

# Boston

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Bad Medicine  
by Michael Blanding  
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**Drug companies, already under fire for selling medications that don't work, are bribing doctors to prescribe pills you don't need.**

Under normal circumstances, Dr. Joseph Gerstein wouldn't have taken the call. His assistant knew that the Tufts Health Plan administrator didn't approve of so-called "detailers" -- pharmaceutical-company representatives who ply doctors with free samples and high-priced dinners to get them to prescribe particular drugs. She was under strict orders not to put them through.

On this day, though, Gerstein's regular assistant was away, and a temp transferred the call from TAP Pharmaceutical Products. Gerstein, medical director of the plan's pharmacy program, listened as the detailer on the other end said TAP would pay the HMO \$20,000 in an unrestricted "educational grant" if it would provide patients with the prostate-cancer-fighting medication Lupron instead of Zoladex.

"That scandalized me," says Gerstein, who had supervised three years of study that concluded Lupron was no better than Zoladex, even though it cost \$100 more per dose. The "grant" seemed to him nothing more than an illegal kickback to the hospital for which its patients would ultimately pay.

Gerstein contacted the U.S. Attorney's Office to report the offer (which was later increased to \$65,000). That proved to be just the tip of the iceberg. A whistleblower from TAP told investigators that sales reps offered all kinds of incentives to urologists to switch their patients to Lupron, including free VCRs and trips to resorts for supposed medical seminars.

Charged with fraud, TAP pleaded guilty to illegal marketing and agreed to settle the case by paying \$875 million -- the largest settlement of a medical-fraud case in U.S. history. In November, a judge approved a \$150 million settlement in a class-action suit brought by Lupron patients, pushing the potential total the company will pay to more than \$1 billion.

Behind the headlines about the safety of the painkillers Vioxx and Celebrex and antidepressant use by children lurks a secretive world in which drug salespeople lavish doctors with gifts and free travel, and doctors charge Medicare the full price for drugs they

get at a discount. The result? Patients pay more for medications they may not need and that may actually have harmful side effects.

A world center of biotech and pharmaceutical research, Boston is home to companies accused of some of the industry's biggest scams. But local courts and hospitals are also now spearheading a backlash, exposing -- and prosecuting -- some of medicine's worst offenders.

No segment of healthcare has seen greater increases in costs than prescription drugs, according to some calculations. And in many cases, those higher costs have little to do with better care. Take, for instance, the widely reported controversy over the safety of Vioxx and Celebrex, which clinical trials showed may increase the chance of heart attacks. (Merck, the maker of Vioxx, has pulled it off the market.) Less attention has been paid to the fact that most patients shouldn't have taken Vioxx in the first place.

"It really is a state of chaos," says Dr. Jerry Avorn, head of a department at Brigham and Women's Hospital that studies the safety and cost-effectiveness of drugs and author of *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs*. Avorn, whose office is just a few blocks from Merck's gleaming research facility in the Fenway, was one of the first to raise concerns about Vioxx. He has spent his career comparing the drugs doctors tend to prescribe with the findings about them in medical journals.

When concerns were raised about Vioxx during its FDA approval process, Avorn and his colleague Dr. Dan Solomon did some research on their own. They concluded that despite Vioxx's high cost, it was no better than aspirin or ibuprofen and should only be given to patients who experienced side effects with normal pain relievers.

Such findings did little to deter drug companies, however. In 2000, Merck spent more to market Vioxx than Anheuser-Busch spent pitching Budweiser. Its ads featuring Olympians Dorothy Hamill and Bruce Jenner ("Vioxx. For everyday victories") were even more ubiquitous than those broadcast by Pfizer, maker of Celebrex, which urged consumers to "Come on and celebrate!" Vioxx and Celebrex became two of the best-selling drugs in history as a result, exposing many more people to their high price tags and potential side effects.

"Some estimate that tens of thousands of people suffered heart attacks from Vioxx, but there were millions of people who paid more for the drug based on an advertising campaign," says Alex Sugerman-Brozan, director of the Boston-based Prescription Access Litigation Project, or PAL.

Sugerman-Brozan's closet-sized office overlooks Winter Street in Downtown Crossing. It is filled with blue binders labeled with the names of drugs -- Augmentin, BuSpar, Cipro, OxyContin -- against which the organization has helped bring class-action civil suits.

Since the federal and state governments generally only prosecute cases of fraud involving Medicare or Medicaid, PAL helps return money to ordinary consumers who pay for medications out of their own pockets. One such person is Helen Donega, a plaintiff in a

class-action suit against AstraZeneca, which opened a new research facility in Waltham in 2003. Donega, who lives in North Adams, survived a mastectomy, then found she'd have to pay more than \$100 a month for tamoxifen to prevent a recurrence. So she delayed taking it.

"You are gambling," she says, "and there are a lot of people who have more aggressive cancer than mine who did the same thing."

At issue in the tamoxifen case, which was dismissed by a trial judge and is now on appeal, is whether AstraZeneca struck a deal with a generic-drug company to extend the length of its brand-name patent, a practice called "evergreening." The cost of a drug often falls by as much as 80 percent when its patent expires, yet the alleged deal, plaintiffs continue to assert, allowed the company to charge 95 percent of its original price.

In another case involving AstraZeneca, filed in California and set to also be filed in Massachusetts, plaintiffs claim the company cheated customers by marketing a copycat version of its own drug. According to the complaint, AstraZeneca stopped marketing its heartburn medication Prilosec -- known to millions of acid-reflux sufferers as "the purple pill" -- just as the drug's patent was running out and the price was about to drop. Instead, it started heavily promoting Nexium, which it dubbed "the healing purple pill."

The problem, says Sugerman-Brozan, is that Nexium is nearly indistinguishable from Prilosec. AstraZeneca claims in commercials that Nexium is more effective than its sister pill; the company neglects to mention that the dosage in a clinical study was twice as high. "It's one of the most sordid tales I've come across in the drug industry," says Sugerman-Brozan. (AstraZeneca insists that all its statements about Nexium are "supported by the data," according to a company spokeswoman.)

"Drugs are not like other consumer products," Sugerman-Brozan continues. "They are not CDs. They are not cars. They are not fabric softeners. Your average consumer doesn't have the knowledge to be able to evaluate the claims in an ad."

Presumably, that's where your physician comes in.

Last year, pharmaceutical companies spent a combined \$3.8 billion on direct-to-consumer advertising, an expense the companies say is necessary to keep the public informed about breakthrough drugs. But the amount spent on consumer advertising was only a small portion of the industry's combined \$21 billion marketing budgets. The rest was spent on detailers, expensive dinners, conferences, and consultancies -- all aimed at a very specific subset of consumers: doctors.

"Candy works after all!" one TAP detailer allegedly wrote after giving out a bag of sweets with a sales pitch. But candy may have been the least of the inducements TAP used to win favor with doctors. Sweeter incentives were hidden in the complicated pricing formula through which some doctors bilked Medicare.

TAP was able to manipulate pricing laws by offering Lupron to doctors at a reduced rate, or even free, knowing the doctors would bill Medicare and other insurers for the full amount. The practice, referred to as "marketing the spread," was used with both Lupron and Zoladex, according to a whistleblower who filed suit against TAP and AstraZeneca, manufacturer of Zoladex.

To gather evidence, prosecutors painstakingly searched through years of billing by individual doctors. "You could see doctors literally switching the cancer medication that a patient would be on based not on the best treatment for the patient, but based on the spread for the doctor on that drug," says Suzanne E. Durrell, former head of the civil division in the U.S. Attorney's Office in Boston, who supervised the case.

To date, four doctors from New England accused of marketing the spread have pleaded guilty to healthcare fraud. One from Plymouth, who charged some \$38,000 for drugs he got for free, faces up to 10 years in prison.

But when 10 TAP employees were acquitted of criminal charges, the outcome shocked many observers. In that case, prosecutors argued that some of the "educational grants" like the one offered to Tufts's Gerstein were used to support cocktail party tabs and pay for golf outings. Each year, the company allegedly would pay \$5,000 apiece for urologists to "consult" in locales such as Aspen. Yet the drug companies were acquitted. In interviews after the case, the jury foreman said the government had failed to establish that the employees were intentionally breaking the law by offering such incentives. Put another way, these marketing practices are so common in the pharmaceutical industry that the employees didn't know they were illegal.

The acquittals brought to an end a remarkable streak by the U.S. Attorney's Office in Boston, which, along with its counterpart in Philadelphia, has prosecuted the most national pharmaceutical-fraud cases. In 2003, Bayer agreed in a federal court in Boston to pay \$257 million to settle charges that it was overbilling Medicaid for its antibiotic Cipro and the blood-pressure drug Adalat CC. That same year, GlaxoSmithKline paid nearly \$88 million to settle similar claims here involving the antidepressant Paxil and the decongestant spray Flonase.

The state Attorney General's Office has also prosecuted companies for defrauding Medicaid. Last year, it helped bring a landmark federal-state case against Pfizer, which paid \$430 million to settle claims that its subsidiary had defrauded buyers of Neurontin by marketing the antiseizure drug for "off-label" uses not approved by the FDA -- a particularly disturbing trend, given the heightened concern over drug safety.

Over an eight-year period, off-label uses of Neurontin grew from 15 percent to 94 percent of the total number of prescriptions. To encourage doctors to prescribe the drug for illnesses such as bipolar disorder, attention-deficit disorder, and migraines, detailers allegedly offered free tickets to the Olympics and "educational" trips to Maui and Palm Beach. (In its settlement, Pfizer denied engaging in any illegal marketing.)

Drug companies insist that cases such as these are rare. But Justice Department officials say some 100 investigations are ongoing, involving hundreds of different drugs.

To the drug companies, detailers and other salespeople play a valuable role. After all, the companies argue, how else would busy doctors find out about the latest advancements? "Many sales representatives are nurses or pharmacists by background," says Jeff Trewhitt, spokesman for the Pharmaceutical Research and Manufacturers of America, or PhRMA. "So they are well-trained technically to talk to doctors about when to use medicines properly." It's up to doctors, Trewhitt says, to set limits on their exposure to sales reps and to assess the information they receive.

Federal law prohibits doctors from taking kickbacks to prescribe a given drug, but many of the inducements fall into a gray area -- companies funding clinical research, for instance, or hiring doctors for lucrative speaking tours. "This is not overt fraud, but it's pretty awful stuff," says Dr. Jerome Kassirer, former editor of the *New England Journal of Medicine* and author of *On the Take: How Medicine's Complicity with Big Business Can Endanger Your Health*.

Kassirer cites studies showing that physicians who accept money from drug companies are much more likely to prescribe the companies' products. One such study found that physicians who attended meetings sponsored by a drug manufacturer at a luxury resort were two to three times more likely to prescribe that manufacturer's product. Another study found that doctors who requested that particular drugs be added to their hospitals' lists of approved drugs were nine to 20 times more likely to have accepted free meals, money to speak at symposia, or research support from the company that manufactured those drugs. A third study found that 61 percent of medical residents said they weren't swayed by company promotions -- yet only 16 percent believed that other physicians weren't.

"There's ample evidence that people are influenced by money," Kassirer says. "For heaven's sake, [drug companies] wouldn't be spending 16, 17, 18 billion dollars if they didn't think it would work."

Compared with those figures, multimillion-dollar settlements for drug fraud seem small. But they have been having an effect. Many of the court settlements, including those involving TAP and Pfizer, have included "corporate integrity agreements" to monitor gift-giving and price-setting.

In response to criticisms, PhRMA has also issued ethics guidelines. According to these guidelines, sales reps should not offer entertainment while making pitches, and the value of gifts should be limited to \$100. Meals, meanwhile, are supposed to be "modest," with doctors prohibited from bringing along their spouses. One of the first companies to adopt the changes was TAP. "We expect our employees to do what's right, not just what's required by law," the company said in a statement after its latest settlement.

Critics like Kassirer doubt that much has really changed. If the system really is going to improve, he says, doctors have to change along with the drug companies. "Reps are honest people who are just trying to make a decent living," writes one former

pharmaceutical salesperson on an online bulletin board. "The problem is the greed of the doctors. There were doctors in my territory who would not even speak to me unless I bought them lunch. [Others] told me depending on the model of Palm Pilot I bought them that they would give me a certain number of [prescriptions]."

Brigham and Women's Avorn suggests that doctors borrow a page from, of all sources, the pharmaceutical firms. Calling his approach "academic detailing," he has his staff sponsor free lunches for doctors where they speak about drug benefits and risks. Similar education programs at the hospital have prompted Brigham doctors to prescribe far less Vioxx and Celebrex than their counterparts at other hospitals. Avorn has been asked to help design programs for the entire Partners HealthCare system, which includes Mass General, Faulkner, and other area hospitals.

Doctors "need to be more critical of the claims of these sales reps and more skeptical of the demands that patients make when they come in waving a magazine ad," Avorn says. But patients have a role, too.

"Consumers have got to be more savvy and skeptical about ads for drugs they are taking," says Sugerman-Brozan. "No one gets off the hook on this."