DOWNLOAD PDF FALSE AND MISLEADING: THE MISREPRESENTATION OF CELEBREX AND VIOXX

Chapter 1 : Overdo$ed America : the broken promise of American medicine

I noticed an article about Celebrex and one about Vioxx, the latest drugs for arthritis pain. Each article presented the results of a study sponsored by the drug's manufacturer claiming that the drug was significantly safer than older anti-inflammatory medication, which was available in much less costly generic form.

Court papers filed in the U. District Court in New Jersey confirm the settlement. Pfizer was to go to trial in just under two weeks to defend the allegations. The class action lawsuit was filed on behalf of a group of investors who claim that they were misled by Pfizer regarding the popular arthritis drug. The Alaska Electrical Pension Fund invested in the company, but it now claims it was misled and is seeking to recoup its investment. Troubles began back in when Pfizer acquired Pharmacia Corporation, the manufacturer of Celebrex. By , shareholders had sued Pfizer for misrepresentation of Celebrex, accusing the company of representing the drug to be safer than was shown in clinical trial data. Years of on-again, off-again litigation ensued with Pfizer eventually asking the Supreme Court to review the case. The Supreme Court denied the petition and the case was sent back to the lower courts in Pfizer attempted to have the case dismissed in January , but the motion was denied and the trial was set for October. Attorneys for the plaintiffs are also seeking a contingency fee from the defendant for Celebrex is in the same drug class as the now withdrawn drug Vioxx, manufactured by Merck. Vioxx also faced a similar class action lawsuit from investors who also alleged wrongdoing regarding the misrepresentation of the safety of Vioxx. Merck agreed to a settlement of the lawsuit back in With the withdrawal of Vioxx from the market, Celebrex enjoyed a notable increase in sales. However, warnings have been raised that Celebrex may present the same risks for adverse events as its former rival Vioxx. Both drugs are known as Cox-2 inhibitors, which are classified as pain killers. Pfizer spokesman, Christoper Loder, confirmed in a statement that Pfizer had, in fact, reached a settlement with the plaintiffs. However, Pfizer does not admit to any wrongdoing in the presentation of Celebrex clinical trial data. No fees or costs until your case is settled or won. We focus on personal injury cases. Settled cases for over 60, clients. More certified personal injury specialists than any other Arizona law firm. Our mission is to treat every client with care and respect, protect their rights, and guide them in their pursuit of justice.

Chapter 2 : Marketing of Vioxx how Merck played game of Catch Up | Beasley Allen Law Firm

Vioxx, a drug in the same class as Celebrex, has been found to be associated with higher rates of heart problems and stroke. Its manufacturer, Merck & Co., pulled the pain killer off the market.

Summary The untold crisis in American medicine, with side effects that may be hazardous to your health. We all know that health care and prescription drug costs are skyrocketing, but few doubt the excellence of American medicine. You -- and your doctor -- will be stunned by his findings. For twenty years, Dr. Abramson cared for patients of all ages in a small town north of Boston. But increasingly his role as family doctor was undermined as pressure mounted to use the latest drugs and high-tech solutions for nearly every problem. Drawing on his background in statistics and health policy research, he began to investigate the radical changes that were quietly taking place in American medicine. At the heart of the crisis, he found, lies the changed purpose of medical knowledge -- from seeking to optimize health to searching for the greatest profits. The lack of transparency that has become normal in commercially sponsored medical research now taints the scientific evidence published in even our most prestigious medical journals. And unlike the recent scandals in other industries that robbed Americans of money and jobs, this one is undermining our health. The hormone replacement debacle, it turns out, is not an isolated case. The same kind of commercial distortion now pervades the information that doctors rely upon to guide the prevention and treatment of common health problems, from heart disease to stroke, osteoporosis, diabetes, and osteoarthritis. The good news, as Dr. Author Notes John Abbamson is currently on the clinical faculty of Harvard Medical School, where he teaches primary care. Falling prey to marketing campaigns, we demand unnecessary and expensive drugs and procedures, believing they constitute the best possible medical care. Similarly, notes Abramson, a former family practitioner who teaches at Harvard Medical School, we spend more on high-tech neonatology than other Western countries but have a higher infant-mortality rate because of inattention to low-tech prenatal care. Abramson deconstructs the scientific sleight of hand in presenting clinical trial results that leads to the routine prescription of pricey cholesterol-lowering drugs even when their effectiveness has not been proven; he examines what he calls "supply-sensitive medical services"-the near-automatic use of medical technologies, such as cardiac catheterization, less because they are needed than because they are available. Still, he makes a powerful and coherent case that American medicine has gone badly astray and needs a new paradigm-one untainted by profits. With a three-city author tour. It was the end of an exhausting but very satisfying day of doctoring indigenous people of all ages in a two-room school building temporarily transformed into clinic for this small medical mission. We were putting the medical equipment and records away, and I was thinking about how nice a cool shower was going to feel, when our interpreter approached me with a look of concern and asked if I would make a house call to a woman who was too sick to come to our makeshift clinic. As we approached, I could see her lying still in a hammock. Her husband was sitting nervously by her side and her four young children were darting playfully in and out of the cabin, pausing for just a moment to check on their sick mother. As I sat down next to her, I could tell from her detached, pained, and frightened look that she was seriously ill. Even the subtle facial expression she mustered to greet me seemed to cause her pain. I was introduced to the sick woman and her husband by our interpreter, and learned that she had had a spontaneous miscarriage severel days before. The pain in her belly and vomiting had been getting worse for the past two days. I asked if I could examine her. She responded with a minimal nod and looked over to her husband to make sure that he agreed. Her temperature was now degrees. Her abdomen was stiff and exquisitely tender to even the slightest touch. Most likely she had developed a uterine infection as a consequence of an incomplete miscarriage, and the infection had spread throughout her abdominal cavity, causing peritonitis. She needed to be hospitalized for intravenous antibiotics and fluids, and she needed dilatation and curettage of her uterus -- a D and C-to remove the infected tissue. Her husband and several other villagers listened attentively as I explained my diagnosis. But their expressions changed from hope to despair when I told them that she needed

to be treated in a hospital. I suggested that they take her there anyway and that someone would care for her. I asked how much it would cost for her to get hospital care. The two other Americans present and I glanced at one another and agreed, without a word being spoken, that we would get the money together. Fortunately, a boat soon came by, headed in the right direction, and off she went, accompanied by our capable interpreter, who could help her with travel and hospital arrangements. The woman returned to the village three days later, weak but much improved. Her look of fear was gone. Her husband and children stared in happy disbelief when they first saw her and realized she would recover. When I got back home, I went to my office the Sunday before resuming my normal schedule to go through the paperwork that had accumulated while I was away. I noticed an article about Celebrex and one about Vioxx, the latest drugs for arthritis pain. The accompanying editorial -- these are typically included in medical journals to provide expert perspective on the most noteworthy articles published in each issue -- reported with unusual candor especially since both authors had financial ties to at least one of the manufacturers of the new drugs that neither of the new anti-inflammatory drugs provided better relief of symptoms than the older alternatives. The editorial also explained that the highly touted safety benefits of the new drugs appeared minimal in people who were not at high risk of developing serious gastrointestinal side effects. So minimal, the editorial said, that such people would have to be treated for one full year with the new drugs instead of the older anti-inflammatory drugs to prevent just one serious but nonfatal stomach ulcer. Still moved by my experience in the Amazon, I wondered how many lives like that of the woman to whom I had made the house call might be saved for the cost of preventing a single nonfatal stomach ulcer by using Celebrex or Vioxx. I could feel myself change when I saw the figure "" on the display and realized the injustice of that equation. This incident sensitized me to the intense marketing of these two drugs. Advertisements for them suddenly popped up everywhere. At first the ads seemed inappropriate, but quickly they claimed their place as normal fixtures of the American cultural landscape. The implication of the ads was that the unspecified superiority of the new drugs allowed people to enjoy activities that they had previously been unable to enjoy because of arthritic pain-though no such superiority had been found in any of the major research. The marketing campaigns were certainly successful Reprinted by permission of HarperCollins Publishers, Inc. Available now wherever books are sold. Excerpted from Overdosed America:

Chapter 3 : Investment Firms Sue Merck Over Misleading Vioxx Claims - Law

Celebrex is in the same drug class as the now withdrawn drug Vioxx, manufactured by Merck. Vioxx also faced a similar class action lawsuit from investors who also alleged wrongdoing regarding the misrepresentation of the safety of Vioxx.

Editors carefully fact-check all Drugwatch content for accuracy and quality. Drugwatch has a stringent fact-checking process. It starts with our strict sourcing guidelines. We only gather information from credible sources. This includes peer-reviewed medical journals, reputable media outlets, government reports, court records and interviews with qualified experts. Bob Ernst, a marathon runner and fitness fanatic, started taking Vioxx rofecoxib in November of for pain in his hands. Less than eight months later, the year-old Texas man died in his sleep of a heart arrhythmia. Carol Ernst became the first of tens of thousands of consumers who sued Merck over allegations that the company had concealed information about the serious health risks of the popular arthritis drug â€" including the risk of fatal heart attacks and strokes â€" to protect sales. It works by selectively targeting a specific enzyme that causes inflammation and pain, but it leaves other enzymes that protect the stomach and intestinal lining untouched. Clues about troubling side effects emerged in a large clinical trial launched in that compared the gastrointestinal side effects of Vioxx with side effects of an older painkiller, naproxen. But during the study, 79 of the 4, patients taking Vioxx suffered serious heart problems or died â€" a number twice as high as in the naproxen group. Topol and other cardiologists at Cleveland Clinic published a report in the Journal of the American Medical Association JAMA alleging that Cox-2 inhibitors such as Vioxx appeared to increase the risk of cardiovascular events. Merck said the report was flawed and dismissed the call for a trial directed specifically at cardiovascular risks. Merck officials denied that claim but in changed their label to warn about higher risks of heart attack. The company finally decided to pull Vioxx from shelves in , after additional studies revealed an increased risk of strokes and heart attacks among patients taking the drug for 18 months or longer. Fact As many as 88, people suffered heart attacks after taking Vioxx, according to a study in the Lancet, and an estimated 38, died. While some of individuals had a prior history of heart problems, others did not. This was the first of several wins for Merck, which went on to successfully argue at least 10 more individual Vioxx lawsuits. Just in its first year, the court noticed depositions relating to witnesses and comprising over 35, pages of testimony. In total, the court conducted six Vioxx bellwether trials, with the first taking place in Houston, Texas. Only one of the trials resulted in a verdict for the plaintiff, while one resulted in a hung jury. Four resulted in verdicts in favor of Merck. During the same time period, approximately 13 additional Vioxx-related cases were tried before juries in the state courts of Texas, New Jersey, California, Alabama, Illinois and Florida. This trial ended in an immediate victory for Merck following a little more than a day of deliberations. To be eligible for inclusion in the MDL, patients had to prove they had taken the drug for a month 30 pills , even though it took 18 months for increased cardiovascular problems to appear. The misbranding charge resulted from Merck promoting Vioxx as a drug for treating rheumatoid arthritis prior to that use being approved by the FDA. This, they claimed, caused them to incur significant losses when the drug was pulled from the market. Vioxx continues to haunt the drug-manufacturing giant as Merck will still have to battle out a few remaining individual securities lawsuits from investors who previously opted out of the class-action lawsuit certified by the judge in Despite its decision to remove Vioxx from the health care market, Merck continues to deny any liability or wrongdoing for claims brought against it. Please seek the advice of a medical professional before making health care decisions.

Chapter 4 : rofecoxib (VIOXX)

Concerns about the sales of Celebrex and Vioxx also came up in connection with Dr. Max Hamburger, a rheumatologist in Melville, N.Y. Dr. Hamburger, who was also on Merck's "neutralize" list.

November 06, Several purported shareholder class action lawsuits have been filed against Merck and certain of its present and former executive officers during The complaint filed alleges that defendant violated sections 10 b and 20 a of the Securities Exchange Act of and Rule 10b-5 by issuing a series of material misrepresentations to the market during the Class Period. Moreover, during the Class Period, defendants failed to disclose material information concerning the degree of the serious adverse side-effects of Vioxx, including significantly increased risks of heart attacks in patients taking the drug. The Pennsylvania lawsuits were filed on behalf of shareholders who purchased, converted, exchanged or otherwise acquired the common stock of Merck between October 23, and September 30, The Pennsylvania and the New Jersey actions allege that defendants failed to disclose material information concerning the safety profile of its arthritis drug Vioxx, and that a growing body of evidence demonstrated that patients who used the drug for more than 18 months were exposed to an increased risk of heart attack. More specifically, the complaints allege that on September 30, , the Company announced that it was immediately withdrawing Vioxx from world markets after a data safety monitoring board, overseeing a long-term study of the drug, recommended that the study be halted because of an increased risk of serious cardiovascular events among members of the study group. According to the Notice of Voluntary Dismissal dated November 23, , the action entitled Arnoff, et al. Docket CV is the sub-master docket for the consolidated securities actions. The defendants responded by filing several motions to dismiss in August and December and one motion in August Chesler dismissing the complaint against the American Arbitration Insurers. District Court in Newark ruled that investor claims should be dismissed because they were time-barred under statutes of limitations. The lawsuit was dismissed with prejudice, meaning investors cannot file the suit again. Investors who had bought Merck stock between May 21, , and Oct. Merck withdrew Vioxx from the market on Sept. The earliest fraud complaint was filed in November , according to court records. In his opinion, the judge said that a Food and Drug Administration warning letter from Sept. Court of Appeals for the Third Circuit from the April 12, Order granting the motions to dismiss the complaint with prejudice. On October 27, , the Court entered the Mandate from the U. According to the Mandate, the judgment of the District Court entered April 12, , be and the same is hereby reversed and remanded. On July 7, , a Stipulation and Order was filed staying the proceedings in the Court pending the adjudication of the Supreme Court Appeal currently before the Supreme Court. According to a press release dated dated April 27, , Merck announced that it is disappointed with the U. The effect of the ruling is to return the case to federal district court in New Jersey for further proceedings. District Court for the District of New Jersey in , on the ground that the claims were time-barred under the statute of limitations. Merck, the second-biggest U. Investors also can pursue claims that Merck misled them about a study, known as Vigor, which reported that the medicine caused five times more heart attacks than another painkiller, naproxen, Chesler ruled. Merck said one explanation was that naproxen protected the heart. On October 5, , the Court ordered Merck to turn over purportedly privileged documents previously produced in connection with government investigations concerning VIOXX. On February 8, , the parties entered into a Stipulation of Settlement. This Settlement was preliminarily approved on February On June 28, the Court granted final approval of the Settlement and dismissed this case.

Chapter 5 : Merck used ghostwriters and selective data in Vioxx publications, JAMA says

Summary. Using the examples of Vioxx, Celebrex, cholesterol-lowering statin drugs, and anti-depressants, Overdosed America shows that at the heart of the current crisis in American medicine lies the commercialization of medical knowledge itself.

These so-called super aspirins, were seen by critics as over-priced painkillers that worked no better than older, safer, and far less expensive drugs. Supporters viewed them as safe and effective drugs that were easier on the stomach than other pain medications. Attractive actors and celebrities, like Olympic figure skating champion Dorothy Hammil, pitched the drug in carefully orchestrated commercials set to The Rascals hit Beautiful Morning. The ad-driven popularity of the drugs, and the enormous cash flow that it created, were more than adequate to stave off challenges from consumer groups, scientists, and even FDA whistleblowers who charged that all COX-2 inhibitors were dangerous in that they significantly increased the risk of heart attacks. Even proof of manipulation of clinical study data, withholding negative information, and a complete failure of the FDA drug monitoring system were not enough to bring down these drugs. The house of cards collapsed, however, when a study designed to gain FDA approval for even wider use of Vioxx ended abruptly in September when the cardiovascular risk posed by the drug could no longer be ignored. Vioxx was pulled from the market at that time and, despite a favorable vote by an advisory panel in February , has never returned. Bextra, which had other problems in addition to the heart-risk possibility, was also pulled from the market in Litigation that had begun while Vioxx and Bextra were on the market increased dramatically once they were pulled. Today, almost 12, individual personal injury and wrongful death cases are pending with respect to Vioxx and there are class-actions by private insurers and individual states to recover billions of dollars in drug-reimbursement costs from the manufacturers. Considering the one-time popularity of these drugs, the favorable FDA panel vote, and the fact that, with Vioxx and Bextra taken off the market, Celebrex was the only game in town, one would have expected sales of the only remaining COX-2 inhibitor to go through the roof. That did not happen, however. To the contrary, Celebrex sales plummeted. DTC advertising is now the most powerful tool in the pharmaceutical industrys arsenal in terms of generating revenue. This fact has prompted a growing concern among consumer advocates, scientists, and even legislators that the notion of marketing prescription drugs directly to the public is simply not a very good idea. Direct-to-consumer advertising was also brought up by Senator John Edwards during the vice-presidential debate as a severe problem in the medical field. For the past several years, there has been an ongoing debate over controversial methods being used by pharmaceutical manufacturers to market prescription drugs. Recent high profile drug withdrawals and potential scandals have only intensified that debate; and no element of marketing is more controversial than direct-to-consumer advertising DTCA. While some experts maintain that DTCA actually strengthens our health care system, others are equally certain that DTCA has caused many of the problems that plague the drug industry over-medicating, over-pricing, and exaggerated and often misleading advertising claims. Before DTCA, pharmaceutical advertisements appeared only in professional publications, promotional materials, and samples intended for physicians, pharmacists, and hospital administrators. Patients were never intended as the primary target for any form of prescription drug advertising. Thus, the commercial success or failure of a drug depended on its effectiveness and safety record not on slick marketing campaigns. Today, however, the rules of the game have changed dramatically. Stiff global competition, expiring patents, generic drugs, sky rocketing research and development costs, and substantial damage awards and settlements have made marketing more important than science when it comes to turning a profit. Moreover, a commercially successful blockbuster drug can mean billions of dollars in annual profits to a company. This has served as justification for bloated advertising budgets, withholding negative information, and ad campaigns that very often become deceptive and misleading. Today, drug advertising has become an industry unto itself and inadequately tested and hastily marketed drugs permeate the market and expose the public to great risk. How

did this all come about? The first advertising specifically intended to target the consumer appeared in the early s. From that time until the mids, the bulk of DTCA appeared in magazines and newspapers. In , however, the FDA issued a draft guidance finalized 1n that permitted the expansion of DTCA into electronic and broadcast mediums. Today, DTCA is regarded as a catchall phrase covering all information provided by drug companies directly or indirectly to consumers. This would include traditional print advertising newspapers and magazines , television, radio, and internet ads, and brochures, newsletters, and samples distributed by physicians and pharmacists. All of this spending is not without reward, however. A recent study by researchers at Harvard University and the Massachusetts Institute of Technology analyzed the effect of DTCA advertising on consumer spending for prescription drugs. In fact, the study found that the 50 most heavily advertised drugs were responsible for Other significant findings were: The number of prescriptions for the 50 most heavily advertised drugs rose While, in a perfect world, the benefits of DTCA touted by some experts would be understandable and even warranted, serious problems plague the system thereby making any such praise undeserved. Some of those problems include: Repeated findings by the FDA that many ads are deceptive, inaccurate, misleading, and otherwise in violation of federal law. The FDA is forced to expend an ever-increasing portion of its budget and manpower on policing advertising instead of more carefully investigating new drug applications and adverse reaction reports. DTCA results in over medicating the public. DTCA results in expensive drugs being taken by patients who would be better off taking safer and cheaper alternatives already on the market. DTCA leads people taking drugs they do not need in the first place. DTCA eliminates the learned intermediary physician from the decision making process in many cases and, in others, doctors are placed in the awkward position of having to prescribe a drug or lose a patient. DTCA uses celebrities, athletes, and even retired news anchors who have no medical or pharmaceutical training to vouch for the safety and effectiveness of prescription drugs. DTCA uses music which is or was popular with the target audience in order to subconsciously influence choice. Warnings are confined to extremely small type at the bottom of the page or TV screen and rapidly spoken segments of commercials. DTCA capitalizes on the widely held but erroneous belief among consumers that newer is better. DTCA ultimately places marketing above science. Many see the problem with the majority of prescription drug advertisements as being that they are just too slick. Critical information such as side effects or other hazards is often omitted or not explained in sufficient detail. Some advertisements do not even specify what condition the drug is designed to treat. People supposedly suffering from extremely serious medical problems are often shown smiling and laughing or engaging in activities that make the drug appear to be far more effective than it really is. As a result, the FDA often issues stern warnings to drug companies about misleading or deceptive statements or unproven claims of superiority. These warnings, however, are usually not made public. In fact, they are even sometimes ignored by the offending company or not acted upon for months or years. Recently, pharmaceutical giants such as Merck, Pfizer, and GlaxoSmithKline have received warning letters from the FDA regarding the use of false or misleading advertisements and promotional materials. Merck was warned as far back as September that its promotional activities and materials with respect to Vioxx were false and lacking in fair balance. On September 17, , the FDA issued an 8-page warning letter to Merck concerning its false and misleading promotional campaign. You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research VIGOR study, and thus, misrepresents the safety profile for Vioxx. The FDA also required Merck to send letters about the deception to the medical community. The letter dealt with so many improper and deceptive practices that it is difficult to imagine Merck, a leader in the field of prescription pharmaceuticals, had not formulated a plan to intentionally deceive the public, prescribing physicians, and the FDA itself as to the dangers posed by Vioxx. The FDA claimed that the ads in question, such as the one featuring a woman playing the long version of a song on the guitar and a minute long infomercial featuring regular people talking about their arthritis pain, are misleading because of their overstatement of effectiveness as well as the omission of risk information. GlaxoSmithKline was likewise warned about misleading advertisements for its hypertension drug called

Coreg. Thus, rather than demonstrate a commitment to truthful advertising, pharmaceutical companies are viewed as likely to attempt to get away with whatever they can in terms of misleading the public. This untrustworthiness forces the FDA to divert valuable resources money and manpower from other important agency functions. DTCA has been blamed for COX-2 inhibitors like Vioxx, Celebrex, and Bextra being greatly over-prescribed for years especially to patients who never needed them in the first place. These drugs were originally touted as being easier on the stomach than other painkillers. This led to countless prescriptions being written to people for that reason alone. Studies have shown, however, that the vast majority of people taking COX-2 inhibitors would have tolerated older, cheaper, and safer painkillers without any significant gastrointestinal problems. We also now know that these drugs are no easier on the stomach and have even been shown to cause abdominal bleeding in certain cases. Over-medicating is a very serious problem and it is occurring more and more frequently with respect to the most advertised drugs such as those for pain, high cholesterol, gastrointestinal disorders, depression, and disorders that cause embarrassment incontinence, herpes, yeast and fungal infections, and erectile dysfunction. In addition, the fact that COX-2 inhibitors cost between 10 and 15 times more than cheaper, safer, and equally effective painkillers such as naproxen, ibuprofen, and aspirin was never conveyed in any of the DTCA. This is a common occurrence in DTCA of designer drugs and one that greatly increases the cost of healthcare. Of course as healthcare expenditures rise, so does the cost of health insurance and government programs that subsidize health benefits to senior citizens and those of limited means. Marcia Angell, a senior lecturer at Harvard Medical School, explains that the pharmaceutical giants are price-gouging Americans. Many people, particularly senior citizens, simply cannot afford prescription drugs anymore. She says that a solution would be for drug companies to ease up on price increases, since there is a growing public resistance, as well as resistance from employers and state governments. Peter Rost, a senior executive at Pfizer, argues that if price controls came in, at first there would be a one time fall in profits, but then they would start climbing again and life would go on. Two in three Americans now believe that drug prices are unreasonably high. Right now, however, the drug companies are doing everything they can to avoid lowering costs such as refusing to legalize drug importation from Canada and trying to hook more and more people on what Angell calls lifestyle drugs. Certainly, spending billions of dollars on DTCA is not helping. While many DTC advertisements feature unknown actors or voice overs, a significant number of ads rely upon celebrities, athletes, and famous musical recordings to entice the public. Prominent broadcast journalists such as Walter Cronkite and Aaron Brown were used to blur the line between journalism and advertising. These reputable news anchors, who were paid handsomely for their appearances, hosted video news breaks produced by a Florida company called WJMK. These ads appeared on local public television stations between regular programs. Another company called Healthology hires journalists to appear in video Web casts for the same purpose. Critics argue that this kind of DTCA misleads viewers by packaging promotional material to look like news. Although all of the news anchors involved maintain that they appeared in the videos or Web casts to advertise drugs for educational purposes only, the true purpose of these videos is to promote the drugs for retail purposes. Steven Haimowitz, the president of Heathology said that the drug companies did not write or edit the videos script. He claims the Web casts are fair and balanced and are editorial in nature. This type of DTCA takes advantage of the relationship between the viewer and a trusted broadcast journalist. Pharmaceutical advertising has always been regarded by many as nothing more than an attempt to get somebody to buy something. Clearly, there is nothing scared about pharmaceutical ads that would make them more reliable or accurate than any other type of advertising. In fact, DTCA advertising suffers from the very same shortcomings as advertising in general which Canadian economist Stephen Leacock characterizes as the science of arresting the human intelligence long enough to get money from it. As discussed above, DTCA leads to over-medicating when consumers become convinced that the answer to their medical or psychological problems can be found in a pill. Many people on cholesterol lowering drugs would benefit more from a healthy diet and exercise.

Chapter 6 : St Pete, Clearwater Vioxx Litigation law firm | Alley, Clark & Greiwe

Vioxx manufacturer, Merck has been warned by the FDA to change their advertising regarding the company's misrepresentation of safety information, unsubstantiated comparative claims, the lack of fair balance, and the misrepresentation of efficacy information.

How did Vioxx debacle happen? The fact that no one can answer that question conclusively, and the fact that Vioxx remained on the market as long as it did, point to serious deficiencies in how the Food and Drug Administration regulates prescription drugs, critics say. Merck yanked Vioxx on Sept. But the new Vioxx study was not the first to raise concerns about heart attack and stroke risk. Yet 2 million Americans were taking Vioxx when it was pulled. Critics describe the rise and fall of Vioxx as a cautionary tale of masterful public relations, aggressive marketing and ineffective regulation. The study, an analysis of a database of 1. Based on their findings, Graham and his collaborators linked Vioxx to more than 27, heart attacks or sudden cardiac deaths nationwide from the time it came on the market in through Graham told the finance committee investigators that the FDA was trying to block publication of his findings, Grassley said in a statement. Graham gave Grassley copies of e-mail that appear to support his claims that his superiors suggested watering down his conclusions. Davis also asked whether the FDA plans to collect more data on related drugs. But the European Agency for the Evaluation of Medicinal Products last week announced it will review all long-term cardiovascular safety data for Vioxx and the four other related drugs licensed in Europe. Merck happens to have a Vioxx classmate called Arcoxia in the wings. It is sold in 47 countries but not yet in the USA. Though the study did demonstrate that Vioxx was safer on the digestive tract than naproxen, it also unexpectedly found that the COX-2 inhibitor doubled the risk of cardiovascular problems. A press release on March 27, , led off with the finding that Vioxx caused fewer digestive tract problems than naproxen. Finally, late last month, Merck confronted unfavorable findings that it could not explain away. Merck had sponsored a three-year, 2,patient randomized trial to see whether Vioxx, like Celebrex, could claim that it protects against the recurrence of colon polyps, which can become cancerous. Again, the study backfired. After 18 months of treatment, researchers observed a higher heart attack and stroke risk in patients on Vioxx, Merck says. Merck has not yet reported the study results, but the FDA says 3. Monitoring the drugs FDA spokeswoman Crystal Rice says the agency will continue to monitor drugs in the same class as Vioxx. The FDA turned down its original application in for lack of data. Wood, Topol and others speculate that drugs in the same class as Vioxx may appear to be safe because the FDA has not yet asked for the randomized, controlled trials necessary for definitive answers. Topol says the drugs should be specifically tested in patients known to have cardiovascular disease, which is common in patients who need medication for osteoarthritis. So far, such patients have virtually been excluded from trials of the COX-2 inhibitors, Topol says. In a yearlong study of more than 18, osteoarthritis patients published in August, Prexige did not increase heart attack or stroke risk when compared with ibuprofen or naproxen. Back in , when Merck first notified the FDA that Vioxx appeared to carry a higher risk of heart attacks and strokes than naproxen, the agency should have quickly ordered a trial comparing Vioxx with a placebo, Wood says. Marjorie Chepp of Milwaukee had been taking Vioxx for nearly two years. Her doctor first prescribed it for a knee injury, but Chepp found that it also relieved her osteoarthritis and fibromyalgia. She asked to remain on it. Merck reveals that a new study found Vioxx patients had double the rate of serious cardiovascular problems than those on naproxen, an older nonsteroidal anti-inflammatory drug, or NSAID. An advisory panel recommends the FDA require a label warning of the possible link to cardiovascular problems. An FDA researcher presents results of a database analysis of 1. Merck says it learned this day that patients taking Vioxx in a study were twice as likely to suffer a heart attack or stroke as those on placebo. Merck withdraws Vioxx from the U.

Chapter 7 : Review of Overdo$ed America, author John Abramson

At times, it is necessary to "neutralize" the opposition, or at least Merck & Company executives seemed to think so. In , the company's new pain drug, Vioxx, was beaten to pharmacy shelves by a competing drug, Celebrex.

In summarizing the objective of the book the author asserts that his goal is that the book "will play a constructive role in helping to redirect American medicine back toward its highest ideals". Abramson traces the "industrial colonization" of medicine and academia by the pharmaceutical industry. He expands on how the pharmaceutical industry is "masterfully" creating a marketing program that involves the synergy between the medical profession and the patient, but at the expense of the patient. Stone, Seymour Hirsch and many others. He invariably cites evidence of "false" information on how "the sponsors drug company presentation of 6-month data are not statistically valid or supportable" Note 30, p. Abramson concludes with a challenge to his readers to "consider the responsibility of citizenship in this time of excessive medical profiteering and corporate influence, and to take up one of the most important challenges of our time: Substance This is a well organized and easy to read book with references to "notes" in the back of the book that provides the source of his information. The notes are really his bibliography, and well worth reading. The inconvenience is that one has to flip pages back and forth from the body of the book to the notes. The substance of the book is presented clearly, concisely and in a clinically pertinent way. However, the reader would like to read what the "other side" has to say about the same issues. The book will serve as a primer for anyone wanting to know more about the interaction between pharmaceutical companies, and medical care. The book strengthens the growing idea that the consumer take a more active role in health care and make a commitment to become more interactive with the treating physician, but not loosing sight how life-style also effects health. This could prove especially difficult for the frail elderly, a growing cohort group needing medical attention. The subtitles of the six chapters in part I clue the reader to the message he is trying to get across: Caring for Patients at the Crossroads"; "Spinning the Evidence: The Saga of Hormone Replacement". In these chapters, Dr. Abramson suggests instances of "unfortunate chapters in medical history" p. It was actually subverting the quality of medical care. Duping the Doctors"; "A Smoking Gun: The Cholesterol Guidelines"; "Direct-to-Consumer: Abramson reviews the impact on medicine of the transition from traditional indemnity insurance to HMOs and managed care plans that now dominate the delivery of medicine in this country. Abramson corrects the impression that managed care companies do not serve patients well. The quality of care has neither improved nor deteriorated under managed care. Abramson places a lot of the blame on lack of primary care practitioners his own field. Part II shows how medical knowledge has been transformed from a public good, "measured by its potential to improve our health, into a commodity, measured by its commercial value. There is nothing intrinsically illegal about such arrangements, but Dr. Abramson questions whether it is possible to serve the public interest and commercial interests simultaneously. Are we paying an enormous amount of money for some mediocre medicines? Abramson at one point cites an editorial that appeared in the Journal of the American Medical Association ; The responsible conduct of medical research involves a social duty and a moral responsibility that transcends quarterly business plans or the changing of chief executive officers. The question is whether this is the best for the public or whether pharmaceutical companies have to integrate, along with their commercial interests, a social responsibility factor into their mission that is more reflective of the "public good" Other interested players in the healthcare game will also have to reconsider their role. Abramson points out how the cost of care and health outcomes varies by regional, ethnic and socioeconomic levels in Medicare patients with a first diagnosis of heart attack, broken hip or cancer of the colon. John Weinberg and Elliot Fisher. The reference in the Notes section fails to give the year the study was published. This seems to be particularly true for the kind of care that is pushed into service by supply side pressure. Citing four features shared by the medical services that are most vulnerable to overuse because of supply-side push, Dr. Abramson involves the patient, the medical technology service providers, the doctors and the

hospitals in a process that disconnects costs from health care value. The headings of these chapters speak for themselves. If you do not have the time to read this book, the last chapter is a must read. It is a concise yet comprehensive guide for the reader to understand steps to provide quality healthcare to all Americans. People need to take some responsibility for their health by staying mentally active, eating a well balanced diet, getting regular exercise, avoiding smoking and excess alcohol. These are all proactive, preventative steps that have a strong positive influence in the health of an individual. At the same time, the government must maintain a level of responsibility to eliminate potential environmental pollutants that are a danger to health, as well as enforcing standards of health care and drug surveillance such that they minimize the risk of medication induced mortality or morbidity. This can only come about if the government enforces its statutory clout to penalize offenders without depriving them of their right to defend themselves. At the same time, the penalty has to be severe enough to get the offender to stop. They will need additional financial and political support and stronger influence on other divisions within the FDA to which they report their findings. An alternative would be the establishment of, an independent panel, similar to the independent advisory panels that exist to give recommendations for drug approval. Those serving on such a panel would not have any connection to the pharmaceutical industry I. The panel would act in an oversight role, monitoring research studies and follow-up when drugs and medical technologies are approved for clinical use. Fixing blame with the pharmaceutical industry, or the FDA as a standard setting organization, or healthcare providers will not solve the problem; successful change requires a team effort. All key stakeholders must work together toward the lasting changes needed to providing much more information about the real benefits of the drugs in place as well as the various advanced medical technologies in use. At the same time, the consumer must take some responsibility for maintaining good health practices, as we must expect from drivers of cars to practice safety without excusing the drug manufacturer or car manufacturer from maintaining a high degree of public safety in their product. Description of author John Abramson, a family medicine physician who had spent time administering to the health needs of individuals in Appalachia, was a Robert Wood Johnson Fellow at Case Western University, and then worked for 20 years in a private family medicine practice in Massachusetts.

Chapter 8 : How Did the Vioxx Debacle Happen? USA Today / Lancet - AHRPAHRP

The FDA demanded that Merck discontinue promoting Vioxx to doctors for unofficial uses and found after a review of several of Merck's promotional conference calls and sales pitches that the promotions by Merck are false, lacking in fair balance, or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and.

Merck apparently hoped that nationally known rheumatologists like Dr. Roy Altman could help it catch up. At a dinner that year in Miami, a Merck executive asked Dr. Altman what it would take to win his support, the doctor recalled. He said those were neither his words nor his intent. He also said his involvement in the trial did not affect his prescribing. Robert Ettlinger, a rheumatologist in Tacoma, Wash. And next week, an advisory panel to the Food and Drug Administration will review whether the agency should add warnings or restrictions on the use of Celebrex and other drugs known as COX-2 inhibitors, a category that also includes Vioxx. In a statement, Merck said that it stood behind its marketing programs and added that all were intended to provide accurate information about its products. But the internal Merck documents offer a rare, behind-the-scenes look into the extremes of this process â€" one that may have blurred the line between legitimate promotion and offering inducements to doctors to prescribe a drug. In recent months, federal investigators, state officials, Congressional committees and lawyers for plaintiffs have obtained thousands of internal Merck documents while pursuing investigations and lawsuits related to Vioxx. The New York Times obtained the documents cited in this article â€" records that include e-mail messages, memorandums and spreadsheets â€" through a public official. To win them over, the documents show, Merck officials planned to offer them carrots like clinical trials, posts as consultants or give them grants. In addition, the Merck documents indicated that some of tactics were meant to counter moves by Celebrex. Over the years, Merck and Pfizer or its marketing partners all received warning letters admonishing them for misleading claims. Both Celebrex and Vioxx were marketed as a safer alternative to traditional pain relievers like Advil and Aleve, which can cause ulcers and stomach bleeding. One physician on the list â€" Dr. A Merck document recommended that Dr. Ettlinger be giving more paid speeches, be invited to more meetings and be asked to do more drug trials. Such work never affected the drugs he prescribed, including Vioxx or Celebrex, he said. But in some cases, Merck sales officials apparently hoped that showering physicians with favors would bring some returns, the records indicate. Keith Feder, a Los Angeles-area orthopedic surgeon. The foundation helps pay medical insurance for low-income students in California so they can have the coverage required by the state to participate in team sports. Feder confirmed that the foundation had received money from both Searle and Merck, but said that the grants helped support a continuing medical education program and were not intended to influence his prescribing habits and did not do so. Concerns about the sales of Celebrex and Vioxx also came up in connection with Dr. Max Hamburger, a rheumatologist in Melville, N. Hamburger was approaching drug companies to subsidize retreats for his group during which the physicians would put together guidelines on what drugs to prescribe. And Merck did so, too, the document shows. In an interview, Dr. Hamburger said that his group solicited funds from a large number of pharmaceutical companies to support its educational meetings and that payments from those drug makers did not influence the medications prescribed. As for his description as an advocate, Dr. James Sheehan, a federal prosecutor in Philadelphia who specializes in health care fraud, did not review the documents. But, speaking generally, he said that while drug companies can give money to doctors for educational or scientific purposes, payments intended to influence whether a physician prescribes a drug might qualify as an illegal kickback. Altman, who is now a professor of medicine at the University of California, Los Angeles, he never spoke for Merck or said he felt any more pressure from the company after the dinner in Miami. He could not recruit enough patients for it. If you feel you have a case or just have questions please contact us for a free consultation. There is no risk and no fees unless we win for you.

Chapter 9 : FDA Sends Warning Letter To Vioxx Maker - Parker Waichman LLP

Merck's marketers, meanwhile, apparently feared it could send the wrong signal about the company's confidence in Vioxx, which already faced fierce competition from a rival drug, Celebrex.