

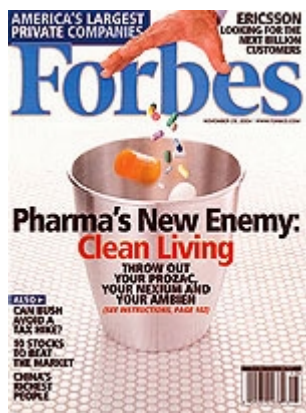
LE Magazine March 2005

AS WE SEE IT

Death by Regulation

Consumers are being defrauded out of their health and money by a regulatory system that is a proven failure.

Back in the early 1980s, the Life Extension Foundation provided compelling evidence that FDA-approved drugs were dangerous and overpriced. We also gave examples of lifesaving medications that the FDA delayed, resulting in the needless deaths of millions of Americans.



We warned of a health care cost crisis if Congress did not abolish the FDA or markedly diminish the agency's powers. We even went so far as to establish the FDA Museum to specifically document how flawed government regulatory policies were the leading cause of death in the US.



by William Faloon

Sadly, most of the reforms we sought did not pass Congress. The result is that health care has become so expensive that record numbers of Americans are without medical insurance.^{1,2} Those who have insurance are paying outlandishly high premiums and deductibles. Medicare faces insolvency, FDA-approved drugs are killing record numbers of Americans,³ and medical innovation is stifled by over-regulation.

One solution discussed on Capitol Hill is to create still another bureaucracy to oversee the FDA. The reason for creating a separate agency is that it has become clear that the FDA is unable to protect Americans against unsafe drugs.

A growing number of influential Americans are alarmed at the FDA's cozy relationship with big drug companies. Those involved in alternative medicine have long argued that the FDA functions to protect the financial interests of large drug companies and not the American public. This allegation was confirmed when the FDA launched an all-out campaign against the right of Americans to purchase lower-cost medications from other countries.⁴

To protect the outrageous profits of drug companies against lower-cost imports, the FDA went so far as to commit perjury before Congress, disseminate knowingly false propaganda to the public, and engage in illegal lobbying activities. Life Extension revealed these immoral and illegal acts years ago.⁵⁻⁷

FDA COMES UNDER GROWING CRITICISM

Because of the Vioxx® scandal, the FDA has come under harsh criticism by members of Congress, the medical establishment, and even one of its own high-ranking officials.^{8,9}

In testimony before Congress, Dr. David Graham, a 20-year FDA scientist, estimated that Vioxx® had caused 88,000 to 139,000 excess cases of heart attack and stroke. Criticizing the very agency he works for, Dr. Graham stated:

"I would argue the FDA as currently configured is incapable of protecting America against another Vioxx®. We are virtually defenseless."¹⁰

Dr. Graham said that he felt pressured by supervisors at the FDA to water down his findings showing that Vioxx® increased heart attack risk. If this sounds like a familiar pattern of improper behavior, it is because you read about this very same problem in an article I wrote one year ago—before Vioxx® was withdrawn from the market!¹¹

After Dr. Graham testified about the FDA's shortcomings, seven other FDA-employed scientists wrote to a Senate committee vouching for Dr. Graham's "unquestioned integrity."¹²

**AMA VOTES FOR
PRESCRIPTION DRUG IMPORTS**

PBS EXPOSES FDA FAILINGS

In early December 2004, the American Medical Association (AMA) voted in favor of allowing Americans to import lower-cost prescription drugs from other countries. This will put additional pressure on the FDA to reverse its current policy opposing such imports. The AMA resolution included some conditions on imports, including FDA approval of the specific drugs to be imported and granting the agency the power to ensure the “authenticity and integrity” of the imports.¹³

On November 17, 2003, the PBS documentary “Frontline” aired a shocking exposé about dangerous prescription drugs and the FDA’s complicity.¹⁴

The “Frontline” producers initially investigated drugs that had been withdrawn from the market because of adverse side effects. After filming began, however, current and former FDA employees started coming forward to offer a powerful critique of what was really going on inside the agency. As the story evolved, instead of making a documentary about drug safety, “Frontline” ended up shifting its focus to the FDA itself.

A major emphasis of the documentary was the FDA’s reliance on drug companies’ research of their own products to determine safety. As “Frontline” discovered, the FDA does not conduct clinical trials, but instead reviews the results submitted by pharmaceutical companies. This means that the basis for FDA approval of a drug is often “safety data” provided by the very company that makes the drug!

COMPANIES SUE RETIREES TO CUT PROMISED HEALTH BENEFITS

The high cost of health care is causing some cruel and unusual events to occur in America. Since the cost of prescription drugs and other medical services has greatly surpassed the rate of inflation, companies that promised lifetime health care coverage to their retired employees are finding they cannot afford to fund what has become a bottomless pit of medical expenses.^{16,17}

As reported on the front page of the November 10, 2004 Wall Street Journal, to get out of this economic quagmire, companies are suing their retirees individually and asking courts to declare that the company is legally entitled to cut their benefits.^{18,19} The retirees find themselves in a terrible bind, facing the prospect of paying their own health care costs as they age, while navigating legal complexities that can take years to resolve.

As despicable as this behavior appears, it reflects the horrendous ramifications of a corrupt regulatory structure that has put America in an economic stranglehold. Employees are paying a greater portion of their medical insurance, if they are lucky enough to have health care coverage at all. Those who have to pay for their own coverage find premium increases greatly exceed the inflation rate. Low-income people on Medicare have to pay more in premium increases this year than the inflation rate adjustment in their meager Social Security checks.^{20,21}

“Frontline” interviewed current and former FDA employees who revealed instances in which drug dangers were clearly present but were ignored or covered up by higher-level FDA officials. Only after numerous injuries and deaths were these drugs withdrawn or relabeled. A survey of all FDA employees showed a significant number felt that they were pressured by others in the agency to give favorable reviews to dangerous and ineffective drugs.

PBS exposed this outrageous conduct before the Vioxx® scandal broke, yet it took tens of thousands of additional deaths before Congress held any hearings. “Frontline” confirmed that the FDA’s drug-approval process is a sham—something Life Extension had revealed 20 years earlier.¹⁵

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Death by Regulation

FDA'S MYTH OF CONSUMER PROTECTION

The public has been deceived into believing that government "regulations" protect consumers against dangerous and ineffective products. The media, the government, academia, and even large drug companies perpetuate this myth.

For those who believe that government regulations provide a benefit, one only has to look at the cost and dangers of heavily regulated drugs and compare them to those of deregulated dietary supplements.

DRUG PRICE INCREASES NEARLY TRIPLE INFLATION RATE

On May 25, 2004, the American Association of Retired Persons (AARP) released a study showing that prices for the brand-name prescription drugs used most frequently by older Americans and available in January 2000 increased, on average, a cumulative 27.6% over the four-year period from 2000 to 2003.²⁹

In 2003 alone, the average annual manufacturer price increase for the most widely used drugs was 6.9%, or triple the general inflation rate of 2.2%.²⁹ Price increases that exceed the inflation rate are especially hard on retired people, whose incomes are often fixed. These steep price hikes are forcing increasing numbers of Americans to buy their prescription drugs from other countries at dramatically reduced costs.

In 1994, Congress weakened the FDA's authority to regulate dietary supplements. Critics predicted that this would expose Americans to all kinds of dangerous and bogus products because the FDA would not be able to "protect" the consumer. Since 1994, whenever a hint of concern arises about a dietary supplement, the media and FDA blame the fact that natural products are not "regulated" and therefore pose inherent dangers.

When looking past the FDA and media's charade about the need for regulation, an interesting pattern of truth emerges. After dietary supplements were deregulated, prices plummeted, more effective nutrients became available, and, most important, virtually no side effects occurred despite the government not overseeing content or potency.^{22,23}



Compare what has happened with deregulated dietary supplements to heavily regulated prescription drugs. Since 1994, drug prices have spiraled so far out of control that the nation's health care system is facing insolvency; overpriced new drugs are often no better than older drugs; no major disease has been cured; and a record-breaking number of adverse drug reactions and deaths have occurred.²⁴⁻²⁷

Those who believe they need FDA regulations to protect them are ignoring historical reality. Regulations are the underlying cause of dangerous drugs, ineffective drugs, and overpriced drugs. Regulations enable incompetent FDA officials to declare a drug "safe." Regulations enable drug companies to exaggerate the purported benefits of drugs approved by the FDA. Regulations protect drug companies against lower-cost competition.²⁸

The most devastating effect of regulations is that they suffocate medical innovation. The FDA has made it so complicated and expensive to get a drug approved that drug companies spend inordinate amounts of their resources just bringing out different versions of existing drugs, instead of investing in novel technologies needed to find cures for the killer diseases of aging. Getting another "statin" drug approved is easy compared to getting the FDA to understand how a new therapy might work by an unprecedented mechanism. Small companies that have innovative ideas but not a lot of money stand little chance of getting their products to market.

TABLE 1: DIETARY SUPPLEMENT PRICE REDUCTIONS FROM YEAR INTRODUCED TO DATE

Product	Year Introduced	Original Strength	Original Count	Original Lowest Member Volume Price	Original Cost Per Mg	Current Strength	Current Count	Current Lowest Member Volume Price	Current Cost Per Mg	Price Reduction to Date
Acetyl-L-Carnitine capsules	1993	500 mg	100 caps	\$93.00	0.0018600	500 mg	100 caps	\$35.00	0.0007000	62.4%

Alpha-Lipoic Acid capsules	1996	100 mg	100 caps	\$30.94	0.0030940	250 mg	60 caps	\$24.00	0.0016000	48.3%
Bilberry capsules	1995	30 mg	100 caps	\$14.96	0.0049867	100 mg	100 caps	\$18.75	0.0018750	62.4%
Boswellia capsules	1992	300 mg	100 caps	\$30.00	0.0010000	300 mg	100 caps	\$22.50	0.0007500	25.0%
NGH powder	2000	6000 mg	325 g	\$32.37	0.0000996	6000 mg	325 g	\$23.25	0.0000715	28.2%
DHEA capsules	1996	25 mg	100 caps	\$20.00	0.0080000	25 mg	100 caps	\$9.38	0.0037520	53.1%
Ginkgo Extract capsules	1994	120 mg	100 caps	\$27.00	0.0022500	120 mg	365 caps	\$32.63	0.0007450	66.9%
Huperzine capsules	2000	50 mcg	60 caps	\$28.13	0.9376667	50 mcg	60 caps	\$18.00	0.6000000	36.0%
Methyl-cobalamin tablets	1998	1 mg	60 tablets	\$8.63	0.1438333	1 mg	60 tablets	\$6.75	0.1125000	21.8%
Methyl-cobalamin tablets	1998	5 mg	60 tablets	\$29.63	0.0987667	5 mg	60 tablets	\$17.25	0.0575000	41.8%
Modified Citrus Pectin powder	1995	15 g	454 g	\$130.00	0.0002863	15 g	454 g	\$71.06	0.0001565	45.3%
NADH tablets	1995	2.5 mg	30 tablets	\$44.00	0.5866667	5 mg	30 tablets	\$18.63	0.1242000	78.8%
SAMe tablets	1997	200 mg	20 tablets	\$25.00	0.0062500	400 mg	20 tablets	\$21.00	0.0026250	58.0%
Saw Palmetto capsules	1992	160 mg	60 caps	\$23.00	0.0023958	320 mg	30 caps	\$9.00	0.0009375	60.9%
TMG tablets	1997	750 mg	90 tablets	\$18.75	0.0002778	500 mg	180 tablets	\$11.63	0.0001292	53.5%

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THE FREE MARKET SOLUTION

The FDA pretends that its regulations protect Americans, yet studies published in establishment medical journals document that regulated drugs are a leading cause of death in the US.^{30,31}

TABLE 2: WHAT PRESCRIPTION DRUGS REALLY COST

Brand Name	Dosage	Consumer Price (100 tabs/caps)	Cost of Generic Active Ingredient (100 tabs/caps)	Percent Mark-up (100 tabs/caps)
Celebrex®	100 mg	\$ 130.27	\$ 0.60	21,612%
Claritin®	10 mg	\$ 215.17	\$ 0.71	30,206%
Keflex®	250 mg	\$ 157.39	\$ 1.88	8,272%
Lipitor®	20 mg	\$ 272.37	\$ 5.80	4,596%
Norvasc®	10 mg	\$ 188.29	\$ 0.14	134,393%
Paxil®	20 mg	\$ 220.27	\$ 7.60	2,798%
Prevacid®	30 mg	\$ 344.77	\$ 1.01	34,036%
Prilosec®	20 mg	\$ 419.00	\$ 0.52	80,477%
Prozac®	20 mg	\$ 247.47	\$ 0.11	224,873%
Tenormin®	50 mg	\$ 104.47	\$ 0.13	80,262%
Vasotec®	10 mg	\$ 102.37	\$ 0.20	51,085%
Xanax®	1 mg	\$ 136.79	\$ 0.02	569,858%
Zestril®	20 mg	\$ 89.89	\$ 3.20	2,709%
Zithromax®	600 mg	\$1,482.19	\$18.78	7,792%
Zocor®	40 mg	\$ 350.27	\$ 8.63	3,959%
Zoloft®	50 mg	\$ 206.87	\$ 1.75	11,721%

Table 1 shows the astounding price decreases of dietary supplements after their deregulation. We state unequivocally that if Congress took the bold initiative of deregulating prescription drugs, their costs would fall even more dramatically than did the costs of dietary supplements.

The reason is that it costs more to extract nutrients from plants and to synthesize vitamins and amino acids than it does to make most synthetic drugs. In a deregulated environment, prescription drug prices would drop to such low levels that cost would no longer be an issue.

As you can see in Table 2, the cost of the active ingredients in prescription drugs is so low that anyone could afford them in a deregulated environment.

Cynics say drug companies need this money to develop better drugs. This argument rings hollow when one realizes that the costs of even FDA-regulated generic drugs are excessive.

The facts are that regulation and artificially high prices have created an

environment in which innovation is a distant second to marketing, political lobbying, campaign contributions, bloated administrative budgets, etc. If prescription drugs had to compete in a deregulated free market, companies would be forced to develop better products because the FDA would not be delaying competing products for years or decades as it does now.

In a free market, the better-quality, lower-priced products rise to the top while inferior and overpriced products sink into oblivion. In today's upside-down regulatory environment, less effective but heavily marketed drugs outsell superior medications.^{32,33}

Large pharmaceutical companies have grown accustomed to multibillion-dollar blockbuster drugs that have 17-20 years of patent protection. Enormous resources are devoted to marketing these drugs. Even when the patent expires, drug companies often allocate considerable financial resources to litigating against potential generic competitors, paying generic companies not to compete, and taking other steps to delay generic competition. None of these shenanigans could occur in a deregulated market where any company could compete on a level playing field.

TABLE 3: PRESCRIPTION DRUG PRICE INCREASES, 1994-2004

	1994	2004	Cost
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Drug Brand Name (Generic Name)	Company	Dosage (mg)	Count	Consumer Price Per Bottle	Consumer Price Per Bottle	Cost Per Count	Increase Per Count (%)
Premarin®	Wyeth-Ayerst	.625	100	37.08	\$106.99	N/A	189%
Synthroid®	Boots-Knoll-Abbott	0.1	100	20.46	\$49.99	N/A	144%
		.075	100	19.98	\$49.99	N/A	150%
		.05	100	18.00	\$45.99	N/A	156%
*Lanoxin® (Digoxin)	Glaxo Well	.125	100	10.82	\$24.99	N/A	131%
		.25	100		\$28.29	N/A	131%
Lasix® (Furosemide)	Aventis/Mylan	40	100	4.73	\$31.99	N/A	576%
Pepcid® (Famotidine)	Merck	20	30	43.08	\$54.47	N/A	26%
Zocor®	Merck	10	60	\$108.03	\$78.99/30	157.98	46%
		20	60	\$195.76	\$125.09/30	250.18	28%
Zolofft®	Roerig	50	100	\$186.64	\$232.99/90 tabs	258.88	39%
Zestril® (Lisinopril)	AstraZeneca	10	100	78.01	\$71.99/60	119.98	54%
		20	100	\$83.48	\$77.99/60	119.98	56%
Prilosec® (Omeprazole)	Astra/Merck	20	30	\$11.23	\$419.00/100	125.70	1019%
Norvasc® (Amlodipine)	Pfizer	5	90	\$102	\$135.19	N/A	33%
		10	90	\$176	\$183.19	N/A	4%
Paxil®	SmithKline Beecham	20	100	\$174	\$270.19/90 tabs	300.21	73%
Claritin®	Schering-Plough	10	30	53.17	\$98.99	N/A	86%
Humulin N®	Lilly	100 iu	10	16.83	\$83.70/5 vials	167.40	895%
K-Dur 20®	Schering-Plough	20 mEq	100	34.57	\$57.15/90 tabs	63.5	84%
Klor-Con 10®	Upsher-Smith	10mEq	100	9.88	\$14.99	N/A	52%
Lopressor® (Metoprolol Tartrate)	Mylan	50	100	43.04	\$144.99/25 mg	289.98	574%
Pravachol® (Pravastatin)	Bristol-Myers Squibb	20	90	\$155	**\$134.99/40 tabs	303.73	96%
Toprol-XL®	AstraZeneca	50	100	\$42.59	**\$85.99/90 tabs	95.54	124%

*The above prices are somewhat more expensive than some Internet pharmacies.

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DEFENDING THE FREE MARKET

In the late 1980s, Life Extension led the charge that blocked the FDA from gaining totalitarian powers under the guise of needing to “protect” the public against “dangerous vitamin supplements.” We then turned this anti-FDA momentum into an onslaught of letter writing to Congress that resulted in the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994.

DSHEA may be coming under siege, as increasing numbers of Americans are switching to safe, low-cost dietary supplements in lieu of side effect-prone, expensive prescription drugs.

The cover of the November 29, 2004, issue of *Forbes* magazine was titled “Pharma’s New Enemy: Clean Living.” The cover graphic shows a hand dropping prescription drug pills into the garbage can, with the subtitle, “Throw Out Your Prozac®, Your Nexium®, and Your Ambien®.”

The *Forbes* article described natural lifestyle changes that have enabled people to reduce or eliminate prescription drugs. The article also quoted mainstream doctors saying that Americans are overmedicating with side effect-prone drugs whose benefits are exaggerated by the drug companies.

Clearly, drug companies have an emerging new competitor: sellers of dietary supplements. There appears to be a concerted effort to discredit the safety and value of dietary supplements. The media is fed blatantly false and misleading reports about supplements, and then turns these stories into headline news because so many Americans now take vitamins.^{34,35} Congressional investigations have revealed how drug companies spend enormous amounts of money to persuade the media to publish stories that are favorable to their industry.³⁶

Shortly after Merck withdrew Vioxx® from the market, the media disseminated a negative report about vitamin E that contained so many omissions that its conclusions had no basis in fact.³⁷⁻³⁸

The Life Extension Foundation analyzed every statement in this negative report, and we are including a thorough and meticulous rebuttal in this issue of Life Extension. In this instance, the media was duped into facilitating a massive deception against aging people who are in critical need of antioxidants to stave off degenerative diseases.

For longer life,



William Faloon

PROOF IS IN THE NUMBERS

As you can see in Table 3, prescription drug prices have skyrocketed over the past 10 years. The cost of supplements, on the other hand, has significantly declined, as shown on Table 1.

The reason for this disparity is that stringent FDA regulations protect prescription drugs against competition. Dietary supplements, in contrast, became free-market commodities back in 1994 with the passage of the Dietary Supplement Health and Education Act (DSHEA).

Once the FDA deregulated dietary supplements, manufacturers sought more efficient methods of producing high-quality, high-volume ingredients. New companies began producing the active ingredients that go into the thousands of supplements on the US market.

The competitive forces of the free market have kept steady downward pressure on dietary supplement prices, while regulated drugs have become obscenely expensive. The arcane regulatory structure that limits innovation also protects drug prices against competitive forces.

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