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PHARMACEUTICAL STRESS FROM FRAUD AND DECEIT

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This is the third in a series of Newsletters exposing how large drug companies have wreaked havoc in their persistent pursuit of even higher revenues that have made them the most profitable U.S. industry. Constantly rising drug prices are the main reason for skyrocketing health costs and insurance premiums. As a consequence, many, especially senior citizens, have been forced to choose between essential medications and food.

Schering-Plough hiked the price for its top-selling allergy pill Claritin thirteen times during the five years before its patent expired, resulting in an increase of over 50 percent — more than four times the rise in rate of general inflation. To keep from losing its $2 billion/year cash cow, the company began a promotional blitz for Clarinex during the months prior to Claritin becoming generic and available without a prescription. Clarinex was allegedly so superior to Claritin that it was touted as the official allergy medication of major league baseball.

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Doctors received inducements and discount coupons for their patients to switch to Clarinex. In point of fact, there was actually very little if any difference between the two, since Claritin is actually converted into Clarinex in the body. Both drugs claimed not to cause the drowsiness that was commonly seen with most of the other antihistamines available at the time.

Claritin sales really rocketed when Hismanal and Seldane, the first two approved non sedating allergy medications, had to be withdrawn because of significant drug interactions, serious cardiovascular side effects and deaths. However, the scientific studies the company had submitted to the FDA for Claritin approval used a 10-mg. dose that was only 10 percent better than a placebo. Some advisory committee members voted to withhold approval, since it was common knowledge that European patients often required three or four 10-mg. tablets to get relief, and that this amount frequently made them drowsy. However, legally, it was only necessary to show Claritin was better than a placebo. How much better was not specified. Although the company was also obviously aware that the 10-mg. pills didn't work very well, they believed that their aggressive non-sedating marketing campaign would take care of this minor glitch, and they were absolutely right.

Once Claritin went OTC and generic and the price dropped 75 percent, it was no longer very profitable, and the marketing campaign shifted remarkably. It now proclaimed that Claritin was really not very effective for treating allergies after all. Instead of taking that ineffective old drug, you really needed Clarinex, the new super medication to prevent and relieve symptoms. And since the Clarinex patent does not expire until 2020, there would be no generic U.S. competition for fifteen years, allowing the company to continue to charge top dollar. The fine print in Clarinex ads has plenty of information about adverse reactions, but nothing about the drug's efficacy. (The combined clinical trial results submitted for Clarinex approval showed only an 8 percent improvement over placebos.) The European Agency for the Evaluation of Medicinal Products subsequently reviewed all of the studies conducted here and abroad on both drugs and concluded that Clarinex is "probably not superior" to Claritin. The Agency is also investigating concerns about a possible link with birth defects when these drugs are given during early pregnancy. **And being "Claritin clear" might not necessarily cost less, since around $30 for 30 pills might be more than the Clarinex copay for insurance plans. Either way, patients receive little benefit and the drug companies continue to profit.**

AstraZeneca (AZ) did the same thing when their Prilosec patent was due to run out. A Massachusetts class action suit alleges that the company sought to preserve their market share and profits by initiating a massive and misleading advertising and promotional campaign to deceive consumers into purchasing Nexium, a nearly identical new drug. According to one plaintiff, "AstraZeneca's Nexium promotional campaign has resulted in billions of dollars of unnecessary drug expenditures at a time when rising drug prices have created a health care crisis in this country. As a result, hundreds of thousands of patients take Nexium when they don't need to or when more affordable substitutes are readily available." Another critic complained,

"The Nexium campaign is a perfect example of a 'me-too' drug being falsely marketed as a medical improvement. Adding yellow stripes to the Purple Pill only improves AstraZeneca's bottom line, not consumers' health."

According to a *Wall Street Journal* article, "As part of its strategy to switch patients from Prilosec to nearly identical Nexium, **most of AZ's clinical studies compared 40mg of Nexium to 20 mg of Prilosec**." John Abramson, M.D., author of *Overdosed America: The Broken Promise of American Medicine*, complained that the company "refused to release detailed descriptions of **two studies that showed even the higher dose of Nexium to be no more effective than Prilosec** . . . . In the case of Nexium, doctors and patients have been misled into believing that Nexium, which costs up to 7 times as much, is superior to over-the-counter Prilosec."

There are numerous examples of similar chicanery, such as bribing generic manufacturers to delay bringing a competitive product to market. Bristol-Myers Squibb stock fell 22% in 2006 when a generic Apotex version was approved for its blockbuster Plavix, whose $5.2 billion/year in sales was second only to Lipitor. They offered to pay Apotex $400 million to delay marketing any Plavix generic until 2011, 6 months before their Plavix patent expired. This arrangement fell through after ten lawsuits by health plans, unions and other businesses were immediately filed alleging that the deal violated antitrust laws. The Department of Justice subsequently launched a criminal investigation to probe the possibility of Federal antitrust violations.

Illegal Pricing, Kickbacks, False Advertising, And Whistleblowers

A few weeks ago, Merck agreed to pay over $650 million to settle several lawsuits and probes related to illegal pricing and kickback schemes, They also signed a Corporate Integrity Agreement, which requires appointing a compliance officer or committee, developing written standards and policies, implementing a comprehensive employee training program, and being subjected to intense monitoring and scrutiny over the next five years. Federal law requires pharmaceutical manufacturers to offer Medicaid the lowest price given to any other customer. The only exceptions would be products discounted at 90 percent or more to charitable organizations that serve the needy. The litigation involved Pepcid, for heartburn, Mevacor and Zocor statins, and Vioxx, its popular anti-inflammatory drug. But Merck also sold them to hospitals at a 90 percent discount in exchange for their promise to use certain amounts of each drug rather than rival medications. They also made huge payments to doctors to prescribe Merck products that were disguised as for "training," "consultation," or "market research". These practices stopped once Pepcid, Mevacor and Zocor became generic because they were no longer profitable. Vioxx was withdrawn in 2004 because of a higher incidence of heart attack

and strokes, that the company should have been aware of but may have concealed. **Four months ago, Merck announced it would pay $4.85 billion to end thousands of Vioxx lawsuits in what appears to be the largest drug settlement ever.**

Several other drug companies have been found guilty of similar fraudulent activities. GlaxoSmithKline **knew as early as 1989 that there was an 8-fold increased risk of suicide for patients taking Paxil but did not acknowledge this until 2006.** It also concealed Paxil's lack of efficacy in pediatric trials, which led New York State's Attorney General to sue them for fraudulent marketing. The company had previously agreed to pay $150 million to settle fraud allegations over inflating the price of their anti-nausea drug Zorfran when billing Medicare and Medicaid. In May 2004, Pfizer admitted criminal guilt in marketing Neurontin, and paid a $430 million settlement. **Lilly is currently considering paying $1 billion for false marketing** and encouraging off-label use for Zyprexa, which was approved only for adults with schizophrenia and later the manic phase of bipolar disease. It has been linked to increased rates of suicide, diabetes and marked weight gain, especially in children, for whom it is not approved. As emphasized in previous Newsletters, other antipsychotic drugs not indicated for children have also been responsible for deaths and other disastrous consequences, particularly when included in a cocktail that often combines three or more. **The Justice Department recently said that over 500 drugs are being reviewed for illegal pricing and marketing practices.**

In addition to drugs, medical device manufacturers are also being sued for widespread kickbacks to doctors, hospitals and groups in return for exclusive or preferential use of their products. Medtronic agreed to a $40 million settlement last year for paying illegal kickbacks to doctors for using its spinal devices in back surgery. According to a whistleblower suit from a former employee, **a Washington surgeon was paid $400,000 a year for a consulting contract that required him to work only eight days**. Another Virginia doctor received almost $700,000 in consulting fees for the first nine months of 2005. **Internal documents revealed that the company spent at least $50 million in similar kickbacks from 2001 to 2005. However, this is a mere drop in the bucket since Medtronic's annual sales are over $10 billion for medical devices.**

Five months ago, four makers of orthopedic devices agreed to pay $311 million to settle criminal and civil probes into kickbacks. A fifth company voluntarily cooperated with the Justice Department investigation in exchange for not being prosecuted. These companies supply 95 percent of the hips and knees used in 700,000 replacement surgeries each year. **The kickbacks, which amounted to more than $200 million last year,**

were paid directly to surgeons and hospitals to use their products. One company alone reported 21 instances of having made payments of over $1 million to various "consultants". The largest was $8.67 million to Massachusetts General Hospital Corp. **The chairman of the Department of Orthopedic Surgery at Brigham and Women's hospital in Boston received $6.75 million.** The president of the Institute for Bone and Joint Disorders in Phoenix was paid well over $3 million, as was another orthopedic surgeon at the Midwest Orthopedic Research Foundation in Minneapolis. Over $2.4 million went to Alabama Medical Consultants Inc. and several other surgeons also received more than $2 million. The chairman of the Department of Orthopedic Surgery at Hackensack University Medical Center, who is president of the American Knee Society, was paid $1,043,028 and the director of the Hartzsman Total Joint Replacement Service in Paramus took in close to $1 million. It was not only surgeons and hospitals that were the recipients of this largesse. The University of Wisconsin Board of Regents received around $250,000. one can only wonder what consultant services they provided, or what they may have agreed to in return.

Much of this is coming to light because of increasing lawsuits and document supplied to the government by whistleblower informants. The term whistleblower derives from the practice of English Bobbies who would blow their whistle when they noticed the commission of a crime to alert both law enforcement officers and the general public of danger. A former Merck district manager will receive $68.2 million, and Dr. William LaCorte, a Louisiana specialist in geriatric and internal medicine, will get $27 million of the Merck $4.85 billion settlement, to satisfy their lawsuits. LaCorte sued Merck in 1999 when he found that hospitals were substituting Pepcid for the inexpensive antacids he had ordered. At the time, Pepcid was a prescription only drug and several patients, including an uncle, had mental side effects, including confusion and agitation. He found that the hospitals were being charged 10 cents/pill so that Pepcid became 85% of antacid prescriptions with the hope that patients would continue taking it as outpatients. At the same time, Medicaid was billed $1.65 per pill and the outpatient price was over $2.00. LaCorte said he feels whistleblower suits should be a last resort and tried for years to stop the Pepcid practice before going to court. He made records of prescription changes, and whether patients were having mental problems that ended when they were taken off Pepcid. He explained that Pepcid is excreted via the kidneys and because kidney function declines with age and Pepcid is fat-soluble, it accumulates in the brain. LaCorte has been involved in prior whistleblower or *qui tam* suits involving other drug companies. *Qui tam* is a provision in the U.S. False Claims Act that allows a private individual or relator who is aware of fraud against the government to file a suit on its behalf. It is an abbreviation of the Latin phrase "*qui tam pro domino rege quam pro se ipso in hoc parte sequitur*", meaning "he who sues

for the king as well as for himself." The relator need not have been personally harmed and the provision provides incentives for such suits by giving them 15% to 30% of the settlement and reimbursement for legal fees. After taxes and legal fees, LaCorte will net $10 million to $15 million.

The most famous drug company whistleblower is probably Peter Rost, a 48 year-old-physician who conjured up promotional plans for Wyeth and Pharmacia, where he was Vice President of Marketing. After Pfizer bought Pharmacia in April 2003, Dr. Rost retained his position, but two months later, he filed a suit alleging that Pharmacia had offered doctors inducements to use its human growth hormone, Genotropin, as an anti-aging drug for adults and to treat short stature in children. Genotropin was also widely used to improve athletic performance in a $2 billion/year industry that allegedly included major sports figures like Marion Jones, Lance Armstrong, Barry Bonds, Andy Petite and Roger Clemens, who is currently being investigated by Congress. Rost was concerned since these were unapproved off label uses and he had tried unsuccessfully to get Pharmacia and Pfizer to inform the FDA about these illegal marketing tactics. He cited some 200 instances from Indiana's Medicaid dispensing and diagnosis coding database to support his claims. Pfizer has already paid $35 million in fines for Genotropin off label marketing and could face additional civil penalties of between $5,000 and $10,000 for each false claim. Extrapolating from the 200 cases in Indiana, this could result in $50 million to $100 million in penalties. That's before treble damages based on sales to the government for off-label indications, which could add up tens of millions of dollars more, depending upon whether both off-label and kickback claims are proven. Since the law provides that whistle-blowers can receive part of the money the government recovers in a lawsuit that is begun as a result of information they have provided, Rost could reap enormous rewards.

Starting in August 2004, he repeatedly criticized Pfizer for its efforts to block Americans from saving money by importing prescription drugs from other countries. He wrote articles for the *New York Times* and other publications and appeared in TV interviews complaining that U.S. drug prices were too high. In testimony before a Congressional Committee, he urged that importing brand name medications from Canada should be allowed. In a June 2005 *60 Minutes* interview, he explained that **American taxpayers are being charged up to 10 times higher prices for the exact same drugs being manufactured in the exact same plants, that are being sold at much lower prices in every other country in the world.** He completely debunked the allegations that drug importation would pose safety hazards made by drug companies, organizations they control, the FDA, and the U.S. Surgeon General. He said that the reason for our prescription drug crisis is "drug pricing is not a free market in the United

States, the way it is with most other industries. Brand-name drugs have patents, which means no other drug company can make the same drug until the patent runs out in 20 years." Europe's tightly regulated system of importing drugs from other countries has operated smoothly for more than two decades with no evidence of injury to patients. When Pfizer's vice president of global security was pressed by *60 Minutes* if anyone had ever been harmed by drug imports, he admitted "I don't know that anyone has . . but we're making the safety issue before that happens."

Rost maintained there was no safety issue in the coordinated campaign to ban drug imports. It was motivated entirely by the greed of drug companies that are protected and abetted by government policies that hurt consumers, especially the poor. As he noted, "We're the wealthiest nation on earth, yet we have between 49 and 67 million Americans without any kind of insurance for drugs . . . and they pay full price, cash, and they can't always afford drugs." Pfizer claimed that Rost lacked the credentials to say anything about importing drugs from other countries and sent a letter to the Senate committee saying, "We have no basis to support Dr. Rost's purported expertise in this area." Pfizer also sent *60 Minutes* a letter saying: "Dr. Rost has no substantive grasp of how importation threatens the safety of the U.S. drug supply." After his Congressional testimony, Rost said he was "grilled" by Pfizer executives about details of all conversations he may have had with any member of Congress on or off the record. He was quoted as saying "The questioning was intense. I am still upset by it." In October 2004, seven Congressmen sent a letter to Pfizer CEO Henry McKinnel asking him to stop intimidating Rost, stating **"it is the height of hypocrisy for a company that encourages its employees to engage in political matters to retaliate against an employee who is expressing his own policy views on his own time."**

It would have been difficult for Pfizer to fire Rost because of legislation that protects most whistleblowers. However, following the *60 Minutes* interview, he was exiled internally by Pfizer and removed from all responsibilities and decision making. He found that his corporate cell phone and e-mail accounts had been turned off and he had nothing to do and nobody to report to, despite the fact that he was being paid about $600,000/year in salary, bonus and other compensation. His Genotropin whistleblower suit was unsealed in November 2005 and a few weeks later he was terminated. Pfizer explained that this was because Rost had failed to receive a vice president-level position with Pfizer after the company acquired Pharmacia and he had been offered a severance package "consistent with that of employees of Pharmacia who did not remain with Pfizer after Pfizer's acquisition of Pharmacia in 2003." In addition, lawyers for Rost had asked the company in July 2004 for a severance package of $12.5 million and Pfizer claimed that

his public criticism began only after the company rejected this. According to Rost, his lawyers had proposed the severance package only in response to Pfizer's request that they specify something, adding, "I have never asked for any money" to drop the suit.

Dr. Rost has filed a wrongful termination suit accusing Pfizer of retaliating against him by denying him positions for which he was qualified. The suit alleges that Pfizer violated the New Jersey Conscientious Employee Protection Act and the whistle blowing prohibition of the federal False Claims Act and seeks unspecified compensatory and punitive monetary damages. Rost's lawyer pointed out that in addition to being ostracized, "They won't give him his job back, and he wants to be compensated. He'll never work in the pharmaceutical industry again. He's been looking for a job. Nobody even wants to interview him." Since his December 2005 termination, Rost has been blogging from the basement of his suburban New Jersey home and has become a litigation consultant and marketing expert. According to *Fortune* "Peter Rost has become the drug industry's most annoying - and effective - online scourge." Rost's *THE WHISTLEBLOWER, Confessions of a Healthcare Hitman* published in 2006 details his experience working for Pharmacia and Pfizer, such as receiving a phone call from someone on behalf of the CEO asking him to pay $2,000 for a fund raising dinner for President Bush's reelection. Many other employees were co-opted into supporting an administration they couldn't stand. What was at stake was a financial windfall for drug companies of $2 billion/year as a result of transferring millions of poor people into the new Medicare Part D program. Unlike Medicaid, where the lowest price must be offered, or insurance companies that are able negotiate prices, Medicare Part D prevented the federal government from any attempt to set prices, so that drug costs would now be much higher than Medicaid. Democrats vigorously opposed this provision and promised to change it. Nancy Pelosi, current Speaker of the House, described it as a product of "corruption, putting pharmaceutical companies and HMOs first at the expense of America's seniors." Few elections were as critical to the drug industry as this one, and as a *Wall Street Journal* article noted, "Assailed by Democrats, drug companies are pouring millions of dollars into close races, giving some Republicans a financial edge." The Medicare Part D program, which began Jan. 1, 2006, was initially such a mess, that **at least two dozen states had to take emergency action to help low-income people who could not get their medications under the program and some states were spending millions of dollars a day to provide such assistance.**

Peter Rost was not the only whistleblower thorn in Pfizer's side. Jesse Polansky claimed he was fired after complaining about certain Lipitor promotional practices he considered to be improper and illegal. Polansky

was Director of Outcomes Management Strategies from 2001 to 2003, and his duties included reviewing marketing materials for Lipitor. His 2004 lawsuit claimed that Pfizer had developed an elaborate and massive educational campaign that "led thousands of physicians to prescribe Lipitor for millions of patients who did not need medication" and could be harmed by overly aggressive treatment. Physicians are free to prescribe an approved drug for any disorder in which they feel it might provide benefits and can talk or write about their opinions and experience. However, drug manufacturers are strictly forbidden to promote any such off-label uses and can face stiff penalties for violating this. Independent educational programs can also discuss uses that aren't FDA approved. These are frequently funded by "unrestricted educational grants" that allow hospitals and organizations to independently select topics they consider important and provide continuing medical educational credits that doctors may need to renew their licenses. According to the lawsuit, the Lipitor "unrestricted educational grants" were for programs that were hardly "independent", since they were organized and run by companies paid by Pfizer to promote Lipitor for unauthorized uses. These programs were then skillfully integrated into their marketing campaign, as evidenced by an internal document entitled "Medical Education Platform Supports the New Positioning". Pfizer wanted to extend Lipitor use through these educational programs that deliberately encouraged prescribing the drug to patients with kidney disease and disorders where benefits had not been demonstrated. The list of other alleged violations included hosting continuing medical education events for physicians at expensive restaurants that provided gourmet dinners and othe deluxe amenities but were also essentially sales pitches for non approved uses of Lipitor. Polansky is currently employed as the senior medical officer for the government in a unit that investigates Medicare fraud and abuse.

Pfizer's utilization of such "educational" programs to illegally promote unapproved uses of drugs is not uncommon. Many other companies send paid lackeys and shills out onto the academic lecture circuit to ''educate" doctors about a drug's unapproved uses and a Congressional Committee convened a hearing about this practice last summer. Two months ago, the *New York Times* published a piece by Dr. Daniel Carlat, who recounted his experiences as a Wyeth-paid lecturer for the anti-depressant Effexor. According to the article, the Effexor information Wyeth instructed him to convey during visits to physician meetings and offices was often incomplete, downplayed risks, and was contrived to favor Effexor over other drugs. Carlat was uncomfortable with the Wyeth script but when he altered it to include more complete data on some of the drug’s risks, he was visited by a district manager, who expressed concern that he was not exhibiting enough "enthusiasm'” in his talks. He quit lecturing shortly thereafter.

Nor was Rost the only person to be the victim of fierce retaliation and intimidation for identifying fraudulent and possibly harmful marketing practices. Dr. John Buse of the University of North Carolina had sent a letter to the FDA in 1999 warning that the toxicity and safety of Avandia, a GlaxoSmithKline (GSK) drug just approved for treatment of type 2 diabetes, were "not yet known". He also indicated there was a possible increased cardiovascular risk during presentations at the Endocrine Society and American Diabetes Association meetings. Later that year, GSK emails described Buse as an "Avandia renegade" who had "repeatedly and intentionally misrepresented Avandia data from the speaker's dais" and who should be sent "a firm letter that would warn him about doing this again . . . with the punishment being that we will complain up his academic line and to the CME-granting bodies that accredit his activities." Buse's department chair was contacted, which prompted Buse to send a letter to GSK three days later stating that he wished to "set the record straight" and to "please call off the dogs. I cannot remain civilized much longer under this kind of heat." Last May, an analysis of Avandia studies published in the *New England Journal of Medicine* confirmed Buse's suspicions by reporting a 43 percent increase in heart attacks and an astounding 64 percent increase in risk of death from heart disease. Other reports indicated that Avandia also increased risk of congestive failure and fractures due to osteoporosis. The FDA issued a safety alert and added a black box warning for Avandia and other drugs in its class being taken by 3.5 million Americans. The stronger Canadian Avandia label warns that it is not to be used as the sole medication for diabetes unless the patient cannot take another drug to lower blood sugar and that any patient with heart failure should not use the drug.

Since it seemed clear that GSK was well aware of these problems years ago but did not report them, a hearing was held last June by the Senate Committee on Finance to look into this. Their report, which was released in November, stated that **if Glaxo had considered the safety issue risk raised by Dr. Buse in 1999 more seriously, "instead of trying to smother an independent medical opinion, some 83,000 Avandia heart attacks might have been avoided."** During his testimony, Dr. Buse, an expert in diabetes with extensive research experience in the Avandia class of drugs, described name-calling and what he said was the veiled threat of a lawsuit by a high-ranking drug company executive after he had criticized Avandia at a medical meeting, stating "I was certainly intimidated by them... It makes me embarrassed to have caved in several years ago." The "heat" he referred to in his previous e-mail were repeated calls to his department chairman with threats to cut off funding for CME programs to the University where he was a professor. "This resulted in a short and ugly set of interchanges that occurred over a period of about a week, ending in my having to sign some legal document in which I agreed

not to discuss this issue further in public." The Senate Committee also identified two high ranking GSK executives that internal documents confirmed had waged a vicious and prolonged campaign to intimidate Buse, including characterizing him as a "liar", as being "for sale" and responsible for a $4-billion plunge in the company's stock value. One of these executives, who now heads the global health program at the Bill & Melinda Gates Foundation, was recently named as a board member of the FDA's new Reagan-Udall Foundation, which is designed to foster drug research. A national survey of department chairs at medical schools and teaching hospitals found that over half have relationships with industry, including receiving financial support, research equipment and consulting fees.

Congress is currently investigating what Sanofi-Aventis knew about the problems with clinical trials for its Ketek antibiotic. Last February, the FDA withdrew approval for two of three uses for the drug, and issued a Black Box warning for its use in treating community-acquired pneumonia because of serious adverse side effects, including 12 deaths. In previous testimony before the same Committee that focused on the FDA's failure to ensure safe drugs, a researcher testified that the company knew of fraudulent clinical trial data involving Ketek but chose to ignore it. An FDA criminal investigator also testified that Sanofi-Aventis "should have known" about the false data in view of the forged signatures and crossed-out results that were submitted. Congress is also investigating the recently released Vytorin and Zetia data that failed to find any statistical advantage over the much cheaper generic Zocor in reducing arterial plaque. In fact, there was evidence that plaque was increased. The results were delayed for nearly two years while the primary endpoint was changed by Merck and Schering-Plough without consulting the lead investigator. During this period, Vytorin and Zetia (which, along with Zocor comprise the Vytorin combo therapy) were heavily promoted, even though executives knew Vytorin provided no advantages. Postings on web sites going back at least a year indicated that even sales representatives knew that "the study is a bust. Adding Zetia to already maxed out statin is useless" and "Word of mouth from investigators involved in running the trial is that it is a negative study." Concerns that top executives from both companies sold large amounts of stock last year have also sparked investigations by Congress and two State Attorneys General. Continuing to promote a worthless drug despite negative results to preserve income from sales is bad enough, but profiting by unloading stock or selling short in anticipation of a fall in price is even worse, and could lead to fines and imprisonment for insider trading.

Generics, Pfizer, Dr. Robert Jarvik, Lipitor And Congressional Investigations

Lipitor is the most successful prescription drug in the world, with sales last year in excess of over $13.6 billion. About 20 million Americans take

statins, three of which (Zocor, Pravachol and Mevacor) are now generic. A generic is a chemical twin of a brand-name drug whose patent has expired. To get FDA approval, a generic substitution must contain the same active ingredient as the brand-name version and prove that it is "bioequivalent" by demonstrating that it enters and leaves the bloodstream as rapidly and completely as the original. Consumers save as much as $10 billion/year by buying generics but brand name drug companies try to discourage this by insinuating that generics are of poorer quality in ways skillfully designed to avoid false advertising suits. They also use deceptive promotional techniques to preserve brand loyalty, as revealed by this month's critical analysis of Lipitor advertising by *Consumer Reports*, which takes no drug or other advertising. It noted that Pfizer's Lipitor patent would expire in 2010, opening the way for much less costly generic equivalents. One TV ad asks, "Did you know there's no generic form of Lipitor?" as part of a campaign that features Robert Jarvik, M.D. as an authoritative cardiologist. Congress is currently investigating Pfizer and Jarvik for "false and misleading statements and the use of celebrity endorsements of prescription medications in direct-to-consumer advertising." It recently released a copy of Jarvik's contract, revealing that Pfizer agreed to pay him a minimum of $1,350,000 over two years for serving as celebrity pitchman for Lipitor. The two-year deal began in March 2006 with the a fake TV commercial in which Dr. Jarvik was depicted as sculling at Lake Crescent near Port Angeles, Washington. "I'm glad I take Lipitor, as a doctor and as a dad." he says, before a final shot shows him rowing in a very vigorous muscular fashion across a serene lake.

The problem is that he was not taking Lipitor at the time; he is not licensed to practice medicine, and didn't know one end of this particular boat from the other. As one heart transplant surgeon well acquainted with Jarvik told the *New York Times*, "He's about as much an outdoorsman as Woody Allen. He can't row." As a result, Pfizer had hired Dennis Williams a double with an impressive late middle-age physique who was also an experienced rower. In this Jarvik was obviously not far from shore at the beginning of the shoot. Many viewers were imprssed with his stunt double's skill in turning the blades perfectly to achieve minimum drag between sculling strokes. The frames that actually included Dr. Jarvik were shot in a rowing apparatus on a platform

Much of the $258 million from January 2006 to September 2007 spent for Lipitor advertising was for the Jarvik campaign and there is little doubt that it was money well spent. Thousands of patients taking other brand name statins asked to be switched to Lipitor. One study reported that one out of five patients taking a much less expensive generic statin said they would ask their doctor about taking Lipitor.

Jarvik tells viewers that Lipitor lowers "bad" cholesterol between 39% and 60%, with a "36% reduction in heart attacks.*" The asterisk indicates that this means 2 heart attacks out of 100 for those on Lipitor, compared to 3 heart attacks for controls taking a placebo. In addition, this slight difference is only for patients with a history of heart attack or who are at very high risk and based on taking Lipitor daily for 14 years. Critics ask if a "36% reduction in the risk of heart attack" is as meaningful to consumers as a "1% lower chance" if you take the drug for over a decade? Spending for direct to consumer advertising is so cost effective that it rose 300 percent from 1997 to 2007, when it approached $5 billion. It is not allowed in Europe, and although a two year moratorium on new drug advertising and other attempts to curtail this practice here have been proposed, nothing is likely to happen because of Big Pharma's clout over regulatory agencies and the media.

Pfizer is also facing several class action suits for false advertising since Lipitor has not been shown to provide benefits for senior citizens or women of any age being treated solely for an elevated cholesterol or LDL. During the past month, a cover story on Lipitor in *Businesssweek,* a feature article in *Fortune*, and columnists in the *Wall Street Journal*, *New York Times* and other publications have correctly questioned the alleged benefits of lowering cholesterol with Lipitor. As Tara Parker Pope wrote in the *Times,* "For healthy men, for women with or without heart disease, and for people over 70, there is little evidence, if any, that taking a statin will make a meaningful difference in how long they live." Articles have also discussed the serious side effects of Lipitor that have been concealed in what now appears to be incomplete labeling as well as deceptive advertising campaigns. A *WSJ* article quoted the vice chairman of medicine at New York Presbyterian Hospital as saying **"This drug makes women stupid."** She had seen two dozen middle aged women with no neurological or other abnormalities complaining of difficulty remembering things. All improved after stopping Lipitor or switching to another statin. All statins are carcinogenic in animals and other articles report that an increase in breast and other cancers is now starting to surface. In addition to peripheral neuropathy and severe muscle complaints despite normal blood tests, **Lipitor has now been linked to a possible increase in Lou Gehrig's and other neurodegenerative diseases.** — Stay tuned for much more on these and other Lipitor laments.

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PAUL J. ROSCH, M.D., F.A.C.P.
EDITOR-IN-CHIEF
www.stress.org
e-mail: stress124@optonline.net