Impressive research published in 2003 indicates that coenzyme Q10 may have broader clinical applications than originally identified. These new human studies further validate the efficacy of coenzyme Q10 in the adjuvant treatment of cardiovascular disease.1-9

In particular, a study of heart attack patients showed that compared to placebo, supplementation with 120 mg a day of coenzyme Q10 reduced secondary cardiac events by 45% and significantly reduced the number of cardiac deaths. Many of these heart-attack patients were prescribed a "statin" drug to lower cholesterol levels. The major adverse effect of statin treatment was fatigue that occurred in 40.8% of the placebo group, whereas only 6.8% of the patients supplemented with coenzyme Q10 experienced fatigue.2

In newly published findings over the past year, positive results were shown when coenzyme Q10 was tested against disorders including macular degeneration, Parkinson's disease, viral myocarditis, and hereditary neurodegenerative diseases.10-21 Additional studies indicate that coenzyme Q10 deficiency is linked with disorders such as infertility and brain atrophy.22-23

The Problem with "Statin" Drugs

Massive advertising by drug companies has resulted in millions of Americans taking statin drugs every day. Because consumers are supposed to take these drugs possibly for the rest of their lives, statins have become the most profitable drug class in the world. While statin drugs do lower cholesterol, there is a controversy as to how effective these drugs are in extending overall life span.

Peter H. Langsjoen, MD, is the foremost authority on the use of coenzyme Q10 in the treatment of heart disease. His numerous research studies can be found in the world's most prestigious scientific journals.24-32

In 1990, the Proceedings of the National Academy of Science published Dr. Langsjoen's studies on the safety of statin drugs. Dr. Langsjoen explained that the mechanism by which statin drugs lower cholesterol also inhibits the natural biosynthesis of coenzyme Q10 in the liver. Dr. Langsjoen said that he conducted these studies because, "if lovastatin were to reduce levels of coenzyme Q10, this reduction would constitute a new risk of cardiac disease, since..."
it is established that coenzyme Q10 is indispensable for cardiac function.” Dr. Langsjoen then reported that his animal and human studies showed that lovastatin does indeed lower levels of coenzyme Q10. Dr. Langsjoen went on to describe case histories of his lovastatin patients who suffered from progressive cardiac degeneration, but whose heart function improved after oral administration of coenzyme Q10.

Move forward to July 8, 2002, and we find that Dr. Langsjoen has become a vocal critic of statin drugs and has published a new paper titled “Statin-Induced Cardiomyopathy.” In an excerpt from this paper, Dr. Langsjoen describes his 17-year experience with statin drugs as follows:

“I have seen a frightening increase in heart failure secondary to statin usage, ‘statin cardiomyopathy.’ Over the past five years, statins have become more potent, are being prescribed in higher doses, and are being used with reckless abandon in the elderly and in patients with ‘normal’ cholesterol levels.”

Dr. Langsjoen attributes these heart failure cases as being caused by “statin-induced coenzyme Q10 depletion” that is preventable if statin drug users supplemented with coenzyme Q10.

The “Forgotten” Merck Patents

Pharmaceutical companies have long been aware that statin drugs can wreak havoc on cardiac patients and that taking coenzyme Q10 along with the statin drug would eliminate these side effects. The evidence supporting coenzyme Q10 as an antidote to statin drug complications is so clear that in 1989 and in 1990 Merck patented the use of coenzyme Q10 in combination with statin drugs to both prevent and treat these complications. However, Merck has neither exercised these patents nor educated physicians or patients about the necessity of taking coenzyme Q10 along with statin drugs. One of the two Merck patents states that:

“Since Coenzyme Q10...is of benefit in congestive heart failure patients, the combination with HMG-CoA reductase inhibitors (statin drugs) should be of value in such patients who also have the added risk of high cholesterol.”

This patent was filed on behalf of Merck & Co on June 12, 1990. Now, almost 14 years later, most doctors and their patients remain ignorant that those taking statin drugs should also supplement with coenzyme Q10.

Last year, Life Extension made numerous calls to Merck’s press and media office to discuss its patent of the statin-coenzyme Q10 combination and why this invention was never brought to market. Unfortunately, we were unable to obtain a response as to why all of this time, money, and research had been undertaken by a leading pharmaceutical company only to let their patents sit in a file cabinet. To this day, few doctors are aware of the coenzyme Q10 depletion problem caused by statin drugs, despite the extensive research undertaken by Merck, Dr. Langsjoen, and others.

Dr. Julian Whitaker Files a Petition Against the FDA

Based on this overwhelming body of evidence, Julian Whitaker, MD, filed a petition against the FDA that meticulously documented the many lethal effects that would occur if patients prescribed statin drugs were not supplemented with 100-200 mg a day of coenzyme Q10. The objective of this petition was to force the FDA to mandate on the package insert that patients taking statin drugs should also take coenzyme Q10.

Dr. Whitaker’s petitions state that statins deplete coenzyme Q10 stores in the body and increase congestive heart failure and cardiomyopathy risk. They call on the FDA commissioner to take immediate action to safeguard the millions of statin drug users.

Dr. Whitaker’s petition explains that statin drug use may be inducing adverse effects in as many as 575,000 people worldwide. The petitions go on to state that statin drugs work by blocking production of cholesterol and coenzyme Q10 in the same pathway, and that consumption of 100-200 mg per day of coenzyme Q10 can reverse depletion induced by statins.

Dr. Whitaker asserts that most patients and doctors do not realize that statin drugs block the production...
of coenzyme Q10. Dr. Whitaker went on to describe how coenzyme Q10 has been found to be essential for cellular energy production as well as for the functioning of the heart muscle. According to Dr. Whitaker:

"Statin drugs have proven in clinical trials to deplete coenzyme Q10, the 'sparkplugs' of the human body. Patients who take statin drugs without coenzyme Q10, particularly those with a history of heart disease, are especially prone to developing complications that can have fatal consequences."}

FDA Fails to Protect Statin Users

Dr. Whitaker’s meticulously documented petition was filed on May 24, 2002. For the past 20 months, however, the FDA has ignored it. The result is that millions of statin drug users are needlessly being subjected to lethal side effects.

The failure of the FDA to amend the drug package insert to recommend that statin users supplement with coenzyme Q10 is a medical travesty. Since the underlying science is irrefutable, this is a blatant example of large drug companies influencing the FDA into not taking actions that would save lives.

Our opinion as to why drug companies may not want this label change is that it could reduce sales of their statin drugs. After all, if doctors told patients that statin drugs could cause heart muscle degeneration, many cardiac patients would refuse to take this class of drug. There is also an economic issue. Those covered by health insurance often have their prescription drugs subsidized, while government programs provide low-income people with free drugs. If these patients were told they had to buy coenzyme Q10 supplements if they are prescribed a statin drug, many would not be willing or able to bear this extra cost.

FORMER FDA COMMISSIONER MAKES SURPRISING ADMISSION

Jere Goyan, MD was FDA commissioner from 1979 to 1981. During that era, the FDA exerted totalitarian authority over what Americans were allowed to read about dietary supplements and drugs. According to the FDA at that time, any advertising claim that even implied that a supplement provided a health benefit automatically turned that supplement into an illegal "unapproved new drug."

Dr. Goyan was FDA commissioner when the Life Extension Foundation published its first newsletter in 1980. Even though Life Extension was not selling products, we were cautioned to avoid any relationship with a supplement maker, as that could draw us into a "criminal conspiracy" if we were to publish information about a particular supplement’s health benefits.

How times have changed! A consumer uprising resulted in Congress passing several bills that limited the FDA’s censorship powers. Federal courts have ruled against the FDA’s suppression of health claims based on First Amendment grounds. Back in 1980, the legal consensus was that the First Amendment did not apply to the FDA.

In response to growing reports that drug companies are engaged in all kinds of nefarious behavior that result in consumers being prescribed dangerous drugs, Dr. Goyan was quoted in the Detroit Free Press on November 5, 2003 as stating:

"We as patients have got to raise the questions ourselves and take care of our own selves." 36

Considering the FDA’s historically rigid position that American consumers are too stupid to make their own health care choices and therefore need the FDA to "protect" them, this statement by a former FDA commissioner that people have to "take care of their own selves" is a revolutionary admission. Too bad so many innocent people had to die because the FDA denied them access to the findings from scientific journals about the disease-prevention benefits of dietary supplements. Consumers back then had a hard time "taking care of their own selves" when the FDA uniformly censored all health claims.
COQ10 IMPROVES PARKINSON’S SYMPTOMS AND SLOWS DISEASE PROGRESSION

In a study of Parkinson’s disease patients, 360 mg a day of coenzyme Q10 was administered for only 4 weeks and there was a mild symptomatic improvement compared to placebo. More important, an established clinical test to measure Parkinson’s symptom function showed significantly better improvement of performance in the coenzyme Q10-supplemented patients compared with the placebo group. This new study helped corroborate a report last year that Parkinson’s patients consuming 1200 mg a day of coenzyme Q10 showed a 44% reduction in the decline of motor skills, movement, and mental function compared to the placebo group. Those receiving this high-dose coenzyme Q10 also demonstrated an improved ability to perform daily living tasks. What was remarkable about this 16-month study was that coenzyme Q10 slowed the progression of the disease, something that Parkinson’s drugs do not do.

On the flip side, more statin drugs could be sold if there were fewer side effects encountered, such as muscle pain, fatigue, liver toxicity, heart failure, etc. A lot of statin drug prescriptions are not refilled because of side effects, so drug companies may be short-changing themselves in the long run by not recommending coenzyme Q10 supplementation.

The fact that the FDA does not mandate this warning on the package insert of statin drugs demonstrates the political nature of the agency’s decisions. The FDA pretends to be a consumer protection agency, but its actions clearly show that its primary function is to protect the economic interests of the drug industry. Statin drugs cause potentially lethal coenzyme Q10 deficiencies in millions of Americans, but drug company profits are obviously more important to the FDA than saving Americans’ lives.

For longer life,

William Faloon

References

FDA SOUGHT TO BAN COQ10

What is truly ironic is that from 1985 to 1994, the FDA made a concerted effort to completely outlaw coenzyme Q10. One of the FDA’s arguments was that because coenzyme Q10 is sold as a prescription drug in Japan, it should not be freely available to Americans as a dietary supplement.

The FDA tried to embargo imports of coenzyme Q10 from Japan and launched criminal investigations against those who promoted it in the United States.

Life Extension’s CoQ10 supplements were seized twice (and won back both times in legal actions). The FDA’s excuse for the first seizure was that the cardiovascular health claims made by Life Extension turned the coenzyme Q10 into an illegal “drug.” During the second seizure, the FDA claimed that coenzyme Q10 was so “dangerous” that it posed an “imminent threat” to the health of the American public. These allegations were of course baseless, and fortunately federal judges eventually saw through the FDA’s charade.

The sad facts were that statin drugs (approved by the FDA) were killing Americans by causing lethal coenzyme Q10 deficiencies. Instead of addressing the statin drug issue, the FDA sought to ban CoQ10—the best antidote for statin drug toxicity.

The FDA continues to proclaim that it “protects” the health of Americans by denying “unproven” therapies. The FDA’s statements about “protecting” consumers’ health may go down in history as one of the greatest medical hoaxes of all time.

It took an enormous amount of effort by health freedom activists to derail the FDA’s efforts to deny Americans free access to CoQ10.