The New Fix

by Charles Wiff


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Under the Court's opinion, the way will be open not only for dissemination of price information but for active promotion of prescription drugs…the use of which it has previously been thought desirable to discourage."

-Justice Rehnquist, *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council*, 1975

The next time a commercial for the newest prescription drug flashes across your television screen, don't just change the channel. You are viewing the culmination of decades of court decisions, legislation, and trial-and-error that has elevated the drug market to the position of one of the most profitable industries in America. A gradual relaxation on the policing of the industry has helped the process, and also created cause for concern over the safety and ethical purity of the entire pharmaceutical scene.

In 1975, the Supreme Court of the United States made one of the first modern decisions relating to the dissemination of pharmaceuticals in America, a case called *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*.

The Virginia Citizens Consumer Council was opposed to a law prohibiting Virginian pharmacists from advertising the prices of their drugs (similar laws applied to alcohol and cigarettes). The consumer watch group felt the law prevented the poor from seeking out the cheapest drugs and, in a 7-1 decision, the court found favor with the Consumer Council.

The sole dissenter in the case was Justice Rehnquist, then the most conservative judge on the court. He was concerned with a slippery slope, that if pharmacists were allowed the leniency to play price games, we would be only a slight nudge away from disrupting the delicate balance of an industry that sells a powerful product and be put on the path to commercialization.

Rehnquist's opinion was forcefully worded. The Justice argued at one point, "In the case of 'our' hypothetical pharmacist… he may attempt to energetically promote their [prescription drugs'] sale so long as he does so truthfully." Later, he presented hypothetical ads:

"Pain getting you down? Insist that your physician prescribe Demerol. You pay a little more than for aspirin, but you get a lot more relief.

"Don't spend another sleepless night. Ask your doctor to prescribe Seconal without delay."

It is important to note that this style of advertising is surprisingly similar to the drug ads that flash across television screens today. Simply replace the phrase "ask your doctor to *prescribe*" with "ask your doctor *about*." The latter may seem more responsible on the part of the advertiser, but of 91 percent of responders to a 2000 *Prevention* magazine survey who said they had seen a prescription drug ad, 26 percent asked their doctor for a prescription of that specific medicine. Of those who asked for the drug, 71 percent walked away with a prescription for it. And that's a significant increase over a similar Food and Drug Administration (FDA) survey conducted the previous year.

The face of health care in the U.S. is changing. It has been a long, somewhat nebulous transition, but it's safe to say that pharmaceuticals are brought to and used by the public in a manner wildly different from the drugs of yesteryear. The entire industry, like so many corners of the American marketplace, has been analyzed, streamlined, commercialized, and turned towards a profit-hungry mode of survival.

And that equates into industry growth—quite a bit in fact. The American health industry was a $1.7 trillion item in 2003, and the annual increase in prescription drug spending has dwarfed the growth of other subsections of the

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industry since 1995 at an average rate of 17 percent per year. The annual average number of prescriptions per person in the U.S. has skyrocketed from seven in 1993 to 12 in 2004.

So, what accounts for this shift in the way Americans handle their health care? Part of it is the current belief that anything can be fixed with proper medication and lifestyle, emphasis on medication. Drug makers have also shifted their sights from battling life-threatening illnesses (like cancer and AIDS) to chronic conditions (like asthma, diabetes, etc.), which have a much larger, if not intrinsically healthier, market.

Then there's advertising. It's now irrefutable that there is a direct correlation between the marketing of a drug and its sales. The development of a new drug not only involves laboratories and clinics, but boardrooms and marketing departments. But some are starting to question the moral health of drug companies. After all, should an industry that sells prescription medication, which has the power to do great harm as well as great good, be given the chance to be motivated by the almighty dollar?

Collateral Damage

While the drug industry has been in transition since the days of *Virginia v Virginia*, only recently have fears been brewing over the state of America's pills. Pharmaceutical powerhouse Merck's arthritis relief and anti-pain drug, Vioxx, has spurred many of those fears. Vioxx was supposed to revolutionize the industry when it came out in 1999, and some even supposed that the miracle pill would replace aspirin for the treatment of everyday pain (Vioxx was being shown to have no negative effects on the digestive tract, unlike traditional pain meds like ibuprofen or aspirin). That was before the truth about Vioxx's potentially lethal side effects emerged.

It was discovered in September of 2004 that the use of Vioxx, which had become Merck's best selling drug, doubled the risk of a heart attack in many people. These heart attacks were written off as a result of patients discontinuing aspirin medication (which has long been know to help in the prevention of heart attacks), but in reality is has been estimated that 55,000 Americans died before Vioxx was pulled from shelves.

The incident left patients around the nation in shock. The FDA was suddenly under fire for the incident, with critics asserting that if agency spending was focused more on drug safety than drug approval, the truth about Vioxx would have been exposed in half the time. Whether the incident could have been prevented by the FDA or not, it is undeniable that Merck's aggressive ad campaign for the new drug was partly responsible for the huge number of prescriptions.

***Virginia* Realized**

Vioxx's success can be attributed to a developing method of bringing drugs to patients: Direct-to-Consumer (DTC) advertising. It wasn't always the case that pharmaceuticals would be peddled through television and magazine ads. Says Professor Alfred Reiman, an instructor in the University at Buffalo's Department of Pharmacy Practice, "There was a time when that was considered unethical and illegal." Regulations also required so much safety information to be displayed that the ads could easily be off-putting. Drug ads were relegated to medical journals, where qualified physicians would see them, research them, and then prescribe the drugs they found most useful to their patients. That was before the rules on DTC ads were gradually relaxed.

The result of deregulated DTC advertising has been an explosion of pharmaceutical ads in all mediums, and the results speak for themselves. Newly approved Vioxx was the heaviest advertised drug in 2000, with Merck pouring $160 million into its promotion. The result was $1.5 billion in sales for Vioxx, quadruple the previous year's take. And the practice has only grown over the years; drug makers spent $2.5 billion on DTC in 2000, but according to the Pharmaceutical Researchers and Manufacturers of America (PhRMA), the industry's trade group, companies shelled out $11.4 billion in 2005.

The Shift to DTC

The crossover to commercialization didn't happen overnight. Like so many modern stories of economic dominance, the major changes began in the '80s, when drug makers began to feel the effects of the economic recession of the previous decade. They were concerned with growing foreign competition,

dwindling sales, and increasing costs of developing new medicines.

If this didn't already leave drug makers in a tight spot, the Hatch-Waxman Act of 1984 (officially billed as The Greater Access to Affordable Pharmaceuticals Act) appeared to be the final nail in the coffin. The act essentially allowed generic drug companies to quickly and easily move to market with their copies of a drug once the patent ran out for the parent company. They were allowed to introduce bioequivalence studies for their generics rather than compile clinical data, a time consuming and expensive process.

Hatch-Waxman didn't bode well for companies developing new drugs, though. The development, testing, and FDA approval process for a drug can be long and expensive (according to the FDA, the average drug approval in 2002 took 8.5 years at a cost of $500 million). Also, the patent on many new drugs (which now lasts 20 years) often starts decaying during this process. Pharmaceutical companies depended on the long-lasting patent monopoly on their new drugs to make back their investment. It's one of the simpler economic adages: you have to spend money to make money.

But Hatch-Waxman threw that equation into chaos. If Americans had greater access to generics and didn't buy "brand name," drug makers wouldn't get their money back. To get the most out of their new drugs, companies had to start selling them faster. In his recent book *Generation Rx*, Greg Crister writes, "It didn't matter how good your drug was if doctors didn't know about it, or if they had gotten a bad first impression. Somehow, you had to find a way to control that first impression—and then reinforce it." In other words, product awareness, plus trust in the product, equals sales.

Such was the case of Seldane, an antihistamine (allergy medication) that hit the market in 1985. Its maker, Merrill, knew that the average allergy sufferer only visited the doctor every three years for the condition. If Merrill advertised in medical journals they would have to wait around three years for the advertising to result in sales, and that's only if doctors decided to support the new drug.

The solution was an inventive new ad campaign that hyped not the drug's ability to suppress allergic symptoms, but rather its unique property of not making the user drowsy. By emphasizing the lifestyle benefits rather than the drug itself, Merrill was able to reach out to patients both directly and legally. They didn't even mention the name of the drug (due to FDA regulations), making it a tantalizing glimpse for the consumer; if the patient was interested and wanted more information, he or she could "go and see their doctor."

Seldane became wildly popular, even after the revelation that it could cause "fatal heart rhythm irregularities" when mixed with other medications or even grapefruit. Seldane stayed on the market with an FDA "black box" warning on the packaging, however, until safer non-drowsy antihistamines made it to patients. The sales slumped after the introduction of Claritin and Allegra (two similar, safer drugs), and Merrill withdrew Seldane in 1998.

America's New Pusher

In the case of Seldane, it is very simple to see the importance of lifestyle image for drug marketers. The newest hypertension drug doesn't just lower your blood pressure, it will help you lead a more active life. The new pill for erectile dysfunction (ED) doesn't just allow for the act of coitus, it could be instrumental in strengthening your marriage. Even ads for the herpes med Valtrex feature patients doing yoga in the sunset. There are celebrity endorsements; Bob Dole lent his support to the ubiquitous ED drug Viagra, and a new ad for the hypertension med Lipitor features Robert Jarvik, the inventor of the artificial heart. Justice Rehnquist would have been appalled.

There is an increasing consensus that DTC advertising (especially television ads, which are second only to free samples in DTC spending) might be reckless for an industry with such powerful products. "I personally think that it's not a good thing for pharmotherapy," says Professor Reiman. "Certainly the physician has the final say… but getting pressure from their patients is eventually going to lead to prescribing something the physician maybe would otherwise not prescribe. And as long as that's the case, there's always the potential for drug misadventures and overprescribing."

The criticism of DTC is not a new phenomenon. In 2001, Nancy Chockley, President of The National Institute for Health Care Management Research and Educational Foundation (NIHCM Foundation), a non-profit group that

compiles data on health care, testified that "in this unique consumer marketplace, DTC ads prompt consumer behavior without providing substantive and complete information about the advertised product, treatment alternatives, or the disease." What she means is there is generally little accompanying information about the drug in television ads. FDA laws require that a website and toll-free number be given that contain more complete information on the drug, but these websites sometimes put offers of free samples first and hard scientific data second.

The Government Watchdog That Couldn't

While Direct-to-Consumer advertising raises ethical questions, it is quite another matter if the drug being advertised is dangerous to patients. The government entity tasked with ensuring new drugs are as safe as possible is the Food and Drug Administration (FDA). The FDA plays a major role in the drug market, since it has the power to bar or remove any pharmaceutical from the market. Changes at the Administration within the last ten or 15 years, however, have produced some serious doubts over whether the FDA is doing that job ably.

The FDA's approval process holds a great amount of importance for drug makers and patients alike; a quick trip through approvals means the drug is on the shelves and money is in the company's pockets faster. In addition, rising awareness of the battle against cancer and the AIDS epidemic in the '80s had created a need for new drugs immediately, not in a few years. For many, the solution was a push for faster approval times.

Enter The Prescription Drug User Fee Act of 1992 (PDUFA). The act allowed drug companies to contribute money to the FDA in return for the promise it would be used to bolster the drug approval process and guarantee faster new drug approvals. This "accelerated development/review," or "fast track," was designed with two types of drugs in mind. First and foremost were drugs the FDA felt "promise[d] significant benefit over existing therapy for serious or life-threatening illnesses for which no therapy exists," meaning drugs for terminal conditions like AIDS.

"There's a need for new drugs," says Professor Reiman, "and when the benefits outweigh the risks of the medication, in other words, if you have a population that is just going to die without the drug, then it warrants perhaps going the fast track method."

There is another grouping of drugs destined for the fast track, those with evidence of a "surrogate endpoint." According to the FDA's website, this endpoint is an initial finding that "may not be a direct measurement of how a patient feels, functions, or survives, but is still considered likely to predict therapeutic benefit for the patient." That means if a drug shows strong signs of success in the initial testing phases, it can be rushed to market sooner. The maker must continue testing to prove the surrogate endpoint, however, and the FDA can also pull the drug more easily if a problem arises.

That doesn't prove the PDUFA is helping patients, however. There are an increasing number of allegations suggesting the FDA's focus on drug approvals has hindered the capacity of its other organs, especially those that monitor the market for drug safety. According to The New York Times, the agency's drug center spent 53 percent of its budget reviewing new drug applications (NDAs) in 1992, when the act was passed. In 2003, that number had skyrocketed to 79 percent. Drug companies are also set to pitch in a record $320 million of their own cash in this year's PDUFA offering to bolster the process. Despite multiple attempts by phone and email, FDA officials did not answer Generation's requests to discuss the effects of the PDUFA.

The PDUFA also stipulates that the FDA's spending on approvals can't fall below 1992's inflation-adjusted levels to ensure the industry's money will be spent on new reviewers instead of just paying for the old system. But financial difficulties across the government mean that the FDA has had to take money out of other programs to meet the requirements. The result is that the FDA now relies solely on reports from the field to track potential side effects, and it's certain this system does not catch every danger. In Reiman's words, "It's a double-edged sword. I definitely believe in the fast track, although I do believe it does have some inherent abuse potentials."

Do-it-Yourselfers Flourish

Perhaps it's the troubles at the FDA or the often contradictory information that

permeates the media, but more and more Americans are now taking their health into their own hands. Many drugs that were only available behind a pharmacist's counter now have their own street prices (drugs like Ritalin, which is now a familiar name to most college students). Pharmaceuticals are being used recreationally by some, but many seek out other drugs that treat anything from depression to insomnia in hopes of self-medicating.

The internet has become a cradle for do-it-yourself pharmacists, where a few clicks and a brief form can land any surfer medications from questionable pharmacists. For those seeking information, consumer watch groups like Public Citizen run sites like worstpills.org, which catalogues drugs still on the market which have been shown to hold a risk for patients. Those who seek support for their conditions can find similar groups of people; crazyboards.org, for example, is a site teeming with free advice about psychological afflictions from other sufferers.

While this may seem like just another facet of the glorious information revolution, when dealing with health matters, it becomes another issue. "I'd have to say that conceptually, people are intelligent beings and that theoretically they can come to the same conclusions that doctors do," says Professor Reiman. "If they do their homework and employ reliable sources, they may feel confident enough to diagnose and/or self-prescribe. One must recognize, however, that there are several highly complicated steps in the diagnosis process, and while some may be intuitively obvious, most are not. As a result, one should regard self-diagnosis and prescribing as extremely dangerous and potentially lethal. Furthermore, the practice of medicine without a license is a felony crime against the public health. If one thing goes wrong, you may end up in jail or dead."

A Change for the Better?

Although the prescription drug market is a complex and sometimes unsafe environment, there are efforts being made to help patients and doctors make the right choices when it comes to medications. Last year PhRMA announced their voluntary Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines in an effort to change the image of DTC. The Principles are designed to encourage drug companies to better educate physicians before starting a DTC program, which would hopefully cut down on improper prescriptions. The organization asserts that since the Principles took effect, DTC advertising has been much more informative, although Ken Johnson, PhRMA's Senior Vice President, notes that "the length of time this requires will vary from medicine to medicine, and companies will meet this goal in different ways."

Which highlights one of the action's problems: it has no teeth. The ultimate punishment for companies that voluntarily sign on to the plan would be the periodic issue of a report stating the perpetrators violated the plan. Such a report could lead the FDA to scrutinize certain ads for violations of DTC laws, however. While 27 drug makers have signed on, including most of the companies with best-selling meds, only time will tell whether DTC ads will reflect these changes.

Advertisements are now popping up that make no mention of a specific drug in the ad or on the website address given, but these ads are still in the minority. Wyeth Pharmaceuticals, for example, now runs a TV ad for the website yourtimeforchange.com, which encourages antidepressant users to seek out information about their condition and makes no mention of a drug. Wyeth does market an antidepressant called Effexor.

The Middle Ground

If the current trends are any indicator, the prescription drug arena is going to get more complicated before it gets simpler. Patients have to remember to keep their wits about them and resist the urge to turn immediately to pharmaceuticals to solve their health care problems.

"Sometimes the best treatment for a disease state is a non-pharmacologic intervention," says Professor Reiman. "For example, in some cases, the best treatment for high blood pressure may be to lose weight rather than for your physician to prescribe prescription medication." But Americans have become just as accustomed to the fast track as drug makers—a quick fix whose value is measured in dollars is much more appealing than hours of laps at the gym or endless time on a psychiatrist's couch.

The solution is not patients deciding for themselves what treatments are adequate, nor is it patients blindly signing up for the industry's newest pill. Professor Reiman believes that there is a "middle ground" in which the FDA must tread to effectively do its job, and the same is true for the pharmaceutical industry as a whole.

Let's hope we can find it.
