Consequences of Direct-to-Consumer Advertising

Links to Higher Prices and Less Competition

Author: John Mack
A new AARP Rx Watchdog Report released November 15, 2009, finds that manufacturer prices for widely used brand name drugs have climbed dramatically over the last year, despite a negative general inflation rate. The report, by AARP’s Public Policy Institute, shows that brand name drug prices have increased 9.3 percent since October 2008 (see Figure 1, below).

In contrast, prices for the 185 generic drug products most widely used by Medicare beneficiaries fell by 8.7 percent in the 12 months ending with the third quarter of 2009.

Suspected Price Gouging

In the past, blame for rising drug prices has been placed on the cost of direct-to-consumer advertising (DTCA). This time, however, many people suspect “price gouging” in anticipation of future cost containment under any new healthcare legislation.

As reported in the New York Times: “Recent studies have indicated that the industry may be artificially raising prices for certain pharmaceutical products in expectation of new reforms,” House Democrats wrote in a letter to the Government Accountability Office. “Any price gouging is unacceptable, but anticipatory price gouging is especially offensive,” the letter added, asking the G.A.O. to conduct an expedited review of the price increases.

It seems inconceivable that the drug industry would conspire to raise drug prices while at the same time agreeing—as part of its support for healthcare reform—to provide a savings of $8 billion a year for 10 years.

PhRMA Disputes AARP Report

In defense of the industry, PhRMA stated “Contrary to AARP’s claims, the government’s Consumer Price Index shows prescription drug prices grew by 2.7% during the 12-month period ending in September. That’s half of the 5.4% cited by AARP and completely in line with current medical inflation, which grew to 3% during the period.” See “Are U.S. Drug Prices Actually Rising? Flaws with the AARP Report,” next page.

Continues on pg 4...

Figure 1. Average Annual Percent Change in Manufacturer Prices for Widely Used Brand Name Prescription Drugs Continues to Grow in 2009. Source: AARP Rx Watchdog Report

Note: Analyses for 2008 and 2009 exclude Zyrtce 10 mg tablets, which began to be sold over-the-counter (that is, without a prescription) in January 2008. Shaded bars indicate years when Medicare Part D was operational.
Are U.S. Drug Prices Actually Rising? Flaws with the AARP Report

“AARP’s conclusions are based on incomplete information because they do not take into account discounts and rebates generally negotiated between drug manufacturers and payers, which can significantly lower the cost of brand drugs to payers, ultimately benefiting patients,” said Ken Johnson, PhRMA Senior Vice President, (see “PhRMA Statement on AARP Prescription Drug Report”; http://bit.ly/6S5m3b).

John Vernon, a professor in the Department of Health Policy and Management at the University of North Carolina at Chapel Hill and a Faculty Research Fellow with the National Bureau of Economic Research (NBER), testified before the Subcommittee on Health of the Senate Energy & Commerce Committee during a hearing titled, “Prescription Drug Price Inflation: Are Prices Rising Too Fast?” on December 8, 2009. In that testimony, Vernon asserted that “conclusions drawn in the AARP report, which has not been evaluated and vetted through peer-reviewed evaluation—the hallmark of academic/economics journal publications—are based on flawed methods, and thus are misleading and biased.”

Two major flaws mentioned by Vernon were:

1. The AARP report is based on wholesale price data, not retail or transaction prices, which are often substantially lower than wholesale prices, because Pharmacy Benefit Managers (PBMs) and insurers negotiate discounts and rebates with manufacturers.

2. The AARP report is an analysis of branded products only. The burden to U.S. consumers associated with access to prescription drugs should also consider generic drugs, which in the U.S., are among the lowest prices in the world; and, according to a December 2008 AARP report, the utilization percentage for generic drugs in the U.S. has risen from 19% in 1984 (the year the Waxman-Hatch Act was passed) to 67% in 2007. The impact of this significant shift towards greater generic competition and utilization is to reduce the overall burden of access to pharmaceuticals.

“A much better measure of drug price trends in the U.S.,” contends Vernon, “one that is based on retail prices not wholesale prices, and which also captures the cost savings from generic competition and substitution (since 1995), is the prescription drug consumer price index (CPI) reported by the U.S. Bureau of Labor Statistics (BLS). As the BLS reports on their website, their index includes:

‘All drugs dispensed by prescription. Mail order outlets are included, [and] prices reported represent transaction prices between the pharmacy, patient, and third party payer...’

The prescription drug consumer price index trend is plotted in the following chart:
Clearly,” said PhRMA VP, Ken Johnson, “AARP has been trying to muddy the waters—for its own political gain—as we enter the homestretch of the health care reform debate.”

It’s not clear, however, if the industry has won the PR battle, especially after it accuses one of the largest drug consumer stakeholders of playing politics.

Regardless of the purported extraordinary current price increase or motivations of parties concerned, there is evidence that over the years prices for the drugs most prescribed to older citizens—as opposed to the general population—as tracked by AARP have grown faster than inflation, a point often made by AARP.

Engineered Price Increase
The question is: Are brand drug prices artificially set by drug companies in anticipation of competition or to cover the costs of Direct-to-Consumer Advertising (DCTA)?

A new study published in the November 23, 2009 issue of Archives of Internal Medicine (“Costs and Consequences of Direct-to-Consumer Advertising for Clopidogrel in Medicaid”; Arch Intern Med. 2009; 169[21]:1969-1974) offers evidence for the latter: drug price increases may be engineered to cover the costs of DCTA.

The authors examined pharmacy data from 27 Medicaid programs from 1999 through 2005. They analyzed changes in the number of units of clopidogrel (Plavix) dispensed, cost per unit dispensed, and total pharmacy expenditures.

Plavix is a platelet aggregation inhibitor that was approved in 1997 for the treatment of acute coronary syndromes and the prevention of atherosclerosis-related events. In 2005, it was the world’s second highest-selling drug, with sales of $5.9 billion. “In 2003,” the study authors noted, “Medicaid reimbursement for clopidogrel was just under $400 million, making it Medicaid’s 10th most costly drug. No other prescription antiplatelet therapy appeared in the top 40 most costly drugs dispensed to Medicaid patients in 2003.”

A Controlled Study
What’s interesting about this study is that it was able to compare volume and unit cost before and after DTCA initiation.

Plavix has been marketed extensively using DTCA starting in 2001, several years after it was launched. The authors claim that there was no DTCA for Plavix from 1999 to 2000 (see Figure 3, pg 5). From 2001 to 2005, U.S. spending on DTCA for Plavix exceeded $350 million, an average of $70 million per year.

“This preliminary analysis of an ideal case study,” said the authors, “allowed us to estimate changes in prescribing after the initiation of DTCA, while controlling for existing pre-DTCA trends.”

“One could surmise that DTCA might lead to increased expenditures via 3 mechanisms,” noted the authors. These are:

1. Increased use as a result of marketing directed to patients would lead to increased total pharmacy costs.
2. Regardless of increased use itself, pharmaceutical companies might try to offset the expense of DTCA—more than $5 billion in 2006 (see Figure 2, below)—by increasing the price of the advertised drug.
3. If manufacturers expect or receive an expanded indication for a particular product, they may both increase price and initiate DTCA.

Figure 2. DTC Ad Spending by Year. Measured media only (no SEM). Estimate for 2009 is based on TNS Media Intelligence data of the first three quarters of 2009 in which spending was $3,483.6 million, up 0.6% from the same period in 2008.

Industry Says There is No Direct Link to DTC
According to DTC expert, Bob Erhlich, “DTC is a tactic to improve sales not the fundamental driver of sales. For blockbuster drugs like Lipitor DTC may account for an incremental 1-2% of sales. The best DTC campaigns may provide a higher boost to sales, maybe up to 10% of the total for lifestyle drugs.”

In other words, Erhlich supports mechanism #1 above and, like other industry spokespeople,
Pharma Marketing News

contends that DTCA boosts sales volume and use of the advertised drug. Therefore, drug prices are not linked to DTCA. In that case, the Plavix/Medicaid study should NOT find a unit price increase directly linked to the initiation of DTCA. That, however, was not the case (see below).

Smoking Gun Charts
Aside from looking at DTCA expenditures (see Figure 3A), the authors tracked network news for Plavix ads because they thought these ads were “a particularly influential mode of DTCA.”

The authors calculated the number of Plavix commercials on national network news broadcasts on a quarterly basis using the Vanderbilt Television News Archive (see Figure 3B).

The paper included two charts that represent the “smoking gun” proof that Sanofi-aventis and BMS deliberately raised the unit price of Plavix charged to state Medicaid pharmacies immediately upon the initiation of direct-to-consumer advertising (see Figure 4 and Figure 5, pg 6). In other words, the study results support mechanism #2: regardless of increased use itself, pharmaceutical companies try to offset the expense of DTCA by increasing the price of the advertised drug.

The authors assert that the extra reimbursement from Medicaid reflects an increase in the manufacturer’s price for Plavix, because it is “unlikely that there is any other plausible reason for such a sudden and large increase across 27 state programs. However, as data on pricing are confidential, we cannot be sure.”

Several shortcomings were noted by the authors:

- it is unclear whether the results can be generalized for all drugs
- “many Medicaid recipients qualify for benefits by being of low income or disabled,” noted the authors, “so their response to clopidogrel DTCA may differ from higher income or privately insured Americans” although there is some evidence that DTCA is more effective among individuals with low socioeconomic status
- the study did not control for direct-to-physician marketing (ie, journal advertising, sampling, and detailing). The authors noted, however, that DTCA started several years after the drug was launched and that physician marketing usually begins at or even before launch
- the data do not include any state-specific discounts that Medicaid programs might receive from manufacturers. “Such agreements,” noted the authors, “would only change the interpretation of our results in the unlikely circumstance that they were of similar magnitude to the reimbursement increases that we documented and broadly implemented at the same time that DTCA started. Of course, such discounts or rebates would not change our conclusions related to use.”

Plausible or Dubious?
In his DTC Perspectives Blog (http://bit.ly/4zYy00), Bob Erhlich says the Medicaid-Plavix study is "dubious" because:

1. Price increases were common before the DTC explosion in the late 1990's
2. Medicaid patients are not the target of DTC
3. Plavix has been running DTC for years

Continues...
Figure 4: **The number of clopidogrel units** per 1000 enrollees per quarter in 27 Medicaid programs from 1999 through 2005. The vertical line and the gray bar indicate the start of network news advertising in the fourth quarter of 2001. The solid lines represent the fitted interrupted time series analysis, and the dashed line represents the expected use rate based on the pre-direct-to-consumer advertising (DTCA) trend. The analysis indicated no statistically significant change in either the level ($P = .18$) or the trend ($P = .10$) after DTCA initiation. Copyright © (2009) American Medical Association. All rights reserved.

Figure 5: **Pharmacy reimbursement per unit** of clopidogrel per quarter in 27 Medicaid programs from 1999 through 2005. The vertical line and the gray bar indicate the start of network news advertising in the fourth quarter of 2001. The solid lines represent the fitted interrupted time series analysis, and the dashed line represents the expectation based on the pre-direct-to-consumer advertising (DTCA) trend. The analysis indicated a significant increase in level of $0.40$ per unit after DTCA initiation (95% confidence interval, $0.31-0.49$; $P < .001$). It indicated no statistically significant change in the existing trend ($P = .66$). Copyright © (2009) American Medical Association. All rights reserved.
Although all these statements are true, none address the actual data presented in this specific study.

Ehrlich also says “most large drugs that use DTC are in categories with at least 2-3 major competitors. Their pricing power is weak and they can take price increases only if the market forces allow it.” A Congressional Budget Office report refutes this argument (see “Pharmacos Spend More on DTC Advertising When There is No Competition,” Addendum).

One other piece of evidence, however, supports the link between DTCA and unit cost of Plavix: the authors of the study estimate the overall increase the 27 state Medicaid programs paid for Plavix amounted to $207 million. These 27 programs account for 67% of all Medicaid enrollment. If we expand the estimate to cover the other 33% of Medicaid enrollees, then Medicaid may have paid over $300 million in increased costs, which matches pretty closely the $350 million spent on Plavix DTC during the period studied! Coincidence?

**Addendum**

Pharmacos Spend More on DTC Advertising When There is No Competition

A new report from the Congressional Budget Office (CBO), “Promotional Spending for Prescription Drugs” (http://bit.ly/4th4h4), counterintuitively suggests that “drugs with little competition are likely to be marketed to consumers far more aggressively than drugs with a lot of competition” (NY Times). According to the report:

“Pharmaceutical manufacturers tend to spend more, on average, on DTC advertising for drugs that have few or no direct competitors (meaning there are few other drugs that treat the same condition using the same mechanism) than on products with numerous alternatives. Excluding some classes of drugs with the highest-selling and most advertised drugs—where a drug’s potential market size might overwhelm other factors in setting a marketing plan—the data analyzed by CBO show that average spending per drug on DTC advertising generally declines as the number of competitors in the same class increases (see Figure below). When a class includes more drugs, pharmaceutical manufacturers tend to spend less, on average, on DTC advertising because the benefits of that advertising (higher sales) may be diffused among the other drugs in the class.”

"A monopoly," says the NY Times reporter, "reaps any benefits of its advertising alone." See Figure CBO-4.

Figure CBO-4. Average Spending ($millions) per Drug on DTC Advertising, by the Number of Competitors in a Given Class of Drugs, 1995 to 2008. Source: Congressional Budget Office based on data from SDI Promotional Audits. Drug classes are specified at the 5-digit level of the IMS Uniform System of Classification. To account for cases in which a drug’s potential market size might overwhelm other factors, four classes in CBO’s data set were excluded from this figure: nonbarbiturate sleep aids, statins, erectile dysfunction drugs, and proton-pump inhibitors. Drugs in those classes account for 35 percent of the expenditures for DTC advertising reported in CBO’s data set.

The report notes that physician detailing expenditures do not exhibit the same relationship between average spending and the number of competitors in a drug class.

**DTC Maximizes Profits During Monopoly**

The thinking is that if you promote a drug having competitors, it’s just as likely that a competitor drug will be prescribed as will be the drug advertised. This interpretation is consistent with other data—from ad agency sources—which concludes that DTC advertising does NOT result in consumers asking their doctors for the advertising drug by brand name (see "Advertisers Don’t Know How DTC Works. Say wha?: http://bit.ly/3D1ekb).

It appears that DTC may be used as a tool to maximize profits during the period when the drug enjoys a monopoly. Higher prices can be charged during this period because there is no competition. Hence, a link between DTC and high drug prices.

**DTC Moratorium Would Reduce Profits**

Some critics of DTC advertising say that drug companies should wait one, two, or three years

Continues...
before advertising new drugs to consumers. The rationale is that new drugs may have unknown risks that may not be seen until used for a few years.

PhRMA’s DTC Principles waffles on the issue: "In order to foster responsible communication between patients and health care professionals, companies should spend an appropriate amount of time to educate health professionals about a new medicine or a new therapeutic indication and to alert them to the upcoming advertising campaign before commencing the first DTC advertising campaign."

A few pharmaceutical companies have agreed to a voluntary 6-month or 1-year moratorium on DTC advertising for new drugs. Some experts say that DTC typically does not begin immediately after approval in any case.

However, a moratorium of 2 or 3 years would drastically reduce the profitability of those drugs that are "first-in-class"; ie, those without competition in the first few years on the market. This may be the main reason why drug companies are resisting efforts by lawmakers to impose a long moratorium on DTC. By offering a voluntary 6-month moratorium, drug companies seem to be compromising but really are not offering anything they have not already been doing.

Figure CBO-5 shows that drug promotional expenditure usually peaks 1 to years after approval for marketing.

![Figure CBO-5. Time Path of DTC Spending for Prescription Drugs. Congressional Budget Office based on data from SDI Promotional Audits and Food and Drug Administration, Electronic Orange Book (accessed June 2009), available at www.accessdata.fda.gov/scripts/cder/ob/default.cfm](image-url)