

PRESCRIPTION DRUG SAFETY

**10 Secrets the Pharmaceutical Industry
Does NOT Want You to Know**

2nd Edition



Kay L. Van Wey, Attorney At Law

About the Author



Kay L. Van Wey is a veteran trial lawyer who is Board Certified in Personal Injury Trial Law by the Texas Board of Legal Specialization. In her 29 years as an attorney, Kay has been a strong supporter of consumers' and patients' rights and has fought large corporations that put profits over patient safety.

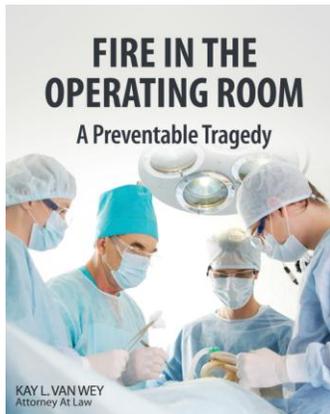
Based on past results she has achieved for her clients, Kay has attained membership in the Million Dollar, as well as the Multi-Million Dollar Advocates Forum.* She is rated by Martindale-Hubbell as AV Preeminent, which is the highest possible rating in both legal ability and ethical standards a lawyer can achieve. Several of the cases Kay has handled over the years have gained both local and national media attention.

For the past ten consecutive years (2003-2012), Kay has been selected as a Texas Super Lawyer by her peers. She has also been named one of the Top 100 Trial Lawyers in Texas.

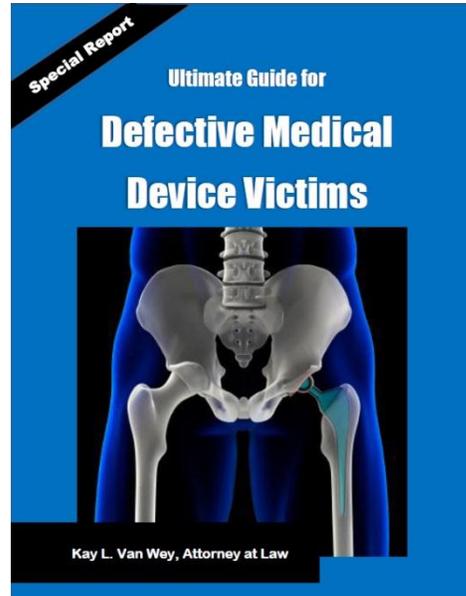
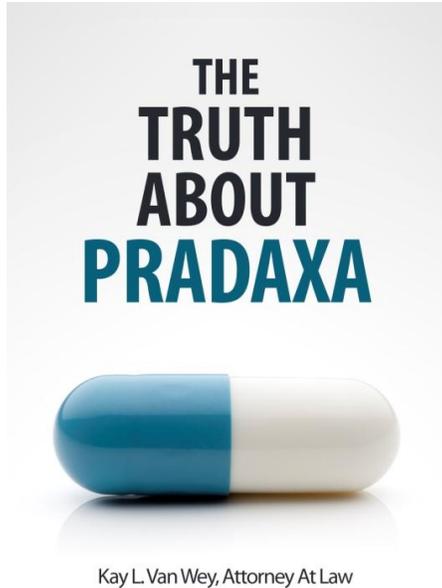
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*Past results do not guarantee the same results for other clients in different matters, or in the same or similar matters. The results of each client's case depend on the specific factual and legal circumstances of the case.

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Prescription Drug Safety: 10 Secrets
the Pharmaceutical Industry Does NOT
Want You to Know

2nd Edition

By
Kay L. Van Wey
Attorney at Law

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Preface

Throughout the course of my career, I have been dedicated to helping the unwitting victims of catastrophic personal injury and wrongful death. I have represented people who were seriously injured by pharmaceutical drugs and medical devices, and frankly, some of the practices of pharmaceutical companies and medical device manufacturers have astounded me. I wrote this because I want my friends, clients, and family to know how terribly flawed our system is and to hopefully spur some of you to cry out for much needed reform of the U.S. pharmaceutical industry. At the very least, I hope this book will make each of you a more informed consumer.

By the time you read this book some of the information will already need to be updated. I keep a close eye on the pharmaceutical industry, and there are literally updates I could add to the book on a weekly basis, especially concerning the specific drugs I discuss.

This book is in no way intended to be legal or medical advice, but rather is an informational guide for consumers. Of course, if you have legal questions, or think you may have a claim against a pharmaceutical manufacturer, please feel free to email me directly at Kay@Vanweylaw.com or call my office at **(214) 329-1350** or **(800) 489-5082**.

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Disclaimer

Kay Van Wey is not a doctor and does not purport to give medical advice. The opinions contained in this book are based on published medical literature. Per U.S. Food and Drug Administration (FDA) recommendations, you should not discontinue any drug that has been prescribed to you without first speaking with your doctor.

Ms. Van Wey is not purporting to give specific legal advice either. This book is intended to be a source of general information about the pharmaceutical industry and potentially dangerous drugs. Please do not construe anything in this book to be legal advice about your case, as each case is different, and an attorney can give you quality legal advice only when she understands the facts involved in your particular case.

THE SECRETS OF PHARMACEUTICAL COMPANIES

The scene plays out countless times every day. A patient goes to his or her doctor for a condition, symptom, real illness, or perceived illness. In this day and age, a patient rarely leaves the office without at least one prescription, if not multiple prescriptions. The patient takes the prescription to the pharmacy, and upon receiving the prescription, the patient also receives a long print out of warnings. These warnings typically range from very minor side effects, such as a rash, to very serious side effects, such as seizures, permanent liver damage, stroke, and even death.

Many of the drugs on the market today are medically necessary, provide needed treatment, and actually do improve the overall health and quality of life of the patient. However, we also hear stories on the news of the FDA recalling prescription drugs that were once considered safe or issuing stricter warnings about the potential danger associated with a drug.

At the same time, we are deluged with commercials about how we need prescription drugs for everything that ails us. We are constantly being marketed prescription drugs that claim to help us stop smoking, lose weight, be happier, have longer eyelashes, be more comfortable in social situations, sleep better, and have better sex.

Both the constant barrage of pharmaceutical ads and the news reports of dangerous drugs led me to ask questions about the safety of our pharmaceutical products and the real motive of pharmaceutical companies. The answers I found astonished me, and will also likely astonish you. In this chapter, I explain several “secrets” the pharmaceutical industry would prefer consumers not know.

Secret #1: Americans should not blindly trust pharmaceutical companies.

Pharmaceutical Companies Ask for Our Blind Trust

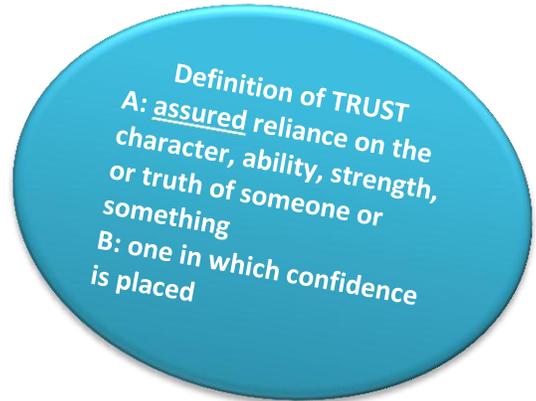
The vast majority of Americans have been taught to trust what they read or are told about the drugs they are prescribed. As a society, we trust that the prescription drugs being offered to us will cure our illnesses, alleviate our symptoms, or be a solution to a medical issue we are experiencing. Above all, we trust that the medications we are prescribed and the physicians who prescribe them will do us no harm.

Where does this trust come from? We have been conditioned to accept what we see in glossy print ads, what we read on labels, and what we are told by credible-sounding spokesmen on TV and radio. We trust because our doctor prescribed the medication and because we believe a government agency has thoroughly tested and approved the drug.



Unfortunately, there are instances where this trust is misguided, and we, as consumers of prescription drugs, have not been told the truth, or at least, not the whole truth.

Certain prescription drugs have been linked to causing heart attacks, strokes, birth defects, uncontrollable bleeding, blood clots, cancer, organ damage, and even death. As medicine and pharmacology become more ambitious and more money-driven, the motivation to introduce the latest miracle drug or must-have treatment on the market becomes stronger, and the danger of marketing medications with dangerous or lethal side effects becomes greater.



So as consumers, how do we know which drugs we really need and which ones are really safe? The good news is that there are some wonderful consumer organizations that track drug safety. The bad news is that the consumer can no longer have confidence in the pharmaceutical industry. Let's face it—Big Pharma's goal is to sell as many pills as possible, and they do so by convincing us that we need their pills. This is called direct-to-consumer marketing. Big Pharma convinces our doctors that they need to prescribe a particular drug to us by sometimes employing questionable methods. In many cases, the consumer has been conditioned by Big Pharma's advertising to actually request drugs by name.

In this era of Big Pharma, and with tens of billions of dollars being made through sales of expensive, proprietary drugs, **the time for blind trust is over**. Consumers must inform themselves of the true nature of the medications they are being prescribed.



Let's face it—Big Pharma's goal is to sell as many pills as possible, and they do so by convincing us that we need their pills.



We Are a Pill Popping Nation

Americans are prescribed more drugs today than ever before. The American appetite for prescription drugs has soared in recent years. Yet we know so little about the hazards these drugs may pose to our health. According to IMS Health, a pharmaceutical consulting company, Americans spent \$307.4 billion dollars on prescription drugs in 2010.¹ The year before that saw an increase in demand of more than five percent, due to a stronger



demand by consumers for prescription drugs, despite a sluggish economy.² And according to IMS Health, spending on medicines in the United States reached \$320 billion in 2011.³

Here are some more statistics to get you thinking:

- The average American filled more than 12 prescriptions in 2009.⁴
- Older Americans fill an average of 38 prescriptions per year.⁵
- The U.S. will remain the single largest pharmaceutical market in the world, with three to six percent growth expected each year. Pharmaceutical sales in the U.S. are expected to reach \$360 to \$390 billion in 2014, up from just over \$300 billion in 2009.⁶
- Worldwide, sales of prescription drugs are expected to grow to \$1.2 trillion by 2016.⁷

Secret #2: Pharmaceutical companies appeal to us directly to convince us that we need to buy their “cure-all” drugs.

The Advent of Direct-to-Consumer (DTC) Advertising

Some of you may remember the days when tobacco companies were free to advertise on television. I may be giving away my age here, but I vividly remember the Marlborough man and the Tarryton “I’d rather fight than switch” commercials. Thanks to consumer advocacy groups and forward-thinking trial lawyers, the tobacco industry is now tightly regulated in how it can advertise its products to consumers. In fact, a federal judge recently ordered tobacco companies to publish statements informing consumers that they had lied about the dangers of smoking.

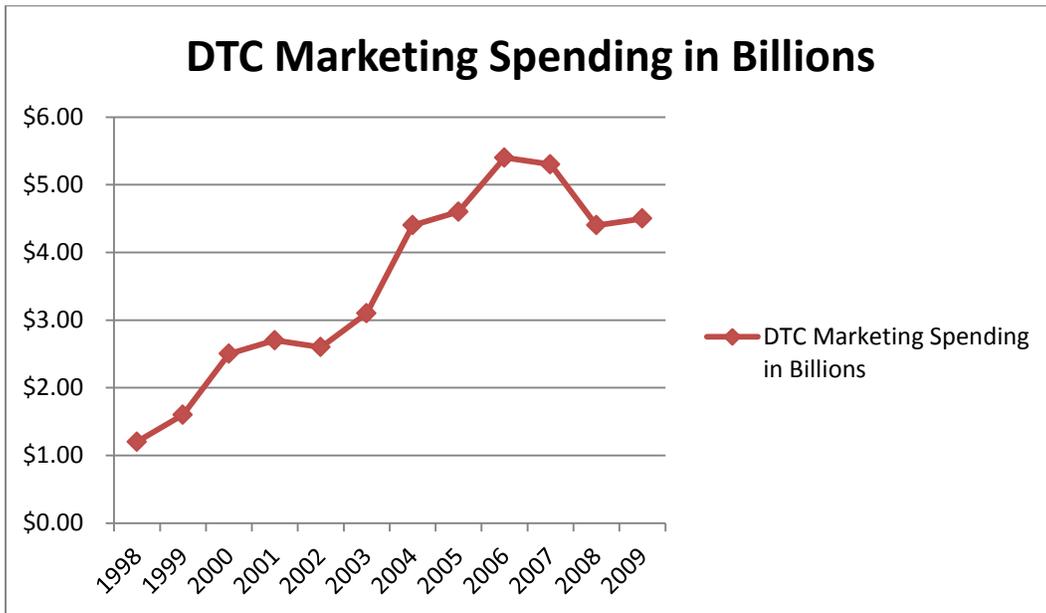
Likewise, for many years liquor companies were banned from advertising directly to consumers. In the past decade, these restrictions loosened somewhat, but there are still tight controls on promoting the use of alcohol.

Medical experts have long recognized that the public needs



to be protected from solely profit motivated corporations that use slick marketing techniques to convince consumers that they would be more attractive, more hip, and more seductive if they were to smoke a particular type of cigarette or drink a particular brand of alcohol. Consumer groups and advocacy organizations recognize that the slick marketing and advertising of alcohol and tobacco can lead persons (especially teens) to engage in activities that are bad for them and that can endanger the health and the safety of others.

However, we live in a world now where we can barely turn on the television or open a magazine without being deluged by advertisements for all types of prescription drugs. The slick advertising seems to convince us that we NEED these drugs, that these drugs are actually GOOD for us and that we should actually go so far as to talk to our doctor about putting us on these drugs. This type of advertising is known as direct-to-consumer (DTC) advertising, and was actually forbidden in this country until about 1997, when the government paved the way for Big Pharma to run massive ad campaigns. Currently, the pharmaceutical industry spends billions annually in the U.S. alone to market its drugs.⁸ A chart of the money pharmaceutical companies have spent on DTC marketing from 1998-2009 is included below. The deep pockets of Big Pharma meant these companies could hire the best Madison Avenue marketing agencies, and later even celebrities, to pitch their products.⁹



Data Source: C. Lee Ventola, Direct-to-Consumer Pharmaceutical Advertising, 36 PHARMACY & THERAPEUTICS 669-74, 681-84 (Oct. 2011), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/figure/f1-ptj3610669/>.

One of the first “celebrities” to partner with a prescription drug company was former Senator Bob Dole. Senator Dole talked openly about his erectile dysfunction and encouraged other men to seek help for the condition in an advertisement. Pfizer paid for the campaign, and it just so happened that its widely popular pill known as Viagra came out at the same time.¹⁰ Neither Pfizer nor Viagra were mentioned in the advertisement though.¹¹

More recently, popular Southern chef Paula Deen has endorsed diabetes drug Victoza, which has potentially dangerous side effects like thyroid cancer and pancreatitis. Deen has admitted that drug maker Novo Nordisk is paying her, but has declined to state the specific amount. Ms. Deen played right into the hands of Big Pharma by sending a message to consumers that it is okay to eat foods that are loaded with fat, sugar, and calories, but don't worry if you develop diabetes because we have a pill for that.



“The Lady’s Brunch Burger” by Paula Deen

Today, the United States is only one of four countries that allow DTC advertisements.¹² Rather than inform the public about the drugs, the advertisements have become persuasive tools to convince us that we need the drugs and to create an illusion of how much better our lives will be if we take their drugs.

Secret #3: We cannot rely on the FDA to approve only safe products and keep dangerous products off the market.

The Role of the Food & Drug Administration

Some of us have been raised to believe that the government is the protector of the people. The FDA is the government agency charged with

(a) ensuring that dangerous drugs don't get approved, (b) regulating drugs after they are approved, and (c) recalling drugs from the market if they are found to be dangerous.

But can we really trust the FDA to protect us from the greed of Big Pharma? Unfortunately, this question cannot be measured authentically due to the extreme wealth of the pharmaceutical industry, which has been used to buy power and influence in Washington, D.C.

For some of you this may not come as a surprise, but the truth is that the FDA is influenced by politicians, lobbyists, and the treasure chest of the pharmaceutical industry.

First, consider this statistic: Big Pharma spends \$188 million annually lobbying on Capitol Hill and employing more than 1,100 lobbyists.¹³ In fact, Big Pharma spends more on lobbying than most other industries.¹⁴ **Today, the pharmaceutical industry has two lobbyists for every member of the U.S. Congress.**¹⁵



Case Study: Menaflex

Questions about the validity of the FDA's approval process for new drugs and medical devices have recently been called into question by FDA insiders. Written complaints from senior FDA staff members revealed how an intense lobbying campaign led to the approval of Menaflex, a medical device used to treat knee injuries, despite multiple rejections by FDA scientists. After ReGen, the manufacturer of the device, hired four lawmakers to sign a letter asking the FDA commissioner to personally review the device, it landed a personal meeting with the FDA commissioner. Thereafter, the device was put on the "fast-track" and approved, despite the FDA scientists' recommendation that the application be rejected. The paper trail obtained in this case is a textbook example of how political and industry pressure can influence scientific conclusions.¹⁶

Case Study: Big Pharma's Influence within the FDA—Yaz Panel

On December 8, 2011, health experts met at the request of the FDA to determine whether the popular birth control pills Yaz and Yasmin are safe. The panel voted 15 to 11 to keep the pills on the market, citing that the benefits outweighed the risk of blood clots, heart attack, and stroke.



And so Yaz and Yasmin remain on the market—by a small four vote margin. Ironically, four of the experts on the panel—who, by the way, voted in favor of keeping the drugs on the market—have been compensated by Bayer, maker of Yaz and Yasmin, at one time or another.¹⁷

One of the experts with ties to Bayer was Dr. Julia Johnson. She was paid by Bayer for work she had completed and for a clinical trial she had conducted, involving the synthetic hormone drospirenone, which is also found in Yaz, Yasmin, and their generic equivalents.¹⁸

Another expert had been paid as much as \$10,000 by Bayer as recently as 2010.¹⁹ The FDA says it conducted its own investigation of all the experts on the panel and found that the financial ties between Bayer and some of the experts were far enough removed to discount any question of bias. At this time, the FDA has a policy against releasing panelists' financial ties with drug companies to the public.

Yet one panelist that the FDA was outspoken about was Dr. Sidney Wolfe of the consumer advocacy group Public Citizen. In his book entitled *Worst Pills/Best Pills*, Dr. Wolfe warns women that Yaz, Yasmin, and other drugs that contain drospirenone should be avoided because of the risk they pose for causing blood clots. Citing an “intellectual conflict of interest,” the FDA did not allow Dr. Wolfe to serve as a voting member on the panel.²⁰

The FDA is setting a double standard by allowing experts who have received financial compensation from a pharmaceutical company to serve on a panel investigating that company's product. As the old adage goes, we shouldn't let the fox guard the hen house.

Secret #4: Adverse drug reactions are the fourth leading cause of death in the United States.

This may come as a surprise to you, but the FDA has no accurate way of tracking the various adverse reactions people have to different pharmaceutical drugs. Initial studies of drugs conducted on humans use only small subsets of the population. So when approved drugs hit the market, more adverse reactions to the drugs begin to appear. Unfortunately, many of these adverse reactions go unreported.

The FDA tracks adverse drug reactions through its Adverse Events Reporting System (AERS). By relying completely on patients and doctors to report adverse reactions, the FDA seriously underestimates the effects of new drugs on the population. In fact, recent estimates show the system catches a mere 10 percent of all adverse drug reactions, which means the remaining 90 percent go unreported.²¹ Although deaths from adverse drug reactions are rarely reported, researchers estimate that they are the fourth leading cause of death in the United States.²²

Deaths due to adverse reactions or negligent prescribing cost an estimated \$289 billion annually, which totals to about 13 percent of all health care related expenses.²³

Adverse drug reactions are rarely reported, but are estimated to be the 4th leading cause of death in the United States.

Secret #5: Doctors are pressured to promote and prescribe certain drugs, even for unapproved, off-label uses.

The Role of Our Doctors

Doctors are supposed to be the gatekeepers between us and Big Pharma. The law refers to them as “learned intermediaries.”

Many of us have been raised to have blind faith in our doctors. Here I go again giving away my age, but I can remember good old Dr. Marcus Welby, who with his genial manner always had the best interest of his patient in mind. I still believe that most doctors are well-trained and have the best interest of their patients in mind. However, doctors are at the mercy of Big Pharma to tell them the truth about the drugs they are prescribing to their patients, and many are under constant pressure to prescribe one drug over another drug to their patients.

Some doctors fall prey to the pressure or incentives offered and prescribe drugs for reasons other than a valid medical purpose. How many times have you gone to a medical office building and noticed all of the drug reps rolling their bags of freebies? My doctor friends tell me that every single day they are deluged by drug reps and that in many cases, their breakfasts and lunches are provided every day by pharmaceutical companies. Then there are the conferences at luxury resorts, the paid speaking engagements, countless gifts, and other perks.

As shocked as you may have been to learn about the billions Big Pharma is spending on DTC advertising, consider this: the vast majority of Big Pharma’s marketing dollars are directed at physicians. Author Melody Peterson put it beautifully in her book, *Our Daily Meds*, when she stated:

“There is now one drug salesperson for every six physicians, each with an expense account that lets him shower doctors with gifts and cash. Surveys show that virtually every American physician now takes these handouts.”²⁴

We can no longer deny the unprecedented access and influence the sellers of prescription drugs have on the decision makers—our doctors—who decide whether or not to prescribe us a particular drug.



I was browsing the bookstore last year and the cover of *Consumer Reports* (March 2011) caught my eye. If you read beyond the catchy headline, you will find this nugget:

“The majority of doctors we surveyed said that pharmaceutical company representatives contacted them more than 10 times a month. Thirty-six percent were contacted more than 20 times a month. On average doctors said they spend a few hours a week dealing with pharmaceutical salespeople.”¹²⁵

A recent report by independent investigative journalism organization ProPublica revealed an accounting of pharmaceutical payments to doctors for speaking, consulting, and other duties. Drug companies have long kept secret the details of payments they make to doctors for promoting their drugs. But recent legal settlements have forced seven pharmaceutical companies to begin posting the names of the doctors they compensate and the amount of compensation paid.²⁶ The total approached \$295 million, and that only includes seven companies.²⁷ You can now go to the [ProPublica website](#) and type in the name of your doctor to see if he or she has taken money from pharmaceutical companies.²⁸ This does not necessarily mean that your doctor is bad, but it could suggest he or she has a potential conflict of interest, depending on the drug he or she is being paid to promote. In Texas alone, doctors received an estimated total of \$57 million in cash, research funding, meals, and travel between 2009 and 2011.²⁹

Several lawsuits brought by former employees of drug companies have alleged that the money paid to doctors was used for illegal purposes, namely to financially reward doctors for prescribing their products. In

some instances, doctors were paid to promote an “off-label” use of the drug, meaning doctors were paid to convince their colleagues to prescribe drugs for purposes other than what the FDA had approved. In addition to exposing the doctors who are receiving money from drug companies, ProPublica also revealed that some pharmaceutical companies paid doctors who lacked credentials and even paid doctors who had been sanctioned by their medical boards.

In response to growing concern about the potential conflicts of interest doctors face when working closely with pharmaceutical companies, the Cleveland Clinic—one of the most prominent medical research centers in the United States—mandated that all of its doctors publicly report their business relationships with pharmaceutical companies and medical device makers. The Cleveland Clinic changed its policy after a lawsuit filed in December 2007 by a former clinic doctor alleged that “widespread and pervasive conflicts of interest” were occurring at the Cleveland Clinic.³⁰ Since then, many other medical centers have also changed their policies.



In addition, a few drug companies, such as Merck and Eli Lilly, have announced plans to start disclosing the payments they make to doctors. This trend towards creating more transparency is encouraging. I applaud my colleagues who have brought whistleblower and pharmaceutical fraud lawsuits for their role in bringing about some much needed change.

Doctor Kickbacks | Efforts at Reform

Under the new healthcare law, if a pharmaceutical company has even just one product covered by Medicare or Medicaid, it must disclose all of its payments to doctors who are not its own employees. Additionally, pharmaceutical companies must report if they pay a doctor to help develop, promote, or assess any new products, including if a doctor receives fringe benefits from the company, such as food provided for an office meeting. Further, any money paid to teaching hospitals for research will also have to be reported. The government hopes that these new regulations will deter doctors from prescribing drugs in risky and unapproved ways, as some doctors who had taken money from drug companies were doing.

Source: Robert Pear, [U.S. to Force Drug Firms to Report Money Paid to Doctors](http://www.nytimes.com/2012/01/17/health/policy/us-to-tell-drug-makers-to-disclose-payments-to-doctors.html?_r=1&nl=health&emc=healthupdateema4), N.Y. TIMES (Jan. 16, 2012), http://www.nytimes.com/2012/01/17/health/policy/us-to-tell-drug-makers-to-disclose-payments-to-doctors.html?_r=1&nl=health&emc=healthupdateema4

Secret #6: Some research studies conducted on prescription drugs are funded by Big Pharma.

Can We Really Trust the Science?

Many of the so-called “scientific” studies that support the efficacy of drugs are funded by pharmaceutical companies. Medical school faculty and teaching hospitals conduct most of the research and often publish most of the medical literature, which presumably should be free from drug company corruption.

But pharmaceutical sales forces have been known to roam the halls of these venerable institutions, offering branded gifts, free lunches, and cash payments for medical school faculty to give promotional talks for pharmaceutical companies. And many of the studies themselves are funded by drug companies. Some faculty physicians net tens of thousands in additional income by pitching the drug companies’ products. Make no mistake, the message is 100 percent controlled by the drug company. The drug company typically picks the subject of the lecture, trains the speaker, and requires the speaker to use company-provided presentation slides, leading one to question the scientific credibility and reliability of these materials.



Several universities have started to place restrictions on speaking engagements where the sponsor determines the content of the presentation, but even those institutions that have enacted policies have been lax in enforcing them. A 2006 article published in the *Journal of the American Medical Association* began with this statement:

“Conflicts of interest between physicians’ commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products pose challenges to the principles of medical professionalism. These conflicts occur when physicians have motives or are in situations for which reasonable observers could conclude

that the moral requirements of the physician's roles are or will be compromised.”³¹

Secret #7: Big Pharma inflates research & development costs, spends more on marketing, and passes the costs on to the consumer.

Why Are Prescription Drugs So Expensive?

The average cost of manufacturing a single pill is mere pennies. So, why do prescription drugs cost so much? Pharmaceutical companies would like for you to believe that the cost of research and development (R&D) drives up drug prices. However, several studies have shown that pharmaceutical companies inflate the cost of R&D.³² Furthermore, industry insiders tell us that **most pharmaceutical giants spend twice as much on marketing as they do on research.**³³ Also passed on to the consumer is the cost of buying power and influence in Washington—or as politicians call it, lobbying.

To make matters worse, the cost of prescription drugs continues to rise. Critics of the industry say the drug companies are trying to maximize profits and are spending more money marketing expensive name brand drugs to doctors and consumers, causing prices to increase. Consider this: **between 1995 and 2002, the pharmaceutical industry was the United States' most profitable industry, raking in profits of 19.3 percent in 2008 alone.**³⁴

Furthermore, the United States is virtually the only country that does not regulate drug prices. Recent estimates show that, on average, Canadians pay one-half to one-fourth of what American consumers pay for the same prescription drugs.³⁵ In addition, several drug companies have been involved in price-fixing schemes.

Examples of Price Fixing

In 2008, three major pharmaceutical companies including Johnson & Johnson, AstraZeneca, and Bristol-Meyers Squibb were found by a federal judge to have marked up their prescription drug prices to defraud Medicare.

Just recently in April, the state of Idaho settled with drug maker GlaxoSmithKline over allegations that the company sold its drugs at inflated prices.

Secret #8: We are experiencing a critical drug shortage in the United States.

A serious drug shortage has taken hold in this country for certain types of drugs. The types of drugs affected include emergency drugs, pain medications, and anesthesia drugs. Lists of drug shortages are maintained by the FDA³⁶ and the American Society of Health System Pharmacists (ASHP).³⁷

The FDA's list is less extensive, as it includes only shortages of "medically necessary" products, given their significant impact on public health. A "medically necessary" product is defined by the FDA as one that is "used to prevent or treat a serious or life-threatening disease or medical condition, for which there is no other available source with sufficient supply of that drug or alternative drug available."³⁸

On the Frequently Asked Questions page of the FDA website, the question is posed: "What is the major reason for these shortages?" Here is the FDA's answer:

"A major reason for these shortages has been quality manufacturing issues. However there have been other reasons such as production delays at the manufacturer and delays companies have experienced receiving raw materials and components from suppliers. Discontinuations are another factor contributing to shortages. FDA can't require a firm to keep making a drug it wants to discontinue. ***Sometimes these older drugs are discontinued by companies in favor of newer, more profitable drugs. . . .*** When one company has a problem or discontinues, it is difficult for the remaining firms to increase production quickly and a shortage occurs."³⁹

And the Institute for Safe Medication Practices (ISMP) had this to say about it:

"Regrettably, we believe the forecast for drug shortages is grim. There is little relief in sight to halt the rapid escalation of shortages in large part because the conditions that lead to shortages are varied and FDA lacks the necessary regulatory authority to proactively manage potential

shortages. It is not always clear what causes drug shortages, as drug companies are not required to disclose the underlying reason or notify FDA regarding a decision to stop production unless they are the sole-provider of the product and it is a medically necessary product. Few manufacturers will supply letters to healthcare providers regarding the reason behind the shortage and the anticipated duration, which is very frustrating to healthcare personnel.”⁴⁰

Over the years, the drug shortage has become progressively worse. Medicines used by paramedics and emergency rooms are in short supply nationwide because pharmaceutical companies have cut back manufacturing these drugs, arguing that they make little profit on them. With a low supply and high demand, big pharma is able to drive up the prices for these drugs.

Some of the most commonly used drugs in short supply are:

- Midazolam & Valium—used to treat seizures
- Morphine & Fentanyl—used to treat pain
- Zofran—used to treat nausea and vomiting
- Benadryl & Epinephrine—used to treat allergic reactions
- Mannitol—used to control pressure in patients who have head injuries

In an attempt to address the drug shortage, President Obama signed an executive order in 2011 in which he directed the FDA to prevent and reduce the number of drug shortages. Under the executive order, the Department of Justice has launched an investigation into whether these pharmaceutical companies are creating artificial shortages to illegally stockpile medications and price-gouge. If the Department of Justice finds that pharmaceutical companies are in fact creating the shortage on purpose, these companies could be subject to criminal charges and be forced to pay criminal fines.

For the complete list of drugs in short supply, visit www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.

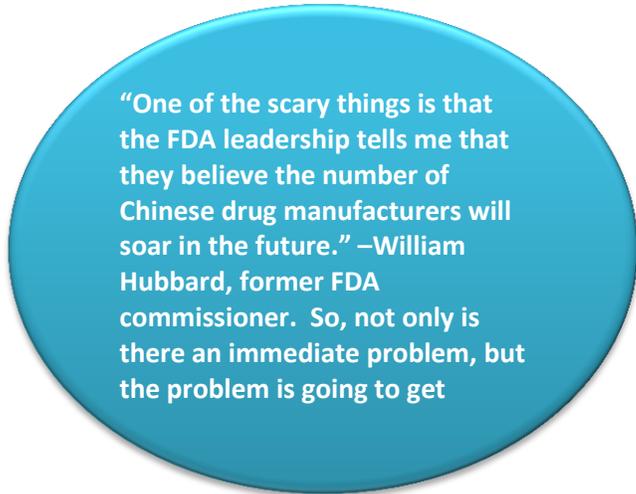
Secret #9: The quality of the prescription drugs we consume is questionable.

To prevent contamination and ensure product quality, the FDA requires companies to follow Current Good Manufacturing Practice (CGMP) regulations for manufacturing drugs. If contamination is discovered during the production of a drug, manufacturers must not distribute the product and must correct the problem using a “corrective action plan.” Sometimes, however, contamination is discovered *after* distribution. If this occurs, the FDA expects manufacturers to recall affected batches, investigate, and take measures to prevent it from happening again.

Determining whether a particular drug is contaminated is virtually impossible to tell from sight, smell, or touch alone. However, recent cases in the news tell us that pharmaceutical companies do not always follow CGMP regulations and do not voluntarily recall affected batches that have found their way onto store shelves.

Many of you will recall reading about the tainted Heparin that was finally traced to a shabby-looking shack in China where the Heparin was being manufactured. Heparin is a blood thinner derived from pig guts, widely used in surgery and dialysis, and is a mainline drug in the medical profession. The drug has been around since the 1930s, but in 2006, the drug’s basic material became contaminated by Chinese suppliers, and patients began to die.⁴¹

A Worldfocus investigation revealed flaws in the FDA’s voluntary Adverse Event Reporting System (AERS),⁴² which relies on timely notification by health care providers of unusual serious reactions to drugs. The study showed that most reports are late, incomplete, and represent only a fraction of the patients harmed. The Worldfocus investigation also highlighted the fact that China is rapidly becoming one of the world’s leading suppliers of the active pharmaceutical ingredients that make drugs work. But according to the report, China also has a “problematic record of



“One of the scary things is that the FDA leadership tells me that they believe the number of Chinese drug manufacturers will soar in the future.” –William Hubbard, former FDA commissioner. So, not only is there an immediate problem, but the problem is going to get

cutting costs by substituting approved ingredients with cheaper products that fool quality control tests—and kill patients.”⁴³

Another case involved allegedly adulterated drugs GlaxoSmithKline made at its Puerto Rico plant. The contaminated drugs involved the anti-depressant Paxil, the anti-nausea medication Kytril, and the anti-infection ointment Bactroban.⁴⁴

The Department of Justice filed charges against GlaxoSmithKline, and the case was eventually settled for \$750 million. The problems were brought to light by the former quality control manager who blew the whistle. Rather than cleaning up the problems at the factory, GlaxoSmithKline fired her.

“Adulterated drugs undermine the integrity of the FDA’s approval process, can introduce substandard or ineffective drugs on to the market and, in the worst cases, can potentially put patients’ health at risk.”

Tony West, Assistant Attorney General for the Justice Department’s Civil Division

So what was GlaxoSmithKline’s explanation for all the unnecessary deaths?

“We regret that we operated the Cidra facility in a manner that was inconsistent with current Good Manufacturing Practice (cGMP) requirements and with GSK’s commitment to manufacturing quality.”⁴⁵

Unfortunately, regret is of little comfort to the families of those who lost their lives after taking the contaminated drugs.

Secret #10: Dangerous drugs can be DEADLY.

Valid estimates of the number of injuries and deaths that prescription drugs cause each year are difficult to ascertain. One reason for this is that reporting adverse drug reactions is strictly voluntary, meaning the FDA’s own statistics are based on the good will of doctors and patients to report. Some adverse drug reactions go unreported because patients simply overlook the fact that their prescriptions are making them sick. After all, we have been taught that drugs are prescribed to help us, not to harm us.

Additionally, the reporting of adverse drug reactions does not take into account the estimated 27,000 deaths every year from accidental prescription drug overdose on drugs like painkillers, tranquilizers, sleeping pills, and muscle relaxers, which may not have been prescribed for a legitimate medical purpose.⁴⁶ In fact, drug overdose deaths from opioids (pain killers) have surpassed deaths from heroin and cocaine combined.⁴⁷ In 2009, the number of deaths due to accidental prescription drug overdoses surpassed the number of deaths due to car accidents.⁴⁸ Within the past decade, prescription drug addiction has become a national epidemic in the United States.⁴⁹

We may now spend more caring for patients harmed by their prescriptions than was spent on the prescriptions in the first place.

For more information on prescription drug addiction, pill mills, and prescription drug overdose, read my article entitled "[America's Growing Addiction](http://www.vanweylaw.com)" at www.vanweylaw.com.

Adverse drug reactions, on the other hand, are among the top 10 causes of death in the United States, accounting for at least 100,000 deaths yearly.⁵⁰ According to the most recent Adverse Drug Reaction learning module, drug-related problems cost the nation an estimated \$136 billion each year.⁵¹ That cost was for emergency room visits, hospital stays, nursing home care, and other expenses incurred by those hurt or killed by prescription drugs.⁵² But note that this study did not include the cost of caring for patients harmed by drugs they received in the hospital, which is estimated to have added tens of billions of dollars to the estimate.⁵³ In comparison to the \$307 billion Americans spent on prescription drugs in 2010, our nation spends more than a third of that total on caring for patients who have had adverse reactions to those prescriptions.⁵⁴

Looking at individual drugs, we can see the damage that has been caused. Vioxx alone was responsible for an estimated 100,000 deaths.⁵⁵ Avandia has been linked to causing at least 83,000 heart attacks, and some estimate that the number of deaths from Avandia will top the carnage of Vioxx.⁵⁶

Aside from deaths, prescription drugs have been linked to severe and sometimes permanent injuries. For example, the popular antibiotic Levaquin has been linked to spontaneous tendon ruptures. The popular birth control pills Yaz, Yasmin, and Ocella have been linked to stroke and

pulmonary embolism. Widely used selective serotonin reuptake inhibitors (SSRIs), which are antidepressants that include Paxil, Lexapro, and Zoloft to name a few, have been linked to severe birth defects. Anticoagulant Pradaxa has caused more than 260 deaths worldwide due to uncontrollable internal bleeding. And finally, diabetes drugs Actos, Byetta, Januvia, and Janumet have been linked to an increased risk of various forms of cancer, including bladder cancer, pancreatic cancer, and thyroid cancer.

The next section of this book focuses on case studies of the above-mentioned drugs and other drugs that have been found to be dangerous over the years.

DANGEROUS DRUGS that Have Been Pulled Off the Market

The FDA has come under criticism lately for approving drugs before they have been completely tested. Time and again we have seen drugs being pulled off the market because the FDA later determined that the risks outweighed the benefits. Below are some examples of drugs the FDA approved, but were later found to cause injuries to consumers.

Avandia

Avandia is a popular medication manufactured by GlaxoSmithKline to treat type-2 diabetes. Annual sales of the drug peaked at approximately \$3.2 billion in 2006, but declined after reports of adverse effects.⁵⁷

On February 10, 2010, the U.S. Senate issued a report stating that GlaxoSmithKline (GSK) knew of the possible heart attack risk tied to Avandia years before the news became public.⁵⁸ Two U.S. Senators have also asked the FDA to explain why it allowed clinical trials of Avandia to continue, even after the FDA estimated that Avandia caused 83,000 heart attacks between 1999 and 2007.⁵⁹ In 2007, the FDA voted eight to seven to allow Avandia to remain on the market, but required GSK to add a warning to its label, advising patients that Avandia may increase the risk of heart attacks. Hundreds of thousands of Americans continued to take the drug and hundreds continued to have heart attacks and die.

Finally, in 2010, the FDA restricted Avandia prescriptions by allowing patients access to the medicine only if they had tried every other diabetes medicine and had been made aware of the risks.



Dr. Sidney Wolfe

Of the FDA's lack of action regarding Avandia, Dr. Sidney Wolfe, director of the Health Research Group at Public Citizen, said:

"The failure of the FDA to act on the recommendations made almost five years ago by its Division of Drug Risk Evaluation is yet another case in which **the conclusions of**

scientists who are engaged in post-market drug safety review are not taken seriously enough or addressed soon enough. As a result, *millions of people—to the detriment of their health—are prescribed drugs whose risks are dangerously understated*, instead of being prescribed safer, equally or more effective alternative drugs."⁶⁰

The former deputy director of the FDA's Division of Drug Risk Evaluation, Rosemary Johann-Liang, has said that she was verbally reprimanded by her superiors when she recommended that Avandia be labeled with a "black box" warning about congestive heart failure.⁶¹ Johann-Liang has criticized the FDA for demanding a higher standard of proof in showing that a drug is unsafe than it requires to prove that a drug is effective. She revealed that the FDA is very resistant to hearing that there might be risks associated with a drug. "I really advocate for drug safety, and a lot of times the agency doesn't want to hear that there are problems. I think, in general, there is a culture of 'The drug is always innocent,'" said Johann-Liang in an interview.⁶²

Darvon & Darvocet

Darvon, first approved for sale in the United States in 1957, is also sometimes combined with a dose of acetaminophen and marketed under the name Darvocet. The generic version is known as Propoxyphene. This 55 year-old drug has long had a bad reputation for its poor pain killing qualities, potential for addiction, and toxicity. However, it continued to be one of the most widely prescribed drugs in this county until 2010.

Darvon, Darvocet, and Propoxyphene have been associated with more than 2,000 accidental deaths in the United States since 1981.⁶³ A large proportion of these deaths were caused when the drug self-converted into a metabolite that is highly toxic to the heart and lasts longer in the body than the original compound, resulting in cardiac depression.

Adverse cardiac events associated with Darvon include an interruption of the heart's transmission of electrical impulses, slowed heartbeats, and a decreased ability of the heart to contract properly. Toxicity can develop at recommended dosage levels, meaning when the drug is taken as prescribed.

In response to the adverse events reported by patients taking Darvon, the FDA commissioned an expert panel to study all drugs containing

Propoxyphene. On January 30, 2009, the panel recommended that the FDA **ban** the drugs. The committee advised the FDA that Darvon, Darvocet, and Propoxyphene had been linked to thousands of deaths and that any benefit the drugs might have had in relieving pain was outweighed by the considerable risk the drugs posed. However, the FDA chose to ignore the advice of its own committee and instead instructed the manufacturer to issue a stronger warning about the drugs' side effects.

Finally, on November 17, 2010, the FDA issued a recall of the drugs, concluding that all painkillers containing Propoxyphene present an unreasonable risk to their users. Manufacturer Xanodyne Pharmaceuticals was instructed to stop selling the drug. Generic manufacturers were also expected to voluntarily stop production of the drugs, but from my research, I have found that the following drugs that contain Propoxyphene are still being sold, largely on the Internet:

- Balacet, Dolene, E-Lor, Genagesic, PC-Cap, Propacet, SN-65, Trycet, Wygesic

In the meantime, experts estimate that thousands of people have died unnecessarily and will continue to die due to abnormal electrical disturbances of their hearts, leading to cardiac arrhythmia, heart attack, and sudden death.

The Sad Saga of Darvocet

In 2011, the U.S. Supreme Court handed down an opinion in *Pliva v. Mensing* that ultimately resulted in the end of all Darvocet cases. An order issued by a Kentucky federal judge dismissed with prejudice 34 claims against various manufacturers, explaining that the claims had been preempted by *Pliva v. Mensing*, which holds that federal law preempts state laws that impose a duty on the generic drug manufacturers to change a drug's label, warning consumers of dangerous side effects. In other words, generic drug manufacturers do not have to update their drug labels if the FDA requires the original manufacturer to update the original drug label.

Because of this pharma-friendly Supreme Court opinion, hundreds of injured patients and their families have essentially been left to pay the bill for injuries they suffered because of generic Darvon drugs.

Vioxx

Vioxx was a widely popular rheumatoid arthritis painkiller. In 2004, Merck pulled Vioxx off the market after concerns about the drug's tendency to cause heart attacks, strokes, and blood clots surfaced. Later evidence showed that Merck had known about the dangers Vioxx posed before it pulled the drug off the market.

Merck's sly marketing techniques and commercially funded studies kept Vioxx on the market longer than it should have been. In fact, doctors in the United States prescribed \$7 billion worth of Vioxx, thinking it was safer for patients than similar drugs available on the market.⁶⁴ Researchers estimate that Vioxx caused upwards of 144,000 cases of heart disease.⁶⁵ An estimated 80 million patients took Vioxx while it was on the market.⁶⁶

Sales representatives for Merck were told not to bring up negative findings of studies relating to the use of Vioxx when speaking with doctors. If the doctors questioned the studies, sales representatives were told to direct any questions to Merck's headquarters and to stick to the information contained on the drug's label.

Merck ultimately pled guilty to a criminal charge that it illegally marketed Vioxx and agreed to pay a \$950 million criminal fine.⁶⁷

Criminal & Civil Penalties Paid by Big Pharma

Over the past two years, record settlements have been reached between federal and state governments and pharmaceutical companies for violations of the Food, Drug, & Cosmetic Act and other laws that regulate prescription drugs. A total of \$10.2 billion in financial penalties have been imposed on pharmaceutical companies, but this is still only a fraction of the yearly profits these large companies make.

(Source: Sammy Almashat, M.D. & Sidney Wolfe, M.D., [Pharmaceutical Industry Criminal and Civil Penalties: An Update](http://www.citizen.org/hrg2073), Public Citizen (Sept. 27, 2012), <http://www.citizen.org/hrg2073>.)

DANGEROUS DRUGS Still on the Market

The following chapter is intended to be a general discussion of some of the drugs that have been the subjects of lawsuits, FDA scrutiny, and/or have been pulled from the market. Pharmaceutical drugs are often quickly approved by the FDA only to find in later studies that the drugs are harmful. If you are taking any of the following drugs, you should know the dangerous risks that come with them and what to do if you are taking these drugs.

Actos Linked to Bladder Cancer

In August 2011, the FDA released a new warning that the popular diabetes drug Actos increases a patient's risk of developing bladder cancer. The warning came after the FDA analyzed five years of data from an Actos safety study. The data is part of a 10 year study, but the FDA found cause for concern when it determined that the risk of bladder cancer was 40 percent higher for patients who had been taking Actos for a year or longer. By that time, France had already suspended the use of Actos, and Germany had restricted Actos prescriptions, not allowing new patients to be put on the drug.

Actos, generic name pioglitazone, is a thiazolidinedione used to treat type-two diabetes by increasing the body's sensitivity to insulin to help control blood sugar levels. When Actos was first introduced on the market, doctors praised the drug for its ability to control blood sugar, boost the effectiveness of other diabetes drugs, and allow patients to reduce their number of daily insulin injections.

Takeda Pharmaceuticals, the maker of Actos, saw a huge increase in its profits after another popular diabetes drug, Avandia, was banned in the European Union and restricted in the United States. In 2006, sales of Actos totaled \$2.9 billion, but rose to more than \$4.3 billion in 2010, making Actos the world's best-selling diabetes drug.⁶⁸ Between January 2010 and October 2010, an estimated 2.3 million patients filled prescriptions for Actos and other prescriptions containing pioglitazone.⁶⁹

The most common symptoms associated with bladder cancer include blood in the urine or red-colored urine, an urgent need to urinate or pain urinating, and pain in the back or lower abdomen. The FDA recommends that patients who take Actos and experience any of these symptoms contact their health care provider immediately. Bladder cancer can spread to nearby body parts, including the prostate, rectum, ureters, uterus, and vagina. Other symptoms of bladder cancer include the following:

- Abdominal pain
- Bone pain or tenderness
- Fatigue
- Urine leakage
- Weight loss

The FDA has stated that patients currently taking Actos should continue to take the drug until advised otherwise by their health care provider. If you are taking Actos and are experiencing adverse side effects, you should speak with your doctor immediately. Other medications that contain pioglitazone include Actolus and Duetact.

Chantix Linked to Violent Outbursts & Cardiac Events

Approved by the FDA in 2006, Chantix was touted by its maker Pfizer as a miracle drug that would help smokers kick the highly addictive habit. Since then, patients taking the pill have reported experiencing adverse cardiac events, violent disturbances or outbursts, and even loss of consciousness.

Sales of Chantix topped \$755 million in 2010, and more than 13 million people have taken the drug.⁷⁰ Despite knowing the risks associated with Chantix, the FDA declined to issue a warning to doctors and patients in 2006, arguing that the data from studies conducted at the time was too inconsistent to warrant a warning label.

But recent studies have shown that patients taking Chantix who have never had heart disease are at a 150 percent increased risk of experiencing an adverse cardiac event.⁷¹ This is troublesome, especially because Chantix is supposed to help people quit smoking, reducing their chances of experiencing adverse cardiac events.

In 2009, the FDA finally issued a black box warning to patients and doctors regarding the risk of developing depression and thoughts of suicide while taking Chantix. Hundreds of lawsuits have been filed against Pfizer for injuries patients sustained while experiencing psychotic episodes linked to taking Chantix. Pfizer has denied that its drug caused any of these injuries.

Fosamax & Other Bisphosphonates Linked to Femur Fractures

More than five million women in the United States take Fosamax to maintain bone strength and prevent bone fractures. But when taken for extended periods, the drug has the potential to cause more bone damage rather than prevent it. The FDA became concerned about the long-term safety of Fosamax after receiving numerous reports about low-trauma femur fractures, bone infection, and bone death in patients taking the drug. Many of these patients had been taking the drug for more than five years, but some had taken it for as few as three years.

Fosamax is in a class of drugs known as bisphosphonates, which are used to treat and/or prevent osteoporosis, or a weakening of the bones. Other drugs that have been linked to femur fractures include Actonel, Boniva, Reclast, Aletvia, and generic Alendronate.

The femur or thigh bone is the longest and strongest bone in the human body. Usually, a high energy impact, like a high-speed car crash, is required to break the femur. However, sudden low-impact breaks of the femur have been reported in women who take Fosamax for a period of three years or longer. Many women who experienced a femur fracture while on Fosamax were doing activities as simple as stepping off a curb.

Two types of femur fractures associated with Fosamax are:

- Subtrochanteric fracture—this type of fracture involves the part of the femur that sits just below the hip joint. Sometimes these fractures extend down the shaft of the leg, causing further injury.
- Diaphyseal femur fracture—this is a fracture of the thigh area.

Unfortunately, these are not simple fractures, but they occur while the victim is doing an every-day activity. Often, Fosamax femur fractures require surgical treatment with a typical recovery period of three to six

months, depending on the severity of the fracture. And a Fosamax patient's likelihood of suffering another fracture is great.

The FDA recently recognized the link between Fosamax and femur fractures and has acted to strengthen the language on the drugs' warning labels. But critics argue that the warnings do little to inform patients of the risk.

If you are currently taking a bisphosphonate like Fosamax, the FDA advises that you continue to take the drug unless you are told to discontinue its use by your health care provider. Often, these femur fractures occur without warning. But if you experience a new hip or thigh pain, the FDA advises that you consult your health care provider.

Byetta, Januvia, and Janumet Increase the Risk of Pancreatic Cancer

More than 366 million people suffer with diabetes daily. That number has more than doubled since 1980 and is expected to grow to 438 million by 2030. As more people are diagnosed with diabetes, the pharmaceutical industry continues to invest in developing medications to treat this chronic disease. The cost of treating diabetes is estimated at \$465 billion each year,⁷² so it's no wonder that pharmaceutical companies are attempting to break into this market with more innovative treatment options.

When insulin was first introduced on the market as a treatment for diabetes, it was a great innovation that saved many lives. Today, pharmaceutical companies have tapped into the diabetes drug market with newer drugs that promise fewer injections and other rewards like weight loss. However, some research suggests that these drugs increase the risk that a patient will develop pancreatic cancer.

Byetta

Byetta is an incretin mimetic, which works by slowing the elimination of stomach contents, thereby slowing the rate that nutrients are absorbed into the bloodstream. Approved in 2005 for the treatment of type-2 diabetes, Byetta also stimulates the pancreas to secrete insulin when blood sugar levels are abnormal. Post-marketing studies conducted on Byetta have revealed reports of life-threatening pancreatic disorders, including acute pancreatitis, which can lead to pancreatic cancer.

Januvia

Januvia is a dipeptidyl peptidase-4 inhibitor, which increases the amount of insulin produced and secreted by the pancreas when blood sugar levels are high. Januvia also reduces the amount of glucose produced by the liver. Approved in 2006 for the treatment of type-2 diabetes, Januvia has recently been linked to pancreatic cancer. The FDA has received adverse event reports for patients taking Januvia, including reports of acute pancreatitis resulting in death.

Janumet

Janumet is a combination of Januvia and diabetic drug metformin. The two drugs work together to stimulate the pancreas to secrete insulin when blood sugar levels are high. Janumet was recently approved in 2012.

These drugs continue to be heavily marketed to consumers as the rates of type-2 diabetes cases across the world, and especially in the United States, continue to increase.

Pradaxa Linked to Fatal Internal Bleeding

Pradaxa, generic name dabigatran, is a relatively new blood thinner that was approved in October 2010 to reduce the risk of stroke and blood clots in patients who suffer from non-valvular atrial fibrillation. Less than one year after being approved, Pradaxa had already been prescribed to 371,000 patients, and more than 1.1 million prescriptions had been filled for the drug.⁷³

On December 7, 2011, the FDA issued a safety communication regarding Pradaxa, warning that some patients have reported experiencing serious bleeding events while on the drug. Manufacturer Boehringer Ingelheim has acknowledged that as many as 260 deaths worldwide have been linked to severe bleeding caused by Pradaxa.

A study recently published in the *Journal of the American College of Cardiology* suggests that Pradaxa is more dangerous than its older counterpart, Warfarin. After following 290 patients for a year, half of them taking Pradaxa, and half of them taking Warfarin, researchers concluded that Pradaxa significantly increases the risk of bleeding or thromboembolic complications compared to Warfarin. Overall, the patients taking Pradaxa were more likely to experience a high rate of internal bleeding.

The extent of the drug's dangerous propensities is still largely unknown because few studies have been conducted on the drug. But many doctors have found that they can do little to treat patients who experience sudden catastrophic bleeding while taking Pradaxa, because the drug has no known antidote. Critical care surgeon Dr. Bryan Cotton recently wrote a letter to the *New England Journal of Medicine*:

"We have noted on multiple occasions patients who have 'bleeding out' from Pradaxa and our hands are tied. **They're bleeding out all over and there's absolutely nothing we can do about it.** I'm helpless when it comes into my emergency room."⁷⁴

Certain Anti-Depressants Linked to Birth Defects (Selective Serotonin Reuptake Inhibitors—SSRIs)

SSRIs are used to treat moderate to severe depression. Popular brands of the drugs include Celexa, Lexapro, Paxil, Prozac, Symbyax, and Zoloft. These drugs adjust the amount of serotonin released in the brain, helping brain cells to send and receive chemical messages.

In some cases, women who have used SSRIs while pregnant have given birth to children with birth defects, including serious heart defects. Common birth defects in children whose mothers took SSRIs while pregnant include:

- **Craniosynostosis:** a birth defect in which the child's skull stops growing before the child's brain has completely developed. This puts increased pressure on the child's skull and can inhibit developmental growth of the brain.
- **Omphalocele:** a birth defect in which the intestines or other organs located in the abdomen of the infant stick out of the belly button. This often occurs in conjunction with other birth defects.
- **Anencephaly:** a type of neural tube birth defect in which the infant is born lacking a large part of his brain and skull. This is a fatal birth defect, often taking the infant's life within days of being born.
- **Atrial septal defect:** a heart defect in which the wall separating the upper chambers of the heart fails to close. Symptoms associated with this defect may not appear until later in the child's life, but can cause atrial fibrillation, heart failure, and stroke, among other conditions.

- **Ventricular septal defect:** a heart defect in which one or more holes forms in the heart wall separating the right and left ventricles. If the hole is large enough, the infant will exhibit symptoms of heart failure.

Additionally, children whose mothers took an SSRI while pregnant may be born with persistent pulmonary hypertension. Babies with persistent pulmonary hypertension usually exhibit symptoms that include rapid breathing, rapid heart rate, bluish skin, difficulty breathing, heart murmurs, and low blood oxygen levels. Although this is usually caught early, an estimated 10 to 20 percent of babies born with this die, even if they have received treatment.

SSRIs have also been linked to causing autism, and recent studies suggest that children born to mothers who took SSRIs while pregnant were two times more likely to have autism spectrum disorder.

Below are two examples of SSRIs that have caused debilitating, even fatal birth defects.

Paxil Linked to Birth Defects & Increased Suicide Risk

Paxil is the trade name of the antidepressant medication paroxetine hydrochloride, which is manufactured by GlaxoSmithKline. The oral medication has been on the market since 1992 and is often prescribed to treat depression, anxiety disorders, obsessive-compulsive disorders, post-traumatic stress disorders, and even premenstrual dysphoric disorder.

Unfortunately, Paxil has been associated with birth defects when expectant mothers were prescribed the medication. The FDA has published the following health advisory regarding the active ingredient in Paxil:

“The FDA has determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA’s request, the manufacturer has changed paroxetine’s pregnancy category from C to D and added new data and recommendations to the WARNINGS section of paroxetine’s prescribing information. FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to

better characterize the risk for congenital malformations associated with paroxetine.

Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician.”⁷⁵

Some of the heart-related birth defects that may be associated with the use of Paxil include holes in the heart, abnormal vessel arrangement, abnormal structure of the heart, and duplication of some heart structures. Pharmaceutical companies like GlaxoSmithKline have a duty to disclose risks of medications that they know, or should know, have the propensity to cause serious injury. Lawsuits have been filed against GlaxoSmithKline across the country alleging that GlaxoSmithKline did not act properly in informing the public of the risks of taking Paxil and that the product caused consumers injuries.

Paxil has also been linked to an increased risk of suicide in young patients. Currently, Paxil is approved for use in adults for the treatment of panic disorders, obsessive-compulsive behavior, social anxiety disorder, and generalized anxiety disorder. The drug has not been approved for use in patients under the age of 18 years, but doctors have prescribed it to these patients. There is no evidence that Paxil is effective in children or adolescents with major depressive disorder.

The FDA is reviewing reports of a possible increase in the risk of suicide in children and adolescents under the age of 18 when prescribed Paxil. The FDA recommends that Paxil not be used in children and adolescents for the treatment of major depressive disorder.

In April 2004, two U.S. Congressmen, Joe Barton and James Greenwood, released a letter they received entitled “Number of US Citizens at Risk to SSRIs.” The letter can be found in its entirety at the following address: www.ahrp.org/risks/aldred0404.php. The author of the letter, Graham Aldred, concludes that **at least 21,000 suicides may be linked to the**

use of SSRIs, including Paxil. He also explains that almost six billion Paxil tablets were taken in the ten year period preceding the publication of the letter.

Pharmaceutical companies are required to perform safety studies on medications that they wish to sell in the United States. Unfortunately, not all studies performed by these companies are reliable. In a disturbing article entitled “Cover Up? Paxil and Suicide Risk” published by *World of Psychology*, the author specifically states that **GlaxoSmithKline covered up and obscured evidence that the drug Paxil was eight times more likely than a placebo (a sugar pill) to cause suicide.** The article goes on to state:

“In other words, *some pharmaceutical companies go to great lengths to ‘stack the deck’ to ensure that when the study begins, they get the best results possible.*”⁷⁶

Some evidence also suggests that there is a link between Paxil and suicidal behavior in adults. In a lawsuit filed in Wyoming, the plaintiffs alleged that Donald Schell killed his family and committed suicide while on Paxil. The jury found a link with Schell’s violent outburst to Paxil and awarded \$8 million to his surviving relatives.⁷⁷

Zoloft Linked to Birth Defects

Zoloft is an SSRI that easily passes through an expectant mother’s placenta into the developing fetus. Common birth defects in babies whose mothers took Zoloft while pregnant include atrial septal defect, ventricular septal defect, and unspecified congenital cardiac malformation.

Recent studies suggest that Zoloft increases the risk of a child being born with these defects by three times. Mothers who took this drug for longer periods of time while pregnant were more likely to have babies born with these birth defects.



The Placebo Effect—Are Anti-Depressants Really Effective?

Nearly 17 million people in the United States take antidepressants, earning the pharmaceutical industry \$11.3 billion each year in sales of antidepressants alone.⁷⁸ Since Prozac was approved in 1980 to treat depression, sales of antidepressants have increased 400 percent.⁷⁹

In a recent interview with *60 Minutes*, psychologist and Associate Director of the Placebo Studies Program at Harvard Medical School, Irving Kirsch, argued that antidepressants are no more effective than placebo pills.⁸⁰ The placebo effect is “the taking of a dummy pill without medication in it that creates an expectation of healing that is so powerful, symptoms are actually alleviated.”⁸¹ And Kirsch says that depression isn’t the only disease or ailment that the placebo effect can cure. In fact, he says studies have shown that placebos are effective when used in the treatment of ulcers, Parkinson’s disease, and even in knee surgery.⁸²

The FDA evaluates the safety and efficacy of antidepressants by requiring companies to show that the drugs are more effective than placebos in at least two clinical trials. This means that even if a drug failed to be more effective in other trials, as long as two of any of the trials were found effective, then the drug is approved. And Big Pharma has tried to conceal studies that have found negative results by making the studies “unpublished.”⁸³

Big Pharma has spent millions convincing consumers via television advertisements that antidepressants will make them feel better if they are feeling down and out. And Big Pharma has been wildly successful at selling these drugs. But are these drugs really safe, or do they just lead to more side effects, causing people to consume more of Big Pharma’s other products?

Topamax

Although Topamax (generic name Topiramate) is approved to treat epilepsy and migraines, in recent years doctors have prescribed it for off-label purposes, like for the treatment of bipolar disorder and more recently weight loss. Doctors can prescribe drugs for off-label uses (i.e., uses not approved by the FDA), but pharmaceutical companies cannot market any

drug for off-label uses. This is exactly what Johnson & Johnson, the manufacturer of Topamax, did in 2010. Johnson & Johnson was charged with and pled guilty to one count of a misdemeanor violation of the Food, Drug & Cosmetic Act for illegally marketing Topamax and faced millions in criminal fines.

Between 2007 and 2010, an estimated 32 million people filled prescriptions for Topamax, making it one of the most widely-prescribed anticonvulsant drugs on the market, especially for women of child-bearing age. Women are three times more likely to suffer from migraines, especially in their child-bearing years, which makes Topamax a popular choice.

Topamax has been shown to cause serious birth defects in children born to mothers who took the drug while pregnant. Often, women taking Topamax do not know they are pregnant until after they have been taking the drug for some time. The most common birth defects reported are cleft palates, cleft lips, and hypospadias, a male genital defect.

Of infants exposed to Topamax in the first trimester, 1.4 percent developed oral clefts. This is relatively high, compared to the number of infants exposed to other antiepileptic drugs, of which an estimated 0.38-0.55 percent had a chance of developing an oral defect. For this reason, the FDA raised the risk level of Topamax from a category C to a category D, meaning there is a risk to the fetus based on human data.

FDA Pregnancy Category Definitions

Category	Definition
A	Adequate and well-controlled (AWC) studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters).
B	Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no AWC studies in humans, AND the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks OR animal studies have not been conducted and there are no AWC studies in humans.
C	Animal reproduction studies have shown an adverse effect on the fetus, there are no AWC studies in humans, AND the

	benefits from the use of the drug in pregnant women may be acceptable despite its potential risks OR animal studies have not been conducted and there are no AWC in humans.
D	There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, BUT the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective).
X	Studies in animals or humans have demonstrated fetal abnormalities OR there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, AND the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).

*Source: Questions and Answers: Risk of Oral Clefts (Cleft Lip and/or Palate) in Infants Born to Mothers Taking Topamax (Topiramate), U.S. FOOD & DRUG ADMIN. (Mar. 7, 2011), <http://www.fda.gov/Drugs/DrugSafety/ucm245470.htm#table>.

Infants with cleft lips and palates struggle with eating, chronic ear infections, hearing loss, language delay, and misaligned teeth. Male infants born with hypospadias may have to undergo several surgeries to correct the problem and can suffer from the defect well into adulthood.

The FDA has warned doctors against prescribing the drug to women of child-bearing age, unless other treatments have failed.

Yaz & Yasmin

Yaz and Yasmin are hormonal birth control drugs manufactured by Bayer. The generic forms of these pills contain drospirenone (dro-SPY-re-known) and ethinyl estradiol (ETH-in-il, ESS-tra-dy-ol), which researchers have linked to an increased risk of blood clots, heart attacks, and stroke. Women have reported experiencing adverse events after using Yaz, including heart attack, cardiac arrhythmia, stroke, pulmonary embolism (a

clot in the lung), other blood clots, kidney failure, seizures, deep vein thrombosis, gallbladder disease, hepatic adenomas, and even sudden death.

In 2006, Bayer acquired Berlex Labs, the developer and original manufacturer of Yaz, and began marketing the product as a “different type of birth control pill.” Bayer claimed that Yaz helped treat emotional and physical symptoms of Premenstrual Dysphoric Disorder (PMDD) and at the same time significantly cleared outbreaks of acne. At one time, Yaz was the top-selling birth control pill in the United States. In 2008, Yaz generated more than \$600 million in sales in the United States alone.⁸⁴ But in 2010, Bayer reported a 10 percent drop in Yaz sales amid growing concerns over the drug’s safety.⁸⁵

Bayer marketed Yaz with the implication that it could also be used to treat PMS symptoms and even acne breakouts. However, the FDA had not approved Yaz for these uses and began investigating Bayer’s claims. The FDA subsequently sent Bayer a warning letter in which it warned the company that Yaz advertisements had overstated the benefits of the pill.

In early 2009, Bayer agreed to submit any television advertisements for Yaz to U.S. regulators for approval and also agreed to conduct a \$20 million advertising campaign to correct its previous advertisements. The agreement came in addition to a court-entered judgment that resolves allegations that Bayer's 2008 marketing of Yaz violated the terms of a 2007 agreement by not disclosing the uses for which Yaz had been approved by the FDA. More than 20 states took part in the action against Bayer.

Other birth control pills that contain drospirenone include Beyaz, Ocella, Gianvi, Loryna, Safyral, and Zarah. These pills have also been associated with dangerous side effects.

Victoza Linked to Thyroid Cancer

Millions of Americans are suffering with diabetes, the complications of which include stroke, heart disease, high blood pressure, blindness, and kidney disease, among other things. Pharmaceutical companies are rushing to develop drugs that “help people control” their diabetes, ultimately sacrificing patient safety in the process. Victoza (generic name

liraglutide) is another drug in a long line of “lifestyle” drugs, or drugs that allow consumers to continue with their unhealthy lifestyles, thinking that a drug will counteract all of bad things they put in their bodies.

On the market since 2010, Victoza is intended to treat type 2 diabetes. But just a year later, the FDA announced that Victoza may increase the risk of thyroid cancer and pancreatitis. Based on evidence that Victoza causes thyroid cancer, the FDA required maker Novo Nordisk to add a warning on the drug’s label that patients with a family history of thyroid cancer should not be prescribed Victoza.

Consumer advocacy group Public Citizen has filed a petition to take Victoza off the market because of the high risks of thyroid cancer and kidney failure. The group believes that the benefits of Victoza are outweighed by its safety concerns. Dr. Karen Mahoney of Public Citizen says “the need for new therapies for type 2 diabetes is not so urgent that one must tolerate a significant degree of uncertainty regarding serious risk concerns.”⁸⁶ Even though safer alternative treatments are available, an estimated 150,000 Victoza prescriptions are filled each month, which adds up to two million prescriptions each year.⁸⁷

Symptoms of thyroid cancer can vary because of the different types of thyroid cancer, but some of the most common symptoms are:

- Coughing
- Difficulty swallowing
- An enlarged thyroid gland
- Hoarseness or a changing voice
- Swelling in the neck
- A lump on the thyroid

With more Americans expected to develop diabetes in the coming years, there is no doubt that the incidence of adverse side effects from diabetes drugs like Victoza will also increase. Drugs similar to Victoza that carry similar adverse side effects include Byetta and Januvia, both of which increase a patient’s risk of developing pancreatitis and either pancreatic cancer or thyroid cancer.

The Paula Deen Principle: Don't Worry, We Have a Pill for That



When Paula Deen announced earlier this year that she had diabetes, few people were shocked, especially those who are familiar with her high sugar, high fat recipes. But news that she had teamed up with pharmaceutical company Novo Nordisk to promote its diabetes drug Victoza did shock some who felt Paula had sold out.

Like other fans of Paula, I was disappointed and looked more closely at why drug companies feel they must team up with celebrities, and here's what I found:

The Gen X and Gen Y kids have grown up being fed a steady diet of pharmaceutical company ads, sending the message that drugs are good and that a little pill will cure us of our ailments. We are being trained by these pharmaceutical companies and their Madison Avenue advertising agencies to eat whatever we want, including that high fat cheeseburger; after all, we have a pill to lower cholesterol. And if you develop diabetes, it isn't a death sentence. We have pills for that.

While I am truly sorry to hear about Paula's diagnosis, I can't help but be disappointed in the fact that she has teamed up with a pharmaceutical company to market drugs for people to rely upon, instead of focusing more on helping people lead healthier lives.

Determining a Legal Claim for a Dangerous Drug

Depending on the extent of your injuries, you may be entitled to compensation for the following: medical bills, future medical expenses, lost income, lost earning capacity, pain and suffering, and wrongful death.

The Role of Lawyers & Lawsuits

Thanks to some powerful media campaigns and political agendas, personal injury lawyers have become reviled. Sure, there are a few bad apples in every profession. Some engage in tacky advertising, and a few became the subjects of widely publicized cases that made consumers believe there is a lawsuit crisis in America. The truth is that hard-working and dedicated trial lawyers have led the charge on holding pharmaceutical companies liable for peddling dangerous drugs to unsuspecting consumers.

Unfortunately, much has been done to try to limit the power of trial lawyers. So-called “tort reform” has been aimed at curtailing lawsuits. Friends of Big Pharma have tried to expand the role of federal pre-emption to prevent trial lawyers from suing manufacturers of dangerous drugs. However, we continue to fight the good fight.

In my 29 years as a trial lawyer, I have observed that it is easy to ridicule trial lawyers until you need one. Many of my clients over the years have actually voted for politicians or supported legislation to limit their own right to sue. But only when they or a loved one were injured or killed by negligence or a defective drug did they realize how important their rights really are.

When the hands of the trial lawyers are tied, we are inviting greed-driven corporations to put profits over patient and consumer safety. Unfortunately, we cannot rely on our government to keep us safe. The reality is that hitting these wrongdoers where it counts (in their pocketbooks) is sometimes the only effective weapon we have to keep them honest.

Special Report—America's Growing Addiction

When we think of prescription drugs, we may conjure up a picture of a person leading a happier, more healthful life thanks to a tiny miracle pill. At least, this is what the drug companies portray in their advertisements. According to the "real patients" on TV, we too can enjoy more pain-free mornings, walks on the beach, and time with the grandkids.

Why are consumers so trusting of major pharmaceutical companies? After all, despite showing the so-called "fabulous" lives led by actors portrayed in their advertisements, pharmaceutical companies are required to disclose the known side effects at some point in the advertisement. We hear it all the time on TV: "XYZ drug has been shown to cause muscle pain, heart attacks, suicide, strokes, liver failure, kidney failure," and the list goes on.

[Yet every year, consumers continue to pay billions for pharmaceutical drugs that could potentially harm them.](#)

The Stigma of Addiction

In addition to all of the side effects that you can potentially experience from taking these drugs, some of the drugs are also highly addictive. [Prescription drug addiction](#) in the United States is rarely talked about outside the realm of reality show housewives and out-of-control stars trying to make sense of their fame.

Addiction to prescription drugs runs much deeper and affects the lives of those around us, even though we may not know it. In fact, within the past decade, hospitalizations due to overdoses on prescription drugs have increased five times over, and deaths caused by overdosing on prescription drugs have nearly quadrupled.⁸⁸

Dr. Nora D. Volkow, head of the National Institute on Drug Abuse (NIDA), has dedicated her entire career to studying addiction. Based on her research, she has found that doctors who prescribe powerful pain medications understand little about pain control. Combine this with

pressure from sales people hired by major pharmaceutical companies to push these strong medications, and you have a recipe for disaster.

These pain killers are some of the most addictive prescription drugs available on the market. And "physicians are the nation's pushers," says Volkow.⁸⁹

In 2010 alone, more than 200 million prescriptions were written for these potentially addictive pain medications. Yet, there is no evidence that these drugs are medically necessary for all patients or that they actually help patients with chronic pain. Rather, the higher the dosage prescribed to the patient, the higher the risk that a patient will suffer an overdose and possibly even die from that overdose.⁹⁰



Addiction is a Brain Disease

Another issue Dr. Volkow has been dealing with is a stigma towards addiction. Addiction is a disease that affects the human brain and behavior, to the point that a person's intake of drugs is out of control.

Scientists have been studying addiction since the 1930s. Some have characterized addiction as a moral failing and have taken punitive rather than therapeutic actions in an attempt to rid patients of addiction. When punitive actions fail to address the problem, doctors often dismiss addicts as hopeless causes and menaces to society.

Dr. Volkow has been working diligently to try to change this view of addiction. According to Dr. Volkow, "drug addiction is a brain disease that can be treated."⁹¹ Initially, people take drugs voluntarily, but scientists have found through brain imaging studies that addicts have physical changes in the areas of their brains that relate to judgment, decision making, memory, learning, and control. The culprit for this change is dopamine. Dopamine is a chemical in our brains that regulates our reward system, thereby motivating future behavior. All drugs activate this system, creating a chemical issue in some.

Dr. Volkow is quick to point out that addiction is not a moral weakness, but rather is a chemical change in the makeup of a person's brain. She believes that to help those addicted to prescription drugs, we must first change the perception of addiction. In other words, addiction needs to be recognized as a medical problem, not a willpower problem.

Addiction is Expensive

Experts estimate that addiction costs the United States nearly a half a trillion dollars every year. Since 1990, the number of deaths due to overdosing on prescription drugs has increased to more than 27,000 deaths in 2007. Within the past decade, deaths related to overdoses of prescription pain killers have skyrocketed from fewer than 4,000 in 2000 to more than 11,000 in 2007.

An Addiction Epidemic

According to the U.S. Centers for Disease Control & Prevention (CDC), "[t]he United States is experiencing an epidemic of drug overdoses."⁹² Emergency room visits due to overdoses doubled over a five year period (2004-2009) to 1.2 million.

In response to these grim statistics, the Obama Administration has launched its plan to address prescription drug abuse, entitled Endemic: Responding to America's Prescription Drug Abuse Crisis. Under the plan, manufacturers must comply with a risk evaluation mitigation strategy to educate patients about the safe use, storage, and disposal of these medicines.

Dr. Volkow is approaching the problem by addressing both the lifesaving capabilities of these drugs and the dangerous qualities they possess. Of balancing the two, Dr. Volkow says "we need to address the needs of patients in pain, while protecting those at risk for substance use

disorders."⁹³ While she knows this will not be easy, she has the advantage of science on her side to show that the problem of addiction is medical, not moral.

To treat addiction, Dr. Volkow is starting at the source, with the nation's physicians. She emphasizes that they need to understand more about the pills they are prescribing. Right now, physicians are "the nation's pushers" when it comes to prescription drugs. While they are not directly paid to prescribe certain pills, they may be invited to conferences in exotic places where they are housed in luxurious accommodations.

Unfortunately, some doctors are also addicted to these prescription drugs. But Dr. Volkow has found that "the best successes in treatment generally are physicians, for they are also the ones with the strongest support."⁹⁴

Know Your Risk & Your Options

Scientists have not yet been able to determine exactly which patients will become addicted to a certain prescription. But scientists have been able to determine ways to lessen the addictive properties of pain relievers, either by reducing the time it takes for dopamine to reach the brain, or by combining them with other drugs to reduce the effect of opiate-associated highs.

If you are worried that after taking a prescription painkiller you may become addicted to it, you should talk with your doctor about alternative pain therapies. Much is still not known about addiction, so it is difficult to predict whether you will become addicted to a prescription drug.

Resources & Additional Reading

If you are interested in learning more, I highly recommend the following:

Books:

GENERATION RX, by Greg Crister

OUR DAILY MEDS, by Melody Petersen

PAIN KILLER, by Barry Meier

Websites:

www.citizen.org

www.worstpills.org

www.fda.gov

www.propublica.org

Guides available at www.worstpills.org:

“Ten Rules for Safer Drug Use”

“Diseases Caused by Drugs”

“Facts and Myths about Generic Drugs”

“Cutting your Prescription Drug Bill”

To report negative side effects of prescription drugs to the FDA, visit the [FDA MedWatch website](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Newsletters:

Institute for Safe Medicine Practices:

www.ismp.org/newsletters/consumer/default.asp

For the latest updates on dangerous drugs:

- Visit my website at www.vanweylaw.com
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- Connect with me on [LinkedIn](https://www.linkedin.com/company/vanweylaw)
- Follow me on [Google+](https://plus.google.com/u/0/vanweylaw)

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