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## AS WE SEE IT

### Consumer Rape

At the end of this article, we are going to publish shocking information that has never been divulged to the public. For the benefit of new members, however, we will first provide a brief historical overview.

It is no secret that Life Extension has battled the high cost of prescription drugs since the early 1980s. We knew 18 years ago that the drug regulatory system was riddled with corruption and launched a media blitz to expose it. Price comparison charts published in this magazine have been enlarged before the House of Representatives to show how much more Americans pay for drugs than Europeans. Life Extension has spearheaded consumer protests over the monopolistic pricing power granted to pharmaceutical companies.



William Faloan



Drug companies enjoy a virtual monopoly of the American market because of FDA over-regulation. FDA approval requirements make it too expensive for widespread competition to develop. Even after a drug goes off patent, it still costs too much money to obtain "generic" approval from the FDA. These regulatory burdens strangle free market competitive forces and cause Americans to pay the highest prices in the world for their medications.

#### How monopolies are created

Don't be fooled when there are several "generic" companies competing on price. Illegal drug company manipulation still results in severe price gouging. A stark example of this occurred in 1998 when Mylan Labs increased the wholesale price of a generic tranquilizer (clorazepate) from \$11.36 per 500 tablets to \$377.00 in just one year! How could Mylan Labs raise prices 3,000% on an off-patent generic drug? It turns out that Mylan conspired with the primary producer of the active ingredient to enter into an exclusive licensing agreement that cut off the competition. Mylan got caught red-handed and had to pay \$100 million dollars to settle an FTC antitrust case.[1]

What consumers don't realize is that the Mylan case is just the tip of an iceberg of corruption that is only made possible by FDA over-regulation. A recent settlement resulted in another drug company (TAP Pharmaceutical) paying an \$875 million dollar fine for illegally fixing the price of a drug called "Lupron." Prostate cancer patients use this drug to suppress testosterone production. The cost for a four-month supply of Lupron is \$2,200.00.[2] Since there is another drug (Zoladex) that works as well as Lupron, TAP Pharmaceutical resorted to some creative tactics, such as providing kickbacks to prescribing physicians, to maintain this outrageous price.[3]

Even though criminal indictments have been obtained against Tap Pharmaceutical officials, the price of Lupron remains grossly inflated. These are not isolated cases. They are examples of how the drug industry commands extortionist prices from desperate consumers. The solution to this problem will be revealed later in this article.

#### A health-care cost crisis

Life Extension long-ago predicted that the exorbitant price of prescription drugs would bankrupt the U.S. health care system. A recent report from the Department of Health and Human Services says that health costs are continuing to climb faster, even though the economy has been weak.[4] As a result, it says, consumers will have to spend more of their own money on health care, and employers will be less able to afford health benefits.

HMOs and other health insurance companies have gone out of business; this trend is expected to accelerate as drug prices increase. Medicare is expected to become insolvent by as early as year 2007.[5]

Remember, Life Extension predicted all of this in the 1980s. Today, we are not alone in projecting that the U.S. health care system cannot afford to pay for the many expensive new drugs entering the marketplace.

## Why we need new drugs

Knowledge about the molecular processes involved in aging and disease has grown exponentially over the past 20 years. Each new discovery provides an opportunity to cure a human ailment. There are huge numbers of new compounds being considered for submission to the FDA.

Regrettably, there are not enough economic resources to transform all of these scientific advances into a drug that can be legally sold. The decision as to whether to submit a new compound to the FDA is based primarily on the strength of the patent, the potential competition, and whether the company has the economic resources to make it through the FDA's multi-year approval labyrinth. Saving human lives is secondary in today's upside down regulatory environment.

Reforming the drug approval system is crucial if we are to develop medical breakthroughs in time for those living today.

## Does the FDA protect us?

There are more than 9,000 employees who work for the FDA. Some of them do important work that results in consumer protection, while others go out of their way to help out the pharmaceutical industry.

For instance, the FDA warned pharmaceutical-giant Schering-Plough for years that it needed to improve safety and oversight at its manufacturing facilities and for years Schering promised to do so. Among Schering's problems were making asthma inhalers that did not have any medication inside. Acute asthma attacks suffocate 5,438 Americans every year.[6] With no medication in an inhaler, any asthma attack can be lethal. The FDA repeatedly found the same problem with these asthma inhalers (no medicine inside), but it took Schering years to correct the problem. Schering recently stated that they may be forced to pay a \$500 million dollar fine to settle the matter.[7]

It may appear that the FDA is coming down hard on Schering, but the fact is that Schering was given numerous warnings by FDA inspectors and still failed to consistently put medication into their inhaler product. In an article in this issue entitled "FDA Attacks Alternative Clinics—Cancer Patients' Lives Threatened," you will see the brutal tactics the FDA has taken against those involved in alternative medicine. No warnings for these small guys. . . armed SWAT teams and summary seizure of their property was how the FDA introduced themselves.

Last year, American Home Products paid \$30 million as part of a consent decree involving manufacturing defects practices, while Abbott Laboratories paid fines of \$100 million in 1999 concerning manufacturing defects in scores of its products.

The FDA tells consumers to beware of dietary supplements because they are not "regulated," yet regulated products kill over 100,000 Americans every year, and seriously injure over 2.1 million people. This figure does not include prescribing errors or drug abuse.[8] The FDA does inspect supplement manufacturers and has not found the total breakdown of quality-control that has occurred at some drug companies.

The FDA provides a veneer of protection, but the hard facts are that Americans are paying for today's inept regulatory system with their money and their lives. With prescription drugs prices soaring beyond the ability of many Americans to pay, a significant change has to be made in the current regulatory structure that causes these drugs to cost so much!

## The shocking truth about drug prices

Now here are the startling facts I promised would be revealed to you. Did you ever wonder how much it costs a drug company for the active ingredient in prescription medications? Some people think it must cost a lot, since many drugs sell for more than \$2.00 per tablet.

We did a search of offshore chemical synthesizers that supply the active ingredients found in drugs approved by the FDA. As we have revealed in past issues of Life Extension, a significant percentage of drugs sold in the United States contain active ingredients made in other countries.

In our independent investigation of how much profit drug companies really make, we obtained the actual price of active ingredients

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used in some of the most popular drugs sold in America. The chart below speaks for itself.

WHAT DRUGS REALLY COST			
BRAND NAME	CONSUMER PRICE (For 100 tabs/caps)	COST OF GENERIC ACTIVE INGREDIENT (For 100 tabs/caps)	PERCENT MARKUP
Celebrex 100 mg	\$130.27	\$0.60	21,712%
Claritin 10 mg	\$215.17	\$0.71	30,306%
Keflex 250 mg	\$157.39	\$1.88	8,372%
Lipitor 20 mg	\$272.37	\$5.80	4,696%
Norvasc 10 mg	\$188.29	\$0.14	134,493%
Paxil 20 mg	\$220.27	\$7.60	2,898%
Prevacid 30 mg	\$344.77	\$1.01	34,136%
Prilosec 20 mg	\$360.97	\$0.52	69,417%
Prozac 20 mg	\$247.47	\$0.11	224,973%
Tenormin 50 mg	\$104.47	\$0.13	80,362%
Vasotec 10 mg	\$102.37	\$0.20	51,185%
Xanax 1mg	\$136.79	\$0.024	569,958%
Zestril 20 mg	\$89.89	\$3.20	2,809%
Zithromax 600mg	\$1,482.19	\$18.78	7,892%
Zocor 40mg	\$350.27	\$8.63	4,059%
Zoloft 50mg	\$206.87	\$1.75	11,821%

The astounding profit margin enjoyed by drug companies exposes several facts. First, it shows why the pharmaceutical industry is the most profitable of all businesses. But since large drug companies only make around 15% net profit margins, it also exposes the incredible cost drug companies bear to comply with today's burdensome drug approval system. If the FDA relaxed its drug approval standards, the cost of bringing new patented drugs could be reduced.

These exorbitant profit margins also provide incentive for drug companies to get their patented molecules approved by the FDA, whether they kill people or not. Horror stories abound of how drug companies have egregiously falsified data to obtain FDA approval.[9]

Many consumers are nervous about the FDA becoming less stringent, but the facts are that today's regulatory system is allowing lethal drugs on the marketplace and also acting as a disincentive for drug companies to develop novel drugs to save lives.

Take the cholesterol-lowering drug Baychol, for example, which was removed from the market after killing 100 people.[10] Baychol is a "statin" drug that works via a mechanism similar to that in Mevacor, Zocor, Lipitor, Pravachol, etc. Was there a need for tens of millions of dollars to be spent developing "another" statin drug when the market was already saturated? Drug companies think so, because the FDA readily recognizes "statin" drugs, so they are easy to get approved.

The problem is that no life was saved because of Baychol. Anyone who may have benefitted from Baychol could have obtained the same results from other "statin" drugs. So when drug companies justify the high price of drugs because of research costs, remember that most of the so-called novel compounds they develop will not save a single life, as they are no different than what is already available.

Now that you know the outrageous profit margins on prescription drugs, you can understand why drug companies do almost anything to prevent competition from developing. Large drug companies intensively lobby Congress to pass laws that give them extra time of exclusivity, file lawsuits to delay generic competition, petition the FDA to stop the importation of lower cost medications, and go as far as to pay off generic companies to not compete.

Drug companies spend big dollars protecting their illicit monopoly, all of which is reflected in the price consumers pay for their prescription drugs.

Reforming this flawed system

The healthcare cost crisis could be resolved if the FDA allowed any company with OTC manufacturing licensing to produce generic drugs without first obtaining formal FDA approval.

To follow is an explanation of how this deregulated structure would save consumers big dollars and stave off the pending economic collapse of the health care system.



An OTC-registered lab would buy the active ingredient of an off-patent drug like Prozac (fluoxetine) and package it into 20 mg capsules. The raw material cost for a one month supply would be 34 cents. Add another \$1.50 per bottle for quality-control and packaging, and the total cost to make this product would be \$1.84. The OTC-manufacturer could then mark up the price three times and sell this to pharmacies for \$5.52. The pharmacy could then mark this up two times and sell it to the consumer for \$11.04. So instead of the consumer paying \$61.80 for a one-month supply (30 capsules) of generic Prozac[11], their price would be reduced to only \$11.04...an 82% savings.

The one stipulation would be that the label of this OTC-lab version of Prozac would have to state that this generic is NOT approved by the FDA. This would enable consumers to decide if they want to pay \$61.80 for an FDA-approved generic, or \$11.04 for a non-FDA approved generic.

Some would argue that these unregulated generics may not be equivalent to the name brand. For many drugs, however, it is only a matter of putting a certain number of milligrams of active ingredient into each capsule. This is not a difficult feat to accomplish.

Another way of saving money on prescription drugs is for consumer groups with competent medical advisors to identify generic drugs that work almost as well as newly patented drugs.

These low-cost, non-FDA approved generics could be suggested for those who cannot afford to buy the expensive patented drugs.

For example, the drug Prilosec is about to come off patent. The company making Prilosec has patented a new molecule that appears to work via the same mechanism to suppress stomach acid production. The company plans an aggressive marketing campaign to convince the public to buy its new patented version instead of generic Prilosec. The monthly cost for this patented version is expected to be over \$100.00, yet a non-FDA approved generic could be profitably sold for well under \$38.00.

I want to state that the prices I estimate for non-FDA approved generic versions of Prozac and Prilosec are on the high side. Once the full force of free market competition emerged, you could rapidly see the non-FDA approved generic Prozac, Prilosec and other drug prices drop much more sharply.

Under this free market program, a senior citizen paying \$800.00 a month for their drugs could obtain the same benefit for less than \$200.00 a month. As competition intensified, the cost could drop to \$100.00 a month or lower.

Under the proposal, those who could afford the higher prices could choose the greater degree of perceived protection FDA-approved generics offered. For the growing number of Americans who are unable to afford their medications, having the option to use non-FDA approved generic drugs could mean the difference of being able to afford the medication at all.

Remember, the FDA would still inspect the manufacturers of non-FDA approved generics to make sure the proper active ingredient was being put in, that the tablets were disintegrating, sanitary conditions were being met, etc. The difference would be that hundreds of potential generic competitors would emerge to preclude the kind of illegal shenanigans occurring today.

Some of these egregious violations involve large drug companies paying off smaller companies to NOT offer lower generic versions of drugs coming off patent.<sup>12</sup> If any OTC laboratory could offer a non-FDA approved generic, then this free market environment would drastically limit the ability of large drug companies to monopolize the market.

### Abolishing this pillage

Most of the information reported in this editorial has already been reported by the media. The problem is that no organized group has gotten together to petition Congress to change the law to make affordable drugs available to the public.

According to the Department of Health and Human Services, it cost an average of \$4,637 per person in healthcare costs in year 2000. Healthcare accounted for 13.2% of the nation's total output in year 2000, and prescription drug price increases consistently outpace the rate of inflation. Concerned American citizens can no longer tolerate watching this country falter economically because of antiquated laws that serve the special interests of drug companies.

You now know that the price you pay for prescription drugs has nothing to do with the cost of the active ingredients, and that drug companies have engaged in multiple illegal practices to maintain artificially high prices. It is time for citizens to shed their apathy and rise up against the bureaucrats who enable drug companies to economically rape the American consumer.

A new organization called Consumers Against High Drug Prices has formed. Their objective is to mobilize millions of American citizens into a cohesive army that will force Congress to change the law so that a free market can emerge to obliterate the high cost of prescription drugs.

It costs nothing to register with this organization. When proposed anti-FDA/anti-drug company legislation is drafted, you will be informed and asked to contact your Congressional representative to support it. You can register with Consumers Against High Drug Prices by logging on to [www.stopfda.com](http://www.stopfda.com). If you do not have a computer, you can register by sending your name and address to:

Consumers Against High Drug Prices  
P.O. Box 13166  
Silver Spring, MD 29011-3166

The FDA and pharmaceutical giants hope that Americans will remain lethargic to this issue and allow the economic plunder to continue. Please stand up for your rights by enrolling with Consumers Against High Drug Prices so that we can avert the looming health care cost crisis that is a threat to us all.

For longer life,

A handwritten signature in black ink, appearing to read 'W Faloon', written in a cursive style.

William Faloon

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