Contributed by Don Sharpe

THE BATTLE LINES ARE DRAWN


DON SHARPE

In a nod to the founding fathers, several states have started a revolution against the tyranny of high-margin pharmaceuticals with the uninsured elderly playing the role of constituents deprived of their rights. This time the battlefield is the U.S. courts, and lawyers representing both sides are firing shots and sizing up each other's strength. As concerned citizens of the pharmaceutical industry, you should know that we are up against a formidable constituency ready to go to great lengths to balance its budget. The situation is reminiscent of the original 13 colonies with New England once again leading the way. Don't be surprised if you see people dumping large amounts of antibiotics into Boston Harbor soon.

On one side of the courtroom are prescription drug manufacturers with billions of dollars of revenue at stake. On the other side are several states, including West Virginia, New Jersey, Florida, and the strong-arm triumvirate of Maine, New Hampshire, and Vermont, representing millions of moderate- to low-income residents who don't have insurance and can't afford to buy prescription drugs. In the balance is a pool of money that will continue to feed the bottom line of pharmaceutical companies or reduce the burden of prescription pharmaceutical costs on state budgets. The question is: Can both sides win?

THE FIRST SLOT

"The shot heard 'round the industry" was fired by Maine when the state created the Maine Rx Program, which evolved into the Tri-State Initiative, including New Hampshire and Vermont — a state run pharmacy benefits manager (PBM). Like any PBM, the Maine Rx Program allows Maine to negotiate with drug manufacturers to lower prices and pass the savings along to residents. If companies don't negotiate with Maine, use of their products could be restricted in the state's Medicaid program. At the time of the announcement of the Tri-State Initiative, Vermont's Governor, Howard Dean, said his state has seen an 18% increase in pharmaceutical costs and "with these kinds of increases, it was time for states to try a little creativity." Following the Tri-State Initiative's lead, West Virginia approved a plan to form a multistate purchasing pool, which allows the state to "enact fair prescription-pricing policies."

The initiative the pharmaceutical industry should be most worried about comes from Florida, where the state has created a formulary of preferred drugs. If doctors want to prescribe a drug that is not on the formulary, they must first get a verbal authorization from a bank of pharmacists before the prescription can be filled. This hurdle shifts prescribing habits toward those drugs on the preferred list, as evidenced by the shift in market share in Florida from GlaxoSmithKline's migraine medication Imitrex to Merck & Co.'s Maxalt. To get a drug on Florida's preferred list, a company must provide an additional 10% rebate on top of the 15% federal Medicaid rebate.

Not to be left behind, Michigan quickly created a program inspired by Florida's model called the Michigan Pharmaceutical Best Practices Initiative. In this case a pharmacy and therapeutics committee recommends at least two drugs in a class as "best-in-class," meaning doctors don't need prior authorization to prescribe them. This also means that manufacturers can offer rebates if their drugs are not "best-in-class" and avoid the prior authorization process.

In all there are 40 states that have introduced proposals aimed at reducing pharmaceutical prices. New Jersey jumped into the fray by creating a senior discount program allowing lower income individuals to pay 50% of the "reasonable" cost of a drug, and Maryland has been trying to make drugs available to Medicare patients at lower Medicaid prices. At this rate, the states are creating a "union" with greater potential to erode pharmaceutical profits much quicker than the federal government can do with Medicare coverage of prescription drugs.

IN DEFENSE

The industry, which has been successful at fending off price controls and managed care so far, has held the line in its response to the states' actions. The Pharmaceutical Research and Manufacturers of America (PhRMA) has filed suit in federal court to challenge the Maine Rx Program and Vermont's Pharmacy Discount Program. In response, Maine Governor Angus King, has expressed disappointment that the industry is acting as an "adversary rather than a partner." PhRMA also filed suit claiming that Florida's law breaks a federal requirement that all prescription drugs be available to Medicaid recipients. According to PhRMA, only 821 out of 1,827 drugs covered by Medicaid are on Florida's preferred list.

While PhRMA uses legal tactics to fend off the adversary on the front line, they also are lobbying aggressively to prevent pharmacies and wholesalers from importing U.S. approved prescription drugs from foreign countries where prices are lower (remember Al Gore's dog?). And what battle wouldn't be complete without a public-relations campaign to create goodwill and capitalize on the value the industry brings to patients. Between legal maneuvers, lobbying, and public-relations tactics, the industry is going to have to start drafting soldiers for the ensuing battles.

The seriousness of the matter for the pharmaceutical industry escalated in January when a federal judge upheld Florida's law to create a formulary. The judge argued that the law only steers doctors in a direction, but doesn't deny patients' access to drugs. As the momentum shifts to the states, more and more states will begin to follow the successful examples spearheaded by Maine and Florida. What can the industry expect from sleeping giants like California or New York? States contend that they are grappling with double-digit inflation in pharmaceutical costs, and they owe it to their constituents to find ways to reduce these costs. Florida Governor Jeb Bush said in a prepared statement, "Protecting the large profit margins for multibillion-dollar pharmaceutical companies is not a priority," and there are 49 other states that will nod their heads in agreement. Florida expects to save $100 million this fiscal year as a result of the rebates.

While PhRMA is busy with legal and lobbying efforts, a few smart industry representatives have taken up arms by responding directly to the states' challenge. All of Pfizer Inc.'s drugs are on Florida's Medicaid formulary without discounts in exchange for a pledge to save Florida

$33 million by reducing healthcare costs for chronically ill Medicaid patients. Pfizer also recently established the Pfizer Share Card, a national program to provide pharmaceutical insurance for Pfizer drugs to the elderly poor, thus establishing this group's rights as citizens. GlaxoSmithKline's Orange Card, launched in October, and Novartis' CareCard, launched in January, are similar programs targeting the uninsured elderly. People that meet eligibility criteria based on income and age apply for these cards and present them as "coupons" at participating pharmacies. Novartis and GlaxoSmithKline claim participants will save 30% to 40% off the cost of their prescriptions.

A HARBINGER OF THINGS TO COME

But we in the industry need to ask ourselves if this is the direction we want to go? Negotiating state-by-state deals abates the immediate problem, but do we really want to create task forces and disease-management programs for each state that threatens a program to reduce the cost of prescription drugs? And what about the smaller pharmaceutical companies that don't have the resources to put together encompassing programs such as Pfizer's? It seems like negotiating a solution for uninsured elderly at 300% of the federal poverty level is really just picking off the low hanging fruit. States are gaining confidence, and soon they will be introducing proposals that cover more of their constituents, more prescription drugs, all with the aim of reducing the profits of pharmaceutical companies.

These states' actions are a harbinger of things to come, especially as the federal surplus shrinks. The industry's brand image is one of providing innovative medicines to the people of the U.S., but that image may be shifting to one of high margins and excessive spending on sales and marketing. Like it or not, the nature of the healthcare industry is that we have to deal with the emotional aspects of human beings that need healthcare. The states know this and can leverage this fact to create a public-relations campaign of their own. Certainly the war can be resolved through careful planning and negotiation without having to consider a white flag. The first step for the pharmaceutical industry is to understand that the opponent is not the federal government, but a wily and nimble group of states that are probably more willing to negotiate than their bigger counterpart.

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INDUSTRY SNAPSHOT

Discount drug programs for seniors

Medicare only pays for prescription drugs that are given in the hospital. Many seniors have coverage for outpatient prescription drugs through separate Medigap insurance or other programs. But as many as 40 million people — including one-third of low-income seniors (27%), who often are the people least able to afford the cost of prescriptions — do not have such coverage. Costs for this group of consumers are rising rapidly, forcing many seniors to do without needed drugs.

In litigation that targets 28 drug companies for manipulating the average wholesale price of drugs covered by Medicare, the Prescription Access Litigation project filed suit in December 2001 in state and federal court to stop what it says is an industry-wide scheme to defraud those who need medications. A total of 14 coalitions representing healthcare consumers in 11 states are involved in the litigation.

A 2000 survey by Families USA, published in June 2001, found that 50 of the most prescribed drugs for seniors rose in price on average more than twice the rate of inflation, and that 18 of the 50 top prescribed drugs for seniors rose in price by at least three times the rate of inflation.

For most of last year, prescription drug coverage for the elderly and low-income Americans was high on the political agenda — that is until September 11. Before the terrorist attack, a Medicare drug plan was on politicians' priority list. Now, consultants say while there is likely to be continued political posturing this year for a Medicare drug benefit, it is not likely that one will be approved anytime soon. Any budget surplus that would have been used to fund such a plan is expected to be used to cover the costs associated with the Sept. 11 attack and the continued war on terrorism. Given this environment, there is going to be a lot of pressure on both sides when the time comes to enact a pharmacy benefit program in Medicare.

In the meantime, other ways to address the access issue are being considered. In July of last year, President George W. Bush put forth an initial plan for government-endorsed drug-discount cards for Medicare recipients. In the fall, the Centers for Medicare & Medicaid Services in Baltimore began working on plans to implement the program. For now, though, a federal discount card has stalled because of opposition from retail pharmacists.

And at least one state and three pharmaceutical companies are offering a discount drug program for seniors. The state of Iowa has launched a program for residents, which charges a $20 fee for access to the discounts.

Pfizer Inc. is the latest pharmaceutical company to offer such a card. In March, Pfizer expects to launch its senior discount card, called the Pfizer Share Card. Novartis Pharmaceuticals Corp. also launched a program called CareCard and GlaxoSmithKline launched its version called Orange Card.

These cards generally offer discounts on the company's medications to those seniors below a certain income threshold ($26,000 for a single person for the GlaxoSmithKline and Novartis card; $18,000 for a single person for Pfizer's program) and who don't have a pharmacy benefit or other insurance. Pfizer's card offers a flat-rate of $15 for any Pfizer prescription. The companies are estimating savings of 25% or 30%. In some cases, they say, savings could be as high as 40% of retail prices. According to a spokesperson for GlaxoSmithKline, 20,000 people are now enrolled in the Orange Card program. The company is enrolling about 500 people a week; they have distributed 11 million applications.

A study by the General Accounting Office, released in December 2001, found that discount cards only offer minimal savings. The focus of the GAO's study, however, was on discount prescription drug cards offered for a fee by pharmacy benefit managers such as Merck-Medco, AdvancePCS, Express Scripts, and WellPoint. These cards generally charge an annual fee in exchange for the discounts. The GAO found that the largest savings were in smaller, rural areas. Seniors in three large cities — Washington, D.C., Chicago, and Seattle — experienced savings of 8.2% on 12 brand-name drugs bought with the cards compared with buying retail.

Some critics of the discount cards say they are just a stop-gap measure. The discount cards could lead to confusion and administrative hassles for the pharmacies. What critics say is needed is a pharmacy benefit for Medicare seniors. Seniors without coverage for prescription drugs often skip doses or avoid taking their medications because of their high costs, according to a study in The Journal of General Internal Medicine, published in December 2001. This study found that monthly out-of-pocket expenses for seniors without coverage was $60 compared with the monthly out-of-pocket expenses of $24 for those with partial coverage of their prescription drugs.