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AS WE SEE IT

Dangerous Medicine

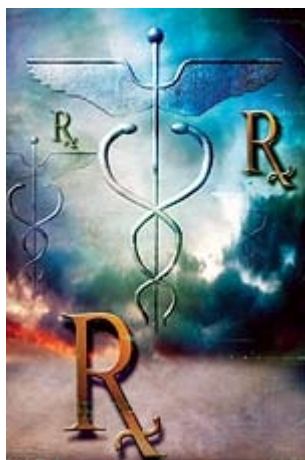
The FDA claims that the drugs it approves are “safe.” This charade is rapidly collapsing. PBS television’s investigative series *Frontline* has aired a shocking exposé of dangerous prescription drugs and the FDA’s complicity in allowing this outrage to occur.¹

The *Frontline* producers initially investigated drugs that had been withdrawn from the market. After filming began, current and former FDA employees started coming forward to give a powerful critique of what really goes on inside the agency. As the story evolved, rather than 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* found out, the FDA does not conduct clinical trials, because the agency is not in the business of conducting medical research. The FDA instead reviews the results submitted by pharmaceutical companies. This means that the basis for FDA approval of a new drug is often “safety data” provided by the very company that makes the drug!



William Faloon



Frontline exposed this questionable drug approval sham to the world in a one-hour broadcast aired November 17, 2003. It was FDA drug reviewers who made the most appalling disclosures. These current and former FDA employees revealed incidences in which drug dangers were clearly present but were ignored or covered up by higher-level FDA officials. Only after many injuries and deaths were these drugs withdrawn or relabeled. A survey of all FDA employees showed a significant number felt they were pressured by others in the agency to give favorable reviews to dangerous and ineffective drugs.

The most absurd part of this saga is the FDA’s historical record of attempting to restrict consumers’ access to dietary supplements. The FDA deceitfully implies that supplements have hidden dangers. Yet the data supporting the safety and efficacy of nutrients usually come from independent sources, as opposed to the company-sponsored studies the FDA relies on to certify drug safety.

Frontline showed that in too many cases, the safety data supplied by drug companies are flawed and altered, with the result being an alarming number of injuries and deaths from prescription drug toxicities. Deaths from adverse drug reactions have become so commonplace that they rarely make the news.

For the past 18 years, Life Extension has harshly criticized this corrupt system of drug approval. What Life Extension lacked was the “inside” data gathered by *Frontline* that show specifically how the FDA conspires with the drug industry to approve dangerous drugs. Even more disturbing are instances in which the FDA allows toxic drugs to remain on the market even after injuries and deaths are reported. If the FDA had even a vestige of credibility remaining about its role of “protecting” the public against dangerous drugs, this *Frontline* documentary tore it to shreds. The emperor (the FDA) clearly has no clothes (credibility).

***Frontline*’s FDA Exposé Tape Available**

If you missed the airing of *Frontline*’s FDA exposé, you can obtain it on videotape for a modest cost. Life Extension long ago exposed the insidious relationship between the FDA and the pharmaceutical industry that allows dangerous and ineffective drugs to be approved.

Despite the evidence we gathered pointing to these improprieties, even we were surprised by how deeply drug company influence has infiltrated the FDA. That is why we have arranged to offer this one-hour *Frontline* video (or DVD) to Foundation members. Not only will this documentary be an eye-opener for you, but it will help rally others who may have been skeptical about how severely the FDA endangers the health of the American public.

The retail price of this *Frontline* documentary is \$29.95. Foundation members can order it for only \$24.95. If four or more copies

Drugs Often Do Not Work

In a stunning admission, a senior executive with Britain's largest pharmaceutical company has stated that most prescription medicines do not work on half the patients who take them.

Dr. Allen Roses is worldwide vice-president of genetics at GlaxoSmithKline. He is a world-class pioneer in the branch of medicine that studies the relationship between our genes and our response to individual drugs. On December 8, 2003, a British newspaper quoted Dr. Roses telling a scientific conference in London:

"The vast majority of drugs only work in 30 or 50% of the people."²

Dr. Roses predicted that in a few years, scientists would be able to give patients a simple genetics test that would predict which medicines would work for them. Drug companies could use the information to tailor new drugs aimed at the 50% of people not helped.

It is an open secret within the pharmaceutical industry that most of its products are ineffective in most patients, but this is the first time that such a senior drug boss has gone public. Dr. Roses' admission corroborates what FDA reviewers told *Frontline*—not only are many dangerous drugs wrongfully approved, but they often are only minimally effective!

Consumers Partially Prevail Against Codex

While adverse effects from regulated prescription drugs are a leading cause of death, governments mislead their citizens with the bizarre notion that dietary supplements are somehow dangerous.

The European Union is aggressively seeking to set maximum upper-limit potencies for vitamin-mineral supplements, even though supplements used by citizens in its member countries have not demonstrated a health risk.

The Codex Alimentarius Commission (Codex) was established to review and evaluate nutrients to determine what potencies are "safe" for human ingestion. The objective is to "harmonize" these maximum upper-limit potencies to guard consumers around the world against the purported risks of vitamins.

After years of deliberations, Codex was on the verge of adopting the Recommended Dietary Allowance (RDA) as the maximum potency allowable in dietary supplements. This would have resulted in nutrient products so low in potency that the consumer would obtain virtually no benefit. For instance, the upper safe limit for vitamin B6 could have been as low as 2 milligrams, which would not provide the positive effects that have been documented in the published scientific literature.



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Codex was about to outlaw high-potency supplements. Vitamin consumers in Europe were backed into a corner. Only one hope remained.

The Life Extension Foundation joined forces with the Nutrition Institute of America to conduct the enormous task of reviewing every single study on 40 different dietary supplements. An overview on each supplement was written, followed by the voluminous abstracts that supported the claims made in the overview. More than 7,000 scientific abstracts that described both preventive and therapeutic potencies were submitted to the Codex commission along with the overviews.

The good news is that the Codex committee responsible for developing international guidelines for vitamin-mineral potency reached a consensus that maximum levels for supplements should be based on scientific risk assessment and not on the politically inspired RDA.³

The debate over using science as opposed to the RDAs has been raging at Codex since the mid-1990s. While this is only partial progress, it could help when the full Codex Commission meets in Geneva in June 2004.

The 7,000 abstracts we submitted to Codex, along with the overviews on 40 different supplements, can be viewed by logging on to www.lef.org.

Codex Still a Major Threat

Health freedom activists who have been battling Codex warn that vitamin consumers should not become complacent. They point out that while matters would be worse if the Codex committee had recommended RDA levels only, the so-called "scientific" standards used by European food committees have been woefully inadequate.

Health freedom fighters cite one example in which a nutrition committee set the maximum safe upper limit for niacin at only 10 mg, based on its interpretation of the scientific literature. It is clear that the war to defeat Codex has not been won, and consumers should continue to aggressively protest attempts by Codex to limit vitamin potencies. For information on battling Codex, log on to www.lef.org/codex

Death by Medicine

Something is wrong when regulatory agencies pretend that vitamins are dangerous, yet ignore published statistics showing that government-sanctioned medicine is the real hazard.

Until now, Life Extension could cite only isolated statistics to make its case about the dangers of conventional medicine. No one had ever analyzed and combined ALL of the published literature dealing with injuries and deaths caused by government-protected medicine. That has now changed.

A group of researchers meticulously reviewed the statistical evidence and their findings are absolutely shocking.⁴ These researchers have authored a paper titled "Death by Medicine" that presents compelling evidence that today's system frequently causes more harm than good.

This fully referenced report shows the number of people having in-hospital, adverse reactions to prescribed drugs to be 2.2 million per year. The number of unnecessary medical and surgical procedures performed annually is 7.5 million. The number of people exposed to unnecessary hospitalization annually is 8.9 million.

How Low Codex Wanted to Go

Codex sought to restrict the maximum potencies to the Recommended Dietary Allowance (RDA) of each vitamin-mineral. These RDAs are determined by governmental committees and represent the bare minimum an individual needs to sustain life.

RDAs are calibrated in terms of deficiency syndromes, rather than optimal intakes for disease prevention. The RDAs represent a bare minimum floor and are by no means an upper-limit ceiling.

Several years ago, the US government changed the definition to **Recommended Dietary Intake (RDI)**, which is the amount it believes to be essential in human nutrition. When making decisions concerning the RDAs or RDIs, governments give little consideration to what potency is needed to achieve optimal health. If Codex had ruled that the safe upper dose for dietary supplements would be based on the RDAs as opposed to a scientific risk assessment, supplements

Vitamin C	60 mg
Vitamin E	30 IU

The most stunning statistic, however, is that the total number of deaths caused by conventional medicine is an astounding 783,936 per year. It is now evident that the American medical system is the leading cause of death and injury in the United States. (By contrast, the number of deaths attributable to heart disease in 2001 was 699,697, while the number of deaths attributable to cancer was 553,251.5)

We had intended to publish the entire text of "Death By Medicine" in this month's issue. The article uncovered so many problems with conventional medicine, however, that it became too long to fit within these pages. We have instead put it on our website.

Vitamin K	80 mcg
Thiamin	1.5 mg
Riboflavin	1.7 mg
Vitamin B6	2 mg
Vitamin B12	6 mcg
Pantothenic acid	10 mg
Selenium	70 mc

We placed this article on our website to memorialize the failure of the American medical system. By exposing these gruesome statistics in painstaking detail, we provide a basis for competent and compassionate medical professionals to recognize the inadequacies of today's structure and attempt to institute meaningful reforms.

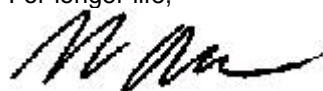
Government-Protected Medicine Is Dangerous Medicine

The word regulate can be defined as "to control or direct according to rule, principle, or law."⁶

In the US, all aspects of medical care are heavily "regulated" by the government. The end result is that health care is expensive, complicated, dangerous, and often ineffective.

The only way out of this bureaucratic abyss is serious free-market reform. This will not happen as long as the public thinks it needs government "protection." We applaud the producers of *Frontline* for exposing the fact that the FDA does not protect Americans against unsafe drugs. Soon after the *Frontline* program aired, the most popular news program in the US contacted Life Extension seeking information about problems with prescription drugs. It appears that the mainstream media may finally be targeting the FDA.

For longer life,



William Faloon.

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