

By going direct-to-consumer, the industry unwittingly unleashed a swarm of opportunities for other players to enter the pharmaceutical fray. And they made the most of it. Now, a decade later, pharma is feeling the fallout in consumer trust and product value. It's time to take back control.

## **CONSUMERIZATION:**

# Pandora's Pillbox



## An Essay by Stan Bernard, MD, MBA

Last fall, pharma suffered one of its blackest days ever, but few in the industry seemed to notice. On September 21, Wal-Mart, the world's largest retailer, announced a generic-drug program offering nearly 300 generic drugs for \$4 per prescription. "Each day in our pharmacies, we see customers struggle with the cost of prescription drugs," said Wal-Mart CEO H. Lee Scott Jr. "By cutting the cost of generics to \$4, we are helping to ensure that our customers and associates get the medicines they need at a price they can afford. That's a real solution for our nation's working families."

The price cut made headlines for days, drawing waves of praise. However, some industry veterans heard in this news a more ominous message. Like many other pharmaceutical stakeholders, Wal-Mart was engaging in the phenomenon called the consumerization of pharmaceuticals: using drug-industry products to promote stakeholders' interests in the name of consumers' interests. Despite its stated pro-consumer intentions, the retailer was actually pushing its own agenda: to drive store traffic and to deflect criticism of its subpar employee-health benefits.

"[The \$4 generics promo] is a loss-leader type program solely aimed at getting people in the door at Wal-Mart," said Charlie Sewell of the National Community Pharmacists Association. Richard Evans, a Sanford Bernstein drug analyst, stated that it "makes more sense as a political air cover [than] as a retail strategy." In other words, Wal-Mart was playing the consumerization game—and doing it, as is increasingly the case, at the pharmaceutical industry's expense.

Ironically, it was pharma that initiated consumerization in the nineties with direct-to-consumer advertising. In the decade since, one stakeholder after another has lined up to seize every opportunity to "consumerize" pharmaceuticals for its own benefit—whether or not it was good for consumers. This Pandora's box of unintended consequences has badly damaged pharma, eroding its image and devaluing its products. The \$4 Wal-Mart price tag, in fact, marked the ultimate devaluation of pharmaceuticals, insinuating that they are mere commodities to be purchased "on sale" like soap or toilet paper. Industry leaders need to recognize and respond to this phenomenon because of its profound impact on their products and their businesses.

### What Consumerization Is and Is Not

Consumerization is not an easy concept. By way of definition, it helps to clarify what it is not. Consumerization is not consumerism, a grassroots movement that advocates for the needs and rights of consumers. Consumerization is driven not by consumers but by other stakeholders, who use a product to promote their own interests in the name of consumers'.

Only a few select product categories, such as oil and gasoline, tobacco, and alcohol, have been consumerized. Yet no product has been consumerized to the extent of the molecules

that pharma discovers, develops, and markets as medicines. These products are in a category of their own, with exceptional clinical, commercial, social, and political value (see "The Unique Case of Pharmaceuticals," page 70). That's why they are so susceptible to consumerization—and why the process escaped pharma's control almost as soon as it was set in motion.

A classic case of pharmaceutical consumerization occurred in 1998 when WellPoint Health Networks became the first managed-care company to initiate an Rx-to-OTC switch by petitioning the FDA to transfer Claritin, Schering-Plough's blockbuster antihistamine, to OTC status. "The OTC status of loratadine, whether Claritin or a generic, is in the best interest of allergy sufferers," said Robert Seidman, Wellpoint's chief pharmacy officer. "It lowers the cost and eases access."

However, according to the *Food and Drug Letter*, Wellpoint's primary motive was "to save the company about \$90 million—\$45 million from prescription costs and \$45 million for co-pays." Said Fred Weissman, associate dean for academics and clinical affairs at the University of Southern California School of Pharmacy: "Healthcare plans do not want to pay for certain drug categories, which is why they promote the use of some OTCs. When a drug makes the Rx-to-OTC switch, the financial burden is placed on the consumer because OTCs are not covered under the prescription benefit."

Schering-Plough initially opposed the switch because OTC products generally have lower prices and fewer sales. But in 2002, shortly before Claritin was to go off-patent, the firm reversed its position—generic loratadine would soon take a big bite out of its allergy-market share. Moreover, Schering was launching Clarinex, a newer version of Claritin, and did not want a generic to cannibalize the sales of the higher-margin, patent-protected Clarinex.

As a result of the switch, nonprescription Claritin became significantly more expensive for the vast majority of insured patients who previously had been paying low co-pays. "Neither the drug companies nor the insurance companies likely had the best interests of people with allergies in mind...when they pursued the switch to over-the-counter Claritin," stated Vincent Iannelli, MD, associate professor of pediatrics at the University of Texas Southwestern Medical School.

If consumerization is driven by stakeholders in the name of consumers, consumerism, by contrast, is the real thing. A classic illustration of pharmaceutical consumerism occurred when cancer patients and advocates initiated a write-in campaign in the late nineties to prod Novartis to develop STI-571, a promising compound for chronic myelogenous leukemia (CML). At that time, Novartis estimated that CML affected only about 5,000 patients, a too-small market. But the activism proved persuasive—and helped win FDA approval in less than three months for the life-enhancing blockbuster we now know as



Gleevec. Novartis CEO Daniel Vasella said, “Normally, it is the company that pushes the most, but in the case of Gleevec, it was the patients who were doing the pushing.”

### A Stampede of Stakeholders

The sentinel event of consumerization was FDA’s landmark 1997 guidance on DTC advertising. This regulatory action—pushed by pharma in order to overcome managed care’s increasing restrictions on drug prescribing by physicians—opened a promotional floodgate to consumers. This access enabled the industry to increase sales by enhancing disease awareness and brand identification—and, of course, encouraging viewers to “see your doctor.” According to Manhattan Research, more than 80 percent of consumers who (appropriately) requested a specific brand from their physicians received those prescriptions. Industry spending soared from \$791 million in 1996 to more than \$5 billion today.

But DTC advertising is far from the only way the industry has propelled pharmaceutical consumerization. Several key developments over the past decade were sparked, in part, by the process. The investment in producing “lifestyle drugs” for conditions like erectile dysfunction (ED), hair loss, and facial wrinkles tops the list. Firms have also mastered the art of life cycle management, extending franchises with reformulations, new applications, and even pushing for Rx-to-OTC switches.

Third-party payers were quick to see the cost-controlling potential of consumerization. Insurers, governments, pharmacy benefit managers, and employers have all been busy finding new ways to shift more of the price burden to consumers. Healthcare plans increasingly restrict use of brands that are new or expensive by limiting formulary choices. Even Medicare Part D contains the infamous “doughnut hole” coverage gap. All of these measures favor the increased use of generics and older, cheaper drugs, regardless of patient need.

Consumerization has extended well beyond the stakeholders who are making and selling drugs. Politicians on both sides of the aisle have been ramping up the rhetoric about a host of industry issues. With the recent Democratic takeover of Congress and the upcoming presidential election, politicians are consumerizing pharmaceuticals for campaign platforms and garnering votes by focusing on a Big Pharma laundry list, including pricing, safety, DTC ads, drug importation, and FDA reform.

Meanwhile, the media have aggressively stepped up their coverage of the industry. Even the *Wall Street Journal*, a bastion of capitalism, runs more and more stories critical of pharma practices. Recent headlines such as “The Real Story Behind Alleged ‘Copycat’ Drugs,” “Off-Label Drug Use Flourishes Despite Curbs,” and “Generic Drugs Often Delayed by Settlements” are testimony to the intense scrutiny of pharma affairs.

Needless to say, the legal profession has also hit the gravy train. With Big Pharma replacing Big Tobacco as the new product-liability cash cow, the courts are swamped with class-action lawsuits. Some 65,000 suits have been filed against drug com-

panies since 2000, by far the most against any US industry.

But not all pharmaceutical stakeholders have capitalized on consumerization. Above all, many physicians—believing that it may undermine their authority—have resisted third-party efforts to influence consumers’ use of drugs. The American Medical Association has called for a moratorium on DTC ads for all products on the market for one year or less, echoing similar calls in Congress.

Clearly, consumerization has had profound effects on the industry. DTC ads delivered what pharma wanted—consumer demand and increased sales. Initially, the ads may even have enhanced pharma’s image: Many surveys show that DTC ads offer useful information, stimulate productive doctor-patient discussions, and promote earlier diagnosis. After a decade, however, the blowback from bringing consumers—and other opportunistic stakeholders—into the pharmaceutical fray is undeniable. Consumers are increasingly frustrated by the high price of healthcare in general and pharmaceuticals in particular. Consumers, politicians, and the media have all taken aim at pharma for what they consider to be disproportionate spending on marketing and “me-too” drugs at the expense of innovative R&D.

### The Unique Case of Pharmaceuticals

**N**o product in the marketplace is as vulnerable to consumerization as pharmaceuticals. Here are 10 reasons why:

- 1. High regulation** No other product requires a consumer to have regulatory approval (FDA), intermediary permission (physician prescription), and reimbursement (third-party payer) to purchase the product. Each stage involves stakeholders’ interest.
- 2. High cost** From discovery to market, a single pharmaceutical usually exceeds \$1 billion. Because governments are the major payers, politicians, bureaucrats, and tax-payers all have input.
- 3. High margin** A slew of stakeholders vie for a piece of the pharma profits along the entire value chain.
- 4. High value** Medicines have the power to confer life and death. From vaccines to antibiotics to chemotherapeutics, pharmaceuticals promote health and prolong life.
- 5. High protection** Drug patents and other intellectual property are highly protected, more exclusive—and more controversial.
- 6. High competition** Despite patent protection, drug companies face competition at every stage of a product’s life cycle.
- 7. High use** Nearly every consumer in the developed world has used pharmaceuticals—and use is rising among all age groups.
- 8. High misuse** Many pharmaceuticals—especially prescription painkillers—are used inappropriately or illicitly.
- 9. High risk** The withdrawal of Vioxx and a dozen other drugs since 2001, as well as the adverse events associated with all pharmaceuticals, demonstrates the safety risks these products pose.
- 10. High success** The pharmaceutical industry ranks as one of the most profitable global industries. Success engenders respect and admiration, but it also breeds envy and contempt.



## To harness consumerization to improve the industry's image and enhance the value of its products, pharma leaders need to focus on the "Four Cs": commitment, choice, collaboration, and customization

Direct-to-consumer TV advertising has also come in for its share of criticism. For instance, controversy erupted after the makers of two of the three ED drugs ran ads during the 2004 Super Bowl. Robert Essner, the chairman and CEO of Wyeth, told the *Wall Street Journal* in 2007, "I thought [the ED ads] were inappropriate for medicines, for the seriousness of what we do, and were sending the wrong image about drugs and drug companies."

Some critics have blamed DTC ads for exposing more consumers to unnecessary drugs with unnecessary risks. The obligatory recital of side effects in DTC ads, combined with the rash of drug recalls and product-liability cases, has accentuated the issue of drug safety, further devaluing pharmaceutical products. Which brings us full circle to the \$4 Wal-Mart promo and the ultimate devaluation to mere commodities.

### From Targeting to Teaming

There are several ways that pharmaceutical executives can harness consumerization to improve the industry's image and enhance the value of its products. The most direct—and challenging—is to commit to developing breakthrough drugs. In fact, the industry recently has commercialized highly targeted cancer therapies, more tolerable HIV agents, and several novel vaccines. Innovative work is also being done in areas of tremendous unmet medical needs, such as Alzheimer's.

But pharma's leaders need to go further than R&D to reach today's consumers. Many executives are familiar with the "Four Ps" of marketing: product, promotion, place, and price. Now they need to focus on the "Four Cs" of consumerization: commitment, choice, collaboration, and customization. Each has important applications for pharma's future.

First, consumers want reaffirmation that drug companies are committed to their welfare and that they can trust pharma's products. And pharma needs to demonstrate such a commitment. Advertising that clearly communicates both the risks and the benefits of drugs will help rebuild trust. For example, Johnson & Johnson, which learned how to regain public trust by handling the Tylenol product-tampering scandal in 1982, produced a 2005 TV spot with a real physician advising a patient about the safety issues of the Ortho Evra contraceptive patch.

Consumers invariably want more control and choice in drug use. The primary mechanism for this is to promote patient-doctor dialogue about treatment options and to provide accurate information. The recently enacted PhRMA Guiding Principles on DTC advertising are a step in the right direction. An excellent illustration is Eli Lilly's 2006 "Depression Hurts" ad, a black-and-white unbranded TV spot that speaks to the real

pain of depression without mentioning the company's new antidepressant, Cymbalta. Many companies have taken a different approach by shifting spending from DTC to "DTP," or direct-to-patient, activities: brand-specific drug-adherence programs, loyalty cards, Web sites and e-mail campaigns, and direct mail. Several analyses suggest that DTP results in higher brand loyalty and better treatment compliance—and is more cost-effective than DTC.

Innovative drug companies are moving from targeting consumers to teaming with them—for example, forming partnerships with patient-advocacy groups on disease-awareness and treatment campaigns. EMD Serono Pharmaceuticals and Pfizer have worked together with the National Multiple Sclerosis Society to establish the MS Lifelines program featuring "patient ambassadors," people with MS who help educate and empower newly diagnosed patients. Other pharma-consumer collaborations include patient advisory boards to provide feedback on everything from consumer advertising to clinical-trial design.

Companies can also benefit from customizing their marketing and products. For example, AstraZeneca's "Sisters" campaign for breast-cancer management provides a Web site ([www.getbcfacts.com](http://www.getbcfacts.com)) enabling users to "personalize their experience" by answering questions related to their diagnosis.

A far more powerful tactic is to customize actual patient treatment with advanced pharmacogenomic technologies. These cutting-edge tests identify genetic markers that transmit critical information, such as which patients are most likely to respond to a particular drug without serious side effects. The classic example is Genentech's breast-cancer agent Herceptin, which is prescribed after a patient gets a positive result from the HercepTest, predicting treatment success. Personalized drug treatment has the potential to increase drug-efficacy rates, which currently average only 30 percent to 50 percent, and to minimize the nation's annual 2 million side effects and 100,000-plus drug-related deaths. By improving patient outcomes, these advances will greatly enhance the value of pharmaceutical products and the overall image of the pharmaceutical industry.

In this way, the pharmaceutical industry can use the consumerization process itself to restore its own health and well-being—and resolve the decade-long series of adverse effects caused by opportunistic stakeholders. And to avoid any relapses in the future, pharma needs its consumer relationships to maintain transparency, accountability, and a continued commitment to making high-value products. **PE**

Stan Bernard, MD, MBA, is the president of Bernard Associates, a management consulting firm for the pharmaceutical industry ([www.bernardassociatesllc.com](http://www.bernardassociatesllc.com)). He can be reached at [SBernardMD@BernardAssociatesLLC.com](mailto:SBernardMD@BernardAssociatesLLC.com).