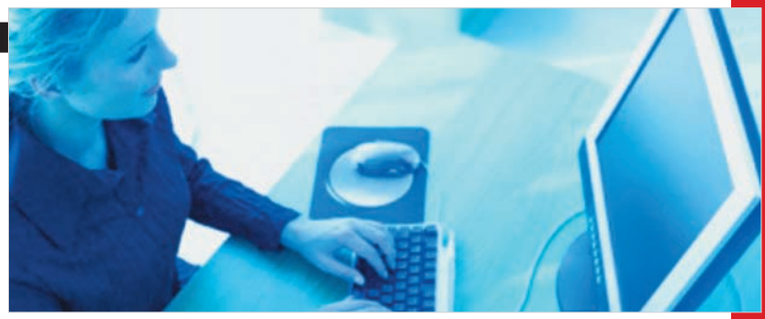
Upcoming WebSeminars

- **Optimizing DTC Performance:** Building the Strategies to Maximize ROI
  September 19, 2006, 2:00 - 3:30 p.m. EST
  Sponsored by TNS Healthcare
- **Practice Makes Perfect:** eClinical Process Change and Standardization
  October 5, 2006, 1:00 - 2:00 p.m. EST
  Sponsored by etrials Inc.

Archived WebSeminars

Log onto pharmavoice.com/weblinx to access these archived sessions:

- **DRA Update:** OIG Recommendations and Issues Under Consideration by CMS
  Sponsored by I-many Inc.
- **Getting Off the Express Train** to Creative Mediocrity
  Sponsored by The Hal Lewis Group
- **Deficit Reduction Act:** Truth, Misconceptions and Open Issues
  Sponsored by I-many Inc.



Featured Podcasts from this Issue

If you would like to listen to a series of Podcasts produced by PharmaVOICE, please log onto pharmavoice.com/podcasts to access the following podcasts and others:

- **A New Paradigm for Drug Development:** How Cross-Functional Teams Can Improve the Process
  Featured Thought Leader: William Jacobson, Ph.D., Director, Project Management, Women's Health & Pharma Business Units, Wyeth
- **Institutional Review Boards**
  Featured Thought Leader: Lynn Meyer, President, IntegReview Ethical Review Board

SOURCE: PHARMAVOICE, TITUSVILLE, NJ