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## AS WE SEE IT

### FDA Approves Deadly Drugs, Delays Lifesaving Therapies

What if a dietary supplement was shown to kill 100 Americans and cause 56,000 emergency room visits each year?<sup>1</sup> Without a doubt, the supplement would be banned immediately and those who knowingly marketed such a lethal product would be subject to severe criminal penalties.

On January 22, 2004, the FDA confirmed what Life Extension members have long known—that acetaminophen is extremely dangerous.<sup>2</sup> Acetaminophen is sold under the brand name Tylenol® and is contained in 600 other drug products. Life Extension revealed the toxicity of acetaminophen more than 12 years ago. We harshly criticized the FDA for not mandating that the label of acetaminophen products warn those with liver or kidney problems to avoid the drug.



William Faloon



In 2002, an FDA scientific advisory committee urged that warnings be put on the labels of acetaminophen drugs.<sup>3,4</sup> Despite overwhelming documentation confirming acetaminophen's toxicity,<sup>5-28</sup> the FDA said no to its own scientific advisors. Instead, the agency has budgeted a mere \$20,000<sup>29,30</sup> to develop material that it hopes will be run in major magazines and distributed by pharmacy chains for free! This is the bureaucratic equivalent of doing nothing.

We at Life Extension are incensed about the FDA's multi-decade failure to mandate warnings on deadly acetaminophen products. The agency spends tens of millions of dollars a year attacking companies selling natural health products that have harmed no one. Yet the FDA is making virtually no effort to prevent the 100 deaths and 56,000 emergency room visits that the agency itself admits are caused by acetaminophen drugs every year!<sup>31</sup>

#### Acetaminophen Risks Understated

Back in 1992, we warned that many more people are dying because of acetaminophen than the number indicated by the official statistics. While the FDA was pre-occupied with acetaminophen-induced liver failure, it overlooked studies showing that regular users of acetaminophen may be doubling their risk of kidney cancer.<sup>11,13,32</sup>

What does that translate to in actual numbers of victims? Each year, almost 12,000 Americans die of kidney cancer.<sup>33</sup> The incidence of kidney cancer in the US has risen 126% since the 1950s,<sup>34</sup> a jump that may be tied to the growing use of drugs containing phenacetin or acetaminophen.

Phenacetin is a painkiller that was banned because it causes severe kidney toxicity.<sup>35-40</sup> Acetaminophen is the major metabolite of phenacetin, which means that some of the destructive properties exhibited by phenacetin could have been caused by its breakdown to acetaminophen in the body. So while phenacetin was withdrawn because too many people's kidneys were shutting down, the FDA had no problem letting the major metabolite of phenacetin (acetaminophen) be freely marketed without any consumer warning whatsoever.

If acetaminophen is responsible for even a small percentage of the overall kidney cancer cases, this drug may have already killed tens of thousands of Americans—and the FDA has done nothing to stop this carnage!

Because acetaminophen generates damaging free radicals throughout the body, it may very well increase the risk of many age-related diseases. In fact, scientists can consistently induce cataracts in the eyes of laboratory animals by giving them acetaminophen. They consider acetaminophen a "cataractogenic agent." Interestingly, if antioxidants are provided to the animals, the cataract-inducing effects of acetaminophen are often completely neutralized.<sup>41-46</sup>

One of Life Extension's medical advisors long ago advocated that acetaminophen products include the antioxidant N-acetylcysteine to help neutralize destructive free radicals. When a person acutely overdoses on acetaminophen, the standard medical therapy is to administer N-acetylcysteine over a period of weeks. Unfortunately, the FDA bans the combination of an over-the-counter drug (acetaminophen) with a dietary supplement (N-acetylcysteine), so it is "illegal" to make a safe acetaminophen drug.

To alert as many people as possible to the risks of acetaminophen poisoning and its antidotes, we have included a chapter on this topic in all four editions of our Disease Prevention and Treatment book. Despite the overwhelming evidence that acetaminophen use should be strictly limited, the FDA capitulates to pharmaceutical companies that earn billions of dollars a year selling this lethal class of analgesic drug.

By failing to mandate a warning on the label of acetaminophen products, the FDA once again demonstrates its propensity for protecting the pharmaceutical industry's economic interests at the expense of the American public's health.



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#### FDA Denies Alzheimer's Drug for 14 Years

At any given time, 4 million Americans suffer the devastating consequences of Alzheimer's disease.<sup>47</sup> Alzheimer's has no cure, and all victims suffer a progressive neurodegenerative process that results in total disability and death.

In 1990, a drug used in Germany was found to slow the progression of the disease.<sup>48</sup> The drug's generic name is memantine, and Life Extension has long recommended it to family members of Alzheimer's victims.<sup>49</sup>

Memantine does not offer miraculous benefits. The studies show that some patients experience improvements in memory and cognitive skills.<sup>50</sup> For the vast majority, however, memantine merely slows the pace of deterioration, enabling patients to perform certain functions a little longer than would otherwise be possible.<sup>51,52</sup> For example, the drug enabled some patients to go to the bathroom independently for an additional six months, a benefit caregivers called very important.<sup>53</sup>

The July 2001 issue of Life Extension featured an in-depth report on the clinical value of memantine in treating a wide range of disorders, including Parkinson's disease, glaucoma, and diabetic neuropathy.<sup>54</sup> We were highly critical of the FDA's attempts to deny Alzheimer's patients residing in the US access to this safe and partially effective medication.

Starting this year, Americans can now purchase memantine sold under the brand name Namenda® at American pharmacies. One reason memantine is available now is the intense pressure put on the FDA by family members of Alzheimer's victims who had to order the drug from Europe and risk FDA seizure.

Americans had to wait 14 years to gain legal access to a drug proven to work in Europe. This is not the first time FDA bureaucrats have needlessly delayed approval of an effective drug for a terminal disease. In 1991, the Life Extension Foundation sued the FDA on behalf of Alzheimer's patients in the US who were being denied access to the drug tacrine. Tacrine's mechanism of action inhibits the acetylcholinesterase enzyme, thus making more of the neurotransmitter acetylcholine available to brain cells.

A judge tossed out our lawsuit on the grounds that the federal courts are not the proper forum in which to determine which drugs the FDA should approve. Six months after our lawsuit was dismissed, the FDA approved tacrine.<sup>55</sup> (A few years later, the FDA approved a safer drug called Aricept® that shares some of tacrine's same mechanisms of action but is less toxic.<sup>56</sup>)



Memantine works by a different mechanism than tacrine or Aricept®. Memantine blocks a reaction known as "excitotoxicity," a pathological process in which too much glutamate is released in the brain, severely damaging the neurons. Those seeking to protect their healthy neurons against the damaging effects of excitotoxicity use dietary supplements such as methylcobalamin and vinpocetine. That it took litigation, harsh media criticism, and a citizens' uprising to motivate the FDA to approve these Alzheimer's drugs is a testament to the agency's inability to differentiate between safe, effective medications that should be approved and lethal drugs that should be removed.<sup>57</sup>

#### Who Will Protect Us from the FDA?

The FDA pretends to protect Americans from dangerous and ineffective products, yet even a cursory review of the agency's track record reveals the opposite to be true. Dangerous and ineffective drugs are approved, while novel lifesaving therapies and natural approaches to disease prevention are brutally suppressed.<sup>58-69</sup>

The FDA's failure to mandate a warning on the label of acetaminophen products is just one example of its failure to protect consumers against lethal drug side effects. The agency's inexcusable delay in approving drugs to alleviate the miseries of Alzheimer's disease reveals its lack of compassion for human beings who have lost the cognitive ability to take care of themselves.

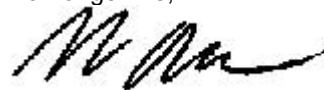
Since 1980, the Life Extension Foundation has recommended to its members drugs that the FDA has not yet approved.<sup>70-73</sup> In many cases, what we recommended was eventually approved, which means that our scientific analysis—as opposed to the FDA's politically motivated decision-making process—was medically correct.

Regrettably, some non-patentable therapies will never receive FDA approval because of the high cost of navigating the agency's bureaucratic labyrinth. When it comes to disease prevention, the FDA has made extraordinary efforts to censor information about proper diet and supplements that would provide guidance to consumers who want to adopt healthier lifestyles.<sup>74</sup>

The Life Extension Foundation is dedicated to breaking down the governmental barriers that cause Americans to needlessly suffer and die while proven methods may already exist to alleviate or eradicate their health problems.

The health choices of most Americans continue to be constrained by FDA politics and bureaucracy. Life Extension members, on the other hand, are an elite group that often gains access to lifesaving information five to 10 years before it is accepted by conventional medicine or "approved" by the FDA.

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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