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## AS WE SEE IT

### DRUGS THE FDA SAYS YOU CAN'T HAVE

Americans suffer and die even though effective drugs to treat their diseases are approved in other countries. The public is generally aware that novel drugs are sold in Europe and Japan, but intense lobbying by the pharmaceutical industry has blocked the wide-scale availability of these better medications.

Drug companies don't want Americans to shop the world for more effective therapies. They prefer the current FDA-protected system where large companies enjoy a virtual monopoly over the American marketplace. This archaic system earns record profits for drug companies at the expense of U.S. citizens, who pay inflated prices for the medications the FDA does allow them to have.

The FDA deceives the public and Congress into believing that drugs approved in other countries are somehow "dangerous," despite having no evidence to support this. What the FDA conveniently ignores is the fact that drugs they say are "safe" kill over 106,000 Americans every year.(1-3)

#### Thalidomide still kills

Proponents of today's drug approval system have to go back 41 years to the thalidomide debacle to find an example of an offshore drug causing a serious side effect. Thalidomide still kills because the FDA is using this old issue as an excuse to embargo life-saving drugs that are approved by health ministries in other countries. Furthermore, these drugs have been used in other countries for years without serious side effects.

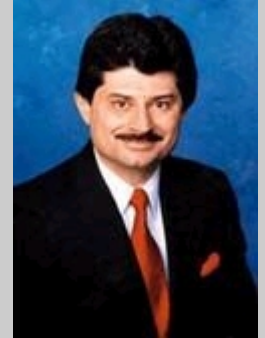
Few people remember that it was not the FDA who discovered the thalidomide problem. It was a German scientist who identified thalidomide's dreadful power to halt limb development in the early stages of pregnancy. The FDA's sole contribution to avoiding this problem in the United States was a delay by a junior FDA officer in reviewing the original application.

There is tragedy on the other side of the thalidomide ledger, too. Thalidomide has been shown to halt the proliferation of blood vessels, an effect that may help starve certain cancers and protect against blindness induced by wet macular degeneration. In 1998, the FDA finally approved thalidomide to treat a complication related to leprosy. That means that doctors can legally prescribe thalidomide to patients with other diseases. The FDA, however, has put up so many restrictions on its off-label use, that few physicians or patients are willing to fight the red-tape.(4)

The rare disease the FDA approved thalidomide to treat only occurs in about 50 Americans every year. The FDA, however, says the company that makes thalidomide cannot promote its use in treating cancer and macular degeneration. Recent First Amendment losses the FDA has suffered in the courts may enable thalidomide to be advertised,(5) but that would mean the company making the drug would incur the wrath of the FDA and be subjected to retaliation against other drugs it might want to get approved.

#### Fearing FDA retaliation

The FDA has taken science out of the practice of medicine and replaced it with an incompetent and biased bureaucracy. To win FDA approval of a new drug, it takes a lot of political influence.



William Faloon



The committees who advise the FDA whether or not to approve a new drug are largely comprised of individuals who are beholden to the pharmaceutical giants.(6) Small biotech companies who cannot afford to put their own people on these advisory committees are at a significant disadvantage. There are FDA-staffers who appear unusually friendly to large drug companies, but find every excuse imaginable to delay the approval of novel drugs from smaller companies.(7-12)



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The FDA intentionally delayed the approval of ribavirin for decades while this anti-viral drug was saving lives in just about every civilized country on earth. The company who made ribavirin committed the terrible “sin” of holding a press conference to extol the virtues of this drug before the FDA approved it. Another victim of FDA retaliation was the immune-enhancing drug isoprinosine. While isoprinosine has been prescribed by doctors throughout the world for nearly two decades, the FDA will never approve it here because the manufacturer helped promote the fact that Americans could import it from other countries for their own personal use. The sad fact is that when effective drugs are not approved because of FDA retaliation, American citizens die.(13,14)

#### Life-saving offshore drugs

An example of a drug that may never be approved in the United States is thymosin alpha-1. In 1981, The Life Extension Foundation wrote a headline article about the multiple benefits of this immune boosting agent produced in the thymus gland.(15) Unfortunately, the small company making the drug lacked the resources to win FDA approval. Thymosin alpha-1 did gain approval in Europe. Published studies show that when used in combination with cancer chemotherapy, it helps mitigate bone marrow toxicity.(16,17) When thymosin alpha-1 is combined with interleukin-2 or alpha interferon, it enhances immune response against cancer cells and the hepatitis C virus.(18-23) Thymosin alpha-1 should be available to Americans, but the FDA says no!

Another drug that could be of benefit to hepatitis C and certain cancer patients is polaprezinc. This ultra-safe Japanese drug has been shown to reduce viral load and induce complete response in Type 1b hepatitis C (when combined with interferon).(24) It may also be effective as an adjuvant therapy in cancer cells that up-regulate a growth factor called nuclear factor kappa beta. If you don't live in Japan, it is very difficult to obtain polaprezinc, a unique compound of carnosine and zinc.

Neurodegenerative diseases such as Alzheimer's have no effective treatment. A drug called memantine may delay the progression of Alzheimer's and Parkinson's disease. Memantine works by a different mechanism than current FDA-approved drugs such as Aricept and Tacrine. Memantine has been used in Germany for the last ten years, but it remains bogged down in FDA-mandated clinical trials. Four million American Alzheimer's disease patients anxiously await.(25-33)

A prime example of a drug that should have been approved by the FDA years ago is a COX-2 inhibitor called nimesulid. Americans suffered from arthritis pain and cartilage degeneration while nimesulid was long-ago approved in other countries. Americans now pay outrageously high prices for FDA-approved COX-2 inhibitors and American cancer patients are dying because this class of drug is not yet approved to treat cancer. Nimesulid was patented way back in 1971, but Americans had to wait for another COX-2 inhibitor called Celebrex to be approved in December 1999. Some studies indicate that nimesulid is safer than Celebrex or Vioxx. Nimesulid may also be more effective in the adjuvant treatment of cancer than Celebrex or Vioxx. It costs about \$125.00 a month for Celebrex or Vioxx, yet nimesulid can be obtained in Europe for only \$22.00 per month. It is unconscionable that U.S. citizens were denied access to COX-2 inhibitors for so long and now have to pay an average of five times more for this class of medication.

#### It's time to revolt

Today's flawed system of drug approval needs a major overhaul or Americans will continue to perish while effective therapies exist in other countries. As a member of The Life Extension Foundation, you are supporting an organization that has been battling the entrenched medical establishment for two decades.

In this month's issue, we publish in-depth research reports on drugs that have been shown to be safe and effective, but are denied to Americans by the FDA. Our objective in publishing these reports is to chronicle, with scientific precision, the carnage being inflicted on the American citizenry by the FDA.

As more Americans learn that they are not getting the best that science has to offer, we believe the citizenry will rebel against the medical establishment, who place their monopolistic profits ahead over the well-being of the patient.

The world is rapidly changing and information about non-FDA approved therapies can easily be found on the Internet. The problem for consumers is separating real science from charlatans who prey on those seeking a solution for a serious medical problem. That is why so many health-conscious people are joining The Life Extension Foundation. Our 21-year track record documents that we have identified credible methods for preventing and treating aging-related disease many years before conventional medicine. We've also weeded out ineffective therapies such as shark cartilage so our members don't waste their money on worthless products.

An encouraging development

There is new hope that the FDA can be reformed in time to save many lives.

Dr. Mary Ruwart is a candidate to be the next FDA Commissioner. In this issue, we have printed a story about her. I ask all members to read about Dr. Ruwart's plan to make the type of changes within the FDA that will eliminate much of what is wrong with the agency. All readers should mail the form letter we provide to President Bush encouraging him to select Dr. Ruwart as the next FDA Commissioner.

For longer life,

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

William Faloon

## WHERE ARE THE BEST DRUGS?

The most advanced drugs in the world are right here in the United States, but remain bogged down in the FDA's approval quagmire. The profit potential in the American marketplace is so large that drug companies are not seeking quick approval in other countries as much as they used to.

As we have previously published, entering controlled clinical trials to obtain experimental drugs is not always a wise choice. The problem with these clinical trials is that the patient is not allowed to use other synergistic therapies and may not obtain the optimal dose of the experimental drug.

Pharmaceutical companies spend gargantuan sums of money on clinical trials before they can earn a penny on the sale of the drug. The inordinate delay created by the FDA not only causes the needless death of those in desperate need, but it makes the cost of drugs astronomical once they finally get approved.

The Life Extension Foundation believes a better approach would be to allow pharmaceutical companies to sell new drugs before they are officially "approved." This change would result in a renaissance of new medications becoming available at far lower prices. Those doctors and people who desire FDA protection could use only FDA-approved drugs, while individuals who think the FDA moves too slow could gain immediate access to medications they believe could help them. Wouldn't it be wonderful if non-profit groups competed to provide unbiased advice about unapproved drugs that could save lives? Those who argue against this libertarian concept are endorsing FDA dictatorship over scientific democracy.

Some argue that the FDA approves new drugs too fast and should mandate more stringent testing. The facts are that the dangerous drugs the FDA approves are often the result of drug company manipulation of the already-flawed approval process. We have specifically reported on inappropriate drug company influence at the FDA in previous month's issues of this magazine.<sup>(34)</sup>

Those who think they need the FDA forget that scientists established the efficacy of vaccines, antiseptics and antibiotics long before lawyers arrived to supervise their work. Medical science does not require the Federal government's rules or approvals to know whether a drug works. We think that the superposed political layer of review on research has been the major roadblock that prevents scientists from finding real cures for diseases that have too long plagued modern man.

Some pessimists are concerned that unethical companies would sell dangerous drugs in an unregulated environment, yet no private company prospers for long selling products that kill, maim or injure in an era when trial lawyers abound.

The following is an excerpt from the Wall Street Journal of an editorial entitled "FDA Caution Can Be Deadly, Too":

"Most ordinary, healthy people probably still take some comfort in the thought that a diligent, generally competent, well-meaning federal agency is keeping an eye on the contents of their medicine cabinets. But we live in an age of enormously rapid progress in medical science. Impelled by genetic science, we are progressing toward ever more individualized, customized therapies. Some therapies already depend on extracting, modifying and cultivating cells, tissues or organs from the patient's own body, or from close relatives. General-issue tailoring of your medicines is fine if you happen to stand smack in the statistical middle of everything, but few real people do. And in the direst circumstances, the best therapies will often be the ones on the edges of science, well outside the bounds of the truths that have been fully certified in Washington."<sup>(35)</sup>

Gaining access to drugs stuck in the FDA's pipeline would save countless lives each year. The Life Extension Foundation Buyers Club is committed to changing today's antiquated drug approval system that we believe is a significant cause of disability and death in the United States.

## 350 cancer treatments await FDA approval

According to the American Cancer Society, more than 552,000 Americans are scheduled to die of cancer this year. The Life Extension Foundation believes that many of these cancer patients could be saved if the FDA allowed more experimental drugs to be sold to those who don't have time to wait for FDA approval.

Lack of participants in clinical trials has caused a delay in the approval of many new cancer therapies. While being more effective and less toxic than their predecessors, new cancer treatments have yet to complete the approval process due to a lack of trial volunteers. It is estimated that less than three to five percent of cancer patients participate in the trials, mostly due to lack of awareness of their existence.

Robert L. Comis MD is president of the Coalition of National Cancer Cooperative Groups, a network of cancer clinical trial specialists. Dr. Comis announced, "Right now there are 350 new treatments out there ready to be tested. If we're stuck at three to four percent of adult patients participating in clinical trials, it will be years before these new treatments are not only tested but become available once we show that they're effective."

Dr. Comis argues that clinical trials of cancer drugs involve giving the patient the best known treatment for a particular cancer, or giving cancer patients the opportunity to try a new one. Dr. Comis says that patients receive leading-edge care during the studies and the drugs have already been screened for safety.

The Life Extension Foundation does not agree that entering clinical trials is the best choice for most cancer patients. For instance, if it is a Phase I study, the primary objective is to test the safety of low doses of the drug and not cure the cancer. In order for statistics to not be skewed, cancer patients in Phase 2 and 3 trials are often not allowed to use other synergistic therapies. Clinical trials often exclude cancer patients who have not yet failed conventional therapy, meaning that to be eligible to enter a clinical study, the cancer patients must first have tried brutally toxic therapies that for certain types of cancer have virtually no chance of working based on historical data. These conventional therapies, do however, damage the immune system so severely that the odds of an experimental therapy working are greatly diminished.

The Life Extension Foundation believes that cancer patients should have access to these 350 potential cancer therapies earlier in their disease process and that these experimental therapies should be combined with other drugs that might work synergistically together to eradicate the disease in its early stages.

Refer to previous issues of Life Extension magazine to review specific synergistic cancer therapies that we think cancer patients should have access to right now. You can view these past issues of Life Extension magazine by checking out the Magazine Archive.

For those cancer patients who want to inquire about entering clinical studies, we suggest logging on to Dr. Comis's group's website at [www.cancertrialshelp.org](http://www.cancertrialshelp.org).

Editor of The Lancet says...  
The FDA is far too cozy with drug industry

According to a May 19, 2001 editorial published in The Lancet, patients taking a controversial new drug for irritable bowel syndrome may have died because the FDA has become a “servant of (the drug) industry.”

This devastating editorial reveals that although Glaxo-SmithKline voluntarily withdrew the drug Lotronex from the US market last November after the deaths of five patients, senior FDA officials are now seeking to reintroduce it.

This editorial goes on to say:

“This story reveals not only dangerous failings in a single drug’s approval and review process but also the extent to which the FDA, its Center for Drug Evaluation and Research (CDER) in particular, has become the servant of industry.”

This two-page editorial is entitled “Lotronex and the FDA: a fatal erosion of integrity.” It accuses the FDA of receiving hundreds of millions of dollars in funding from industry.

The editorial claims the views of FDA scientists who raised safety questions about the drug were dismissed by FDA officials and that these scientists were excluded from further discussion about the drug’s future. It goes on to allege that negotiations between the FDA and the Glaxo on the drug’s future involved a “two-track process, one official and transparent, one unofficial and covert.”

The FDA approved Lotronex in February 2000 but it was never approved by the European Medicines Evaluation Agency. The company withdrew the product in the United States in November 2000 after 49 cases of ischaemic colitis and 21 of severe constipation, including instances of obstructed and ruptured bowel. In addition to five deaths, 34 patients had required admission to hospital and 10 needed surgery.

The Lancet says that as early as July 2000, it was known that seven patients had developed serious complications. The clinical data confirmed “substantial and potentially life-threatening risks.” Instead of withdrawing Lotronex, the FDA issued a medication guide. “This decision was to prove fatal,” according to The Lancet.

The editorial states that FDA scientists knew that the warning advising patients to stop taking Lotronex if they felt “increasing abdominal discomfort” was impractical. The reason is that abdominal pain can be confused as a classical symptom of an irritable bowel.

FDA scientists argued that it was unreasonable to expect patients or physicians to know if this type of pain was an early warning of possibly fatal ischaemic colitis. Their view was dismissed by FDA officials. According to The Lancet, “The scientists who raised these issues felt intimidated by senior colleagues and were excluded from further discussions about Lotronex’s future.”

In a memorandum dated November 16, 2000, FDA scientists said, “Early warning of the dire side effects of this drug is clearly not feasible” and added a “risk management plan cannot be successful.” FDA officials choose to ignore this warning.

By the time of a key November 28th, 2000 meeting between Glaxo and FDA officials, rather than reject the company’s proposal to withdraw Lotronex, the FDA offered several conciliatory options including voluntary withdrawal pending further discussion.

The Lancet claims “many within the FDA’s leadership now want to bring Lotronex back. An advisory committee meeting set up to do so is being planned for June or July.”

The reason this highly critical editorial against the FDA was published is because The Lancet previously published some of the trial data that led to the FDA approving the drug. As increasing reports of adverse effects became known, the editor of The Lancet became “more intrigued about what was happening, it opened up into an issue of how science is dealt with by the FDA and how, because of industry funding, it has fatally compromised its independence.”

The Lancet editor went on to say that “The scientists within the FDA who analyze and interpret adverse drug reactions have been largely ignored after the drug was approved and marketed. That is where there has been a terrible failure in evaluating the safety of this drug.”

The Life Extension Foundation continues to chronicle examples of how the FDA is failing to protect Americans against dangerous drugs, while at the same time denying drugs to terminally ill Americans who have little to lose by trying an experimental therapy.

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