

Pharmaceutical Waterloo

As timely and life-impacting as global warming, the war against terrorism, the national debt, the impending Presidential race, and the issue of whether or not George W.

should attend the Olympic Games in Beijing is the defamation of the big pharmaceutical companies and the calamitous deterioration of the trust of the people in the Food & Drug Administration (FDA).

Every day brings fresh news of the



dangers, prohibitive costs, swindles, warnings, hoaxes, collusions, distortions, monopolies, misrepresentations and general mayhem at play in the world of pharmaceuticals.

Make no mistake: like Walmart, Exxon and General Motors, the pharmaceutical industry is a gigantic, market-based, for-profit conglomeration of businesses just as interested in their bottom line as any organization that has to answer to their investors. Make no mistake, too, that there are bona fide miracle drugs that have made the world a better place, and that the continuing creation of new remedies is an essential and noble endeavor. Unfortunately, so pervasive has the problem of prescribed drugs become, and so shattered our regard for the medical gate keepers, that America finds itself in a dangerous and highly volatile situation requiring immediate remedial action. ♥

Patient Beware!

Caveat Emptor is a Latin axiom meaning, "Buyer Beware," and is sound advice for anyone taking medication of any kind.

Today, heart disease is the number one cause of death in the United States, but in 1900, influenza, pneumonia, tuberculosis and diarrhea were the leading causes, followed by heart disease – perhaps because rampant infectious diseases carried many people off before they were old enough to contract it. Reputable physicians conducted their war against disease with the paltry compounds available to them at the time, such as mercury for syphilis, quinine for malaria, and a variety of herbal remedies.

Fast forward to the new millennium: more than 3-1/2 Billion prescriptions are written in a single year (according to The National Center for Health Statistics, an average of more than 10 per person!) and out of those, 1.5 Million Americans are harmed by their prescriptions. 200,000 people actually go so far as to die because of them. When

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Buddy, can you spare a Quarter?

Twenty five cents out of every dollar spent by Americans is paid for an item regulated by the United States Food and Drug Administration (FDA). According to their website, the FDA's jurisdiction includes most food products (other than meat and poultry), human and animal drugs, therapeutic agents of biological origin, medical devices, radiation-emitting products for consumer, medical, and occupational use, cosmetics, and animal feed. They also monitor the manufacture, import, transport, storage, and sale of about \$1 trillion worth of products annually and visit more than 16,000 facilities a year. Their mandate is a tall order which has been made more complicated by



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the way that drugs are made and brought to market.

One of the essential ingredients in Heparin, for example, is made from the mucous membranes of pig intestines, a process conducted in unregulated private workshops in China. The raw form of the popular blood thinner then moves on to other middlemen, or consolidators, in foreign countries or in the US, who add other ingredients, and finally, to the finished dose manufacturer.

In January of 2008, Heparin was found to contain lethal chemically altered substances that caused 19 deaths and hundreds of negative reactions. Tracing the source of the problem has proved to be nearly impossible since the long arm of the FDA is really only so long. In fact, although more than 500 Chinese plants export drug ingredients to the United States, the FDA only inspected 13 of them in 2007.

The research conducted in the process of approving new drugs is not done by any of the 2100 scientists in the FDA's employ, but by the pharmaceutical manufacturers; the FDA simply examines the results of their research. Furthermore, in the years after a drug is released for public consumption, the FDA depends upon on the pharmaceutical companies themselves to report adverse drug effects, in a sort of an honor system that puts one in mind of finding the fox in charge of the henhouse.

Troubling, too, is the fact that the division of the FDA that approves new drugs receives half of its financial support from drug companies in return for quick reviews. That means that the FDA is dependent upon the industry it's supposed to regulate and, to fill their own coffers, might be tempted to rush drugs to market without making sure they're safe. The FDA's advisory committee members also are on the industry's payroll because many members work as drug company consultants.

In 1785, the state of Massachusetts passed an act making the selling of "unwholesome" meat and drugs illegal. Shortly, other states made similar provisions, but the uniformity of what was considered insalubrious varied

MORE GOOD QUOTES:

"The art of medicine consists in amusing the patient while nature cures the disease."

-Voltaire (1694 - 1778)

"One of the first duties of the physician is to educate the masses not to take medicine."

-Sir William Osler, MD (1849 - 1919)

considerably from state to state. Starting with a single chemist after the Civil War, the Division of Chemistry, as it

*"O, they may get over it
but they'll never look the same,
That kind of bill of fare
would drive most men insane.
Next week he'll give them mothballs a la Newburgh
or else plain;
O, they may get over it
but they'll never look the same."*

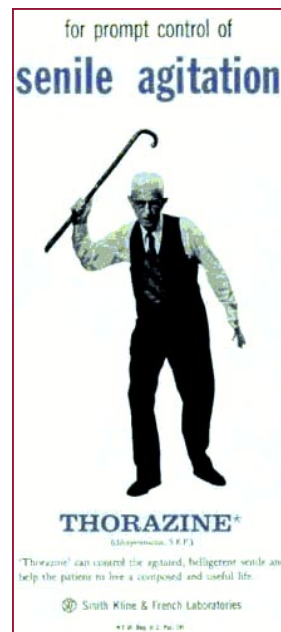
Chorus from "Song of the Poison Squad," 10/ 1903

was then called, was concerned with ferreting out the corruption and mislabeling of food and drugs.

A remarkably colorful history of snake oil salesmen and charlatans scampering about the country disseminating bogus concoctions for profit speaks to the kinds of dishonest and intentional adulterations that were being passed off, but there were also a great many episodes of well-intentioned ignorance imposed on a hopeful public. Bayer, inventor of Aspirin, marketed Heroin as a cough suppressant into the 20th century; as late as the 1920s, Lysol Disinfectant was sold as a feminine douche; and Smith Kline offered Thorazine for gastrointestinal disorders into the 1950s, at about the same moment in history when Thalidomide, notorious for causing birth defects, was introduced.

In 1902, Congress appropriated funds to establish what came to be known as the "Poison Squad," a group of volunteers who, in a scientifically controlled environment, ate meals laced with a variety of substances then in use for the purpose of preserving food. The Hygienic Table Trials investigated the effects of large doses of borax, salicylic acid, formaldehyde, sulphuric acid, sodium benzoate, and copper salts, and looked into the issues of preservative toxicity and the benefits, or lack, of additives of all kinds. The Hygienic Table Trials resulted in legal regulations stipulating that select preservatives in prescribed amounts could be added to foods, but not in order to cover up the use of ingredients unfit for human consumption.

This outrageous project caught the attention of the world, and the media – barred from the dining room –



began to interview the chef through a basement window. Realizing that having the ear of the world would serve to draw the general population into a conversation about the safety of available products, the Poison Squad reported their every move in minute detail on a daily basis. The interest of the reading public helped to pave the way for the 1906

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Websites We Love

www.fda.gov

A truly fascinating overview of the Food & Drug Administration.

www.healthline.com

Provides a free, easy-to-use drug interaction checker. Type in your medication(s), and a list of problematic contraindications come up. Drill down for very specific information.

www.healthfinder.gov

A US Government portal to reliable health information from the Office of Disease Prevention and Health Promotion.

www.csicop.org/sb/9812/snakeoil.html

This is a delicious and all-too-brief history of snake oil salesmen in America. Enjoy! ♥

passage of the Pure Food and Drug Act.

One of the shortcomings of the Act was its failure to authorize its agents to stop the distribution of dangerous drugs; a warning could be issued, but that was the extent of its power. Further, safety tests were not required on updated drugs, or newly formulated versions of existing drugs, a problem made painfully evident in 1937 when more than 100 people across the USA died from the prescription medication Elixir Sulfanilamide, used to treat streptococcal infections, because in its newest incarnation, it contained an ingredient that was commonly used as an anti-freeze and was lethally poisonous. Formulated by the pharmaceutical company Massengill, thousands of telegrams had been sent out to druggists and doctors asking that the drug be sent back to headquarters - but did not mention the urgency or danger of the situation. At the FDA’s insistence, a second round of telegrams was sent out, delineating the fatal toxicity of the substance and an imperative to return all stock at Massengill’s expense. The chemist who had reformulated the elixir committed suicide, but Massengill took no ethical or financial responsibility for the tragedy.

The Elixir Sulfanilamide debacle spurred the passage of the 1938 Federal Food, Drug, and Cosmetic Act, which gave the FDA new powers of control and influence. Now, 70 years later, control is not the word that springs to mind when considering the FDA. We seem to have digressed to an era when anyone could put anything in a bottle and sell it as a “cure-all.” Thirty-one prescription medications were recalled by the FDA between 1980 and 2007. Thousands of over-the-counter and homeopathic-type drugs were also recalled.

In an astute observation, Napoleon Bonaparte said, “[Medicine is] a collection of uncertain prescriptions the results of which, taken collectively, are more fatal than useful to mankind.” More than 500 people die EVERY DAY in America because of prescription drugs. If human lives were lost on such a scale in a spectacular way, such as buildings falling down or gas stations exploding, we would be outraged and demand resolutions. It is a curious world we live in when carnage of this dramatic an extent goes unremarked, but your friends at LifeSpan hold out hope that the future will bring an enlightened attitude in the government, the big pharmaceutical companies, and the consumer. ♥

A final note:

Always explore alternative cures for what ails you. Frequently, there is a drug-free way to resolve your health issues. Thomas Edison, a pioneer of the modern era, foresaw a time when, “the doctor of the future will give no medicine, but will interest her or his patients in the care of the human frame, in a proper diet, and in the cause and prevention of disease.

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one stops to consider that an average of 42,682 Americans die in auto accidents each year, this is a staggering number. We're paying more for the privilege, too. A 2005 study conducted for Senator Gutnecht's (R-Minn.) office shows that a 30-day supply of 10 popular prescriptions costing \$455.57 in Frankfurt, Germany, costs \$1,040.04 in Rochester, Minnesota. US News & World Report estimates that Americans pay somewhere in the neighborhood of 60% more for pharmaceuticals than any other industrialized country in the world.

The top ten pharmaceutical companies make more in profits than the rest of the Fortune 500 combined. Considering that they spend 2.5 times as much on marketing and administration as they do on research and development discredits the picture that they paint of themselves as a righteous industry largely subsisting on crumbs while their research and development departments gorge on the rest of the feast.

The pharmaceutical companies are privately held, multi-national corporations, and, as such, are in the business of making money, mostly by shaking down the American public. Other industrialized countries subsidize their citizens' healthcare, so insist that drug prices are kept in check, while the consumers of this country are bilked for higher prices than anywhere else on earth and kept in a state of fear. Why should it be that a company with manufacturing plants in more than 50 countries across the globe should declare drugs coming out of Canada dangerous and beyond the scope of regulation? Shouldn't one, then, be wary of any drug manufactured outside of the United States and imported over international borders?

In fact, approximately 86% of all drugs sold in the U.S. are manufactured outside of our borders. Among the most popular, Prevacid, is produced in Japan, Lipitor and Viagra are produced in Ireland and Nexium is made in both Sweden and France.

Consider:

- The Center for Drug Safety says that 26.5% of all patients experience an allergic reaction from prescribed medication.
- Newstarget.com headline on 2/20/2006 website: "Statistics prove prescription drugs are 16,400% more deadly than terrorists."
- An average RX costs \$68.26.
- An average name brand RX costs \$111.02.
- An average generic brand RX costs \$32.23.
- A study conducted by Brigham & Women's Hospital in Boston July of 2005 found that 4.2 million hospital visits were for the treatment of an adverse drug event (15 visits per 1,000 Americans).
- The pharmaceutical industry has the largest lobby in Washington, D.C., the industry employs more lobbyists than there are Congress members.

- The pharmaceutical industry's principal output is minor variations or combinations of old drugs—"me-too" drugs. These drugs cash in on already established, lucrative markets. For example, Pfizer's Lipitor, is the fourth of six cholesterol-lowering drugs of the same type.
- According to Families USA, older adults account for approximately 40% of every dollar spent on prescription drugs and consume 34% of all prescriptions dispensed.
- The Federal Interagency Forum on Aging Related Statistics says that Medicare enrollees with 3 or 4 chronic conditions filled an average of 44 prescriptions a year, while those with 5 or more filled 60.

The bottom line as far as the solicitous hearts of the LifeSpan team are concerned is the fact that approximately 40% of all people who enter a nursing home do so because they are unable to take their medications safely at home. 50% of prescriptions are not taken correctly and so contribute to or create problems for the taker. Contraindications, or the prescribing of incompatible drugs, are a growing risk as we get older and see more than one doctor. Unsavory interactions are even reported with the combination of vitamins/herbs/minerals and prescriptions. There is too much for the average person to know about all of the things that can go wrong, to keep straight the voluminous information necessary to safely wrangle prescriptions, and to get the best medicinal bang for the buck. Unlike you, we are medical people and we know one thing beyond a shadow of a doubt:

You are safer and your long-term prognosis is better when you stay in your own home, so an educated and judicious approach to pharmaceuticals might just save your life.

While there *are* legitimate wonder drugs, one would be wise to be skeptical of an industry that prescribes the lion's share of its cures for indigestion, erectile dysfunction, high cholesterol and other important problems that are just as easily cured - for free and without medication of any kind - with simple changes in diet and behavior. A LifeSpan Care Manager knows that the old adage about an ounce of prevention being worth a pound of cure is true.

Healthcare Coordination and Advocacy



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