

LE Magazine January 1996

REPORT

The Threat To Melatonin

The Insider's Guide To Illegal And Unconstitutional Acts By The FDA

A major obstacle to progress in healthcare in the U.S. is the enormous cost of obtaining FDA approval to market new drugs. A few years ago the Center for The Development of New Drugs at Tufts University in Boston determined that the average cost of developing and getting approval for a new drug was \$231 million.

The enormous cost of FDA approval makes it difficult for any but the largest pharmaceutical companies to be players in the development and marketing of new drugs. In addition to their economic advantage, the large companies also have an edge in "expertise" because of their ability to hire ex-FDA officials to guide them through the FDA's regulatory land mines.

Another problem is FDA bias against companies that promote breakthrough therapies before they gain FDA approval. Examples of FDA bias is their failure to approve the immune-boosting drug isoprinosine and the potent anti-viral drug ribavirin because of the agency's vendetta against the companies selling these drugs, ICN Pharmaceuticals and Newport Pharmaceuticals.

The American public pays a heavy price for the FDA's bureaucratic bungling and biases. Drugs that manage to make it through the FDA's regulatory hoops are delayed for many years, sometimes decades, before Americans can have access to them. And when Americans are finally allowed to purchase these drugs, they cost far more than in any other country on Earth.

THE MELATONIN MEDIA BREAKTHROUGH

A good example of these costs is the current threat to the health benefits Americans are now enjoying from melatonin-the pineal gland hormone that enables people to sleep better and protects them against the ravages of cancer and aging. Members of The Life Extension Foundation have been able to obtain pharmaceutical-grade (99.9% pure) melatonin since 1992. But recent mass media publicity on the benefits of melatonin has made this remarkable therapy a household word.

In the last few months, melatonin has been featured in the mass media as a potential breakthrough therapy to cure insomnia, prevent cancer and slow aging. The following is just a sampling of media shows and publications that have carried recent stories about melatonin:

- *Newsweek Magazine* - Aug.7, 1995... "Scientists say this hormone could reset the body's aging clock, turning back the ravages of time."
- *Tony Brown's Journal* - PBS Sep.16, 1995... "Melatonin is the most potent anti-aging agent yet discovered."
- *CBS Evening News* - early Sep. 1995... "Melatonin has made me feel many years younger now that I can finally get a good night's sleep."
- *Miami Herald* - Aug.14, 1995... "You can get 30 more years of healthy life, putting us over the century mark." (this story appeared in newspapers throughout the country).

Melatonin's safety is well established in the peer-reviewed scientific literature. While most people take a 3 mg melatonin supplement every night to help them sleep better and to slow aging, studies in humans have shown that doses of 40 mg, 75 mg, 300 mg, and even 1,000 mg can be taken daily with no adverse side effects. What this means is that if a person swallowed all the melatonin in a typical bottle (60 capsules x 3mg = 180 mg) at once, they would probably suffer no toxic effects.

Because of widespread media reports of the health benefits and safety of melatonin, millions of Americans will soon be sleeping better and improving their odds of living in good health to the age 100 and beyond. Melatonin will not only provide major benefits to individual Americans, but will benefit society as well by helping to lower health care costs and increasing productivity throughout the country.

The only thing holding up this extraordinary health bonanza is the fact that melatonin is currently in short supply because of the sudden, unexpected, large scale demand for it. But by early next year, there should be plenty of melatonin available to provide enormous benefits for millions of people in the US. and abroad.

Dr. Wurtman's Conflict of Interest

However, the FDA's restrictive, "good-old-boys" network is a serious threat to the melatonin healthcare bonanza. Dr. Richard J. Wurtman of the Massachusetts Institute of Technology (MIT) recently obtained a patent to sell melatonin as a sleeping pill and is seeking FDA approval to market his version of melatonin through his pharmaceutical company (Interneuron). In doing so, Dr. Wurtman is using the cloak of FDA approval to attempt to gain a monopoly on the sale of melatonin in the United States. In order for Dr. Wurtman to monopolize the sale of melatonin, he must get the FDA to classify melatonin as a "drug" instead of the natural nutritional supplement status it now enjoys.

On Sep.28, 1995, on the *NBC Nightly News*, Dr. Wurtman alleged that melatonin has "dangerous side effects" and said: "I'm really scared that some-one's going to take chronic doses of melatonin in high doses for a long time, and have all kinds of disturbances in their other biologic rhythms, which might lead them to drive into a telephone pole." What was not said on the show was that Dr. Wurtman has a conflict of interest on the subject because of the tremendous profits he stands to gain if the FDA grants him monopolistic control over the sale of melatonin, and that, as a result, his statements on the alleged "risks" of over-the-counter sale melatonin have no credibility whatsoever!

Following Dr. Wurtman's statement, NBC newscaster Robert Bazell stated that: "Another fear is that melatonin is sold not as a drug, but as a food supplement like vitamins. A law recently passed by congress restricts the Food and Drug Administration's ability to regulate food supplements. While there have been no reports of adverse reactions from melatonin, six years ago a manufacturer accidentally contaminated another food supplement used for sleep called tryptophan with an unknown toxin. Forty-five people were killed and hundreds were disabled in this country alone."

THE TRUTH ABOUT TRYPTOPHAN

What Bazell failed to point out is that, with the passage of the Dietary Supplement Health and Education Act of 1994 on Oct.8, 1994, the law was changed to require dietary supplement manufacturers to conform to stringent quality control requirements known as "Good Manufacturing Practices" or "GMPs". The Life Extension Foundation, and most dietary supplement companies have always employed sound GMPs, and now all such companies will be forced to, so Bazell's statement regarding tryptophan can only be viewed as alarmist.

In addition, Bazell's remark that the contaminant in the batch of tryptophan that harmed people is "unknown" is simply not true. In fact, the contaminant in tryptophan was identified as "peak E" in a manufacturing process employed by the Showa Denka company of Japan. This process was never used before and has never been used since the problem was pinpointed by the Center For Disease Control (CDC) several years ago. (Myeno. et al: "Characterization of 'Peak E', A Novel Amino Acid Associated with Eosinophilia Myalgia Syndrome", *Science*, Vol. 250, Dec. 1990 p.1707-1708.)

Furthermore, Christopher Caston, M.D. has patented a nutritional protocol to *treat* eosinophilia myalgia syndrome (the disease caused by the contaminated tryptophan) which *contains* tryptophan! The fact that this successful treatment protocol contains tryptophan explodes the myth that tryptophan itself caused eosinophilia myalgia syndrome, yet the FDA has refused to consider Dr. Caston's life saving work. (Caston, et al: "Treatment of Refractory Eosinophilia-Myalgia Syndrome Associated with Ingestion of L-Tryptophan Containing Products" *Advances in Therapy*, Vol 7, No.4 July/August 1990)

It should be noted that Dr. Wurtman also holds a use patent on l-tryptophan, and has been trying for years to monopolize its sale of a drug analog, just as he is now trying to monopolize the sale of melatonin.

DR. REGELSON'S CHALLENGE TO DR. WURTMAN

Pioneering scientist William Regelson, M.D. of the Medical College of Virginia, the co-author (with Dr. Walter Pierpaoli) of the book *The Melatonin Miracle*, contends that Dr. Wurtman's *real* agenda is to get the FDA to remove melatonin from the over-the-counter market in order to make way for him to sell a melatonin *analog* that Wurtman is developing and for which he holds a patent (number 5,449,683). Dr. Regelson charges that: "If Dr. Wurtman is successful in his goal to remove melatonin from the marketplace as a dietary supplement as he pushes his drug analog of melatonin, the price of melatonin would become astronomical, and a safe product would be made far less available to consumers to the detriment of the public health. Moreover, there would be no guarantee of safety from an unproven analog, while we already know that melatonin itself is safe."

Since 1992, The Life Extension Foundation has been importing and selling pharmaceutical-grade melatonin (assayed at 99.7%-to-100% purity), verified by Leberco Testing Inc. of Roselle Park, N.J. in assay number 958812, May 24, 1995, which was published in the Dec.1995 issue of *LIFE EXTENSION MAGAZINE*. The Foundation also employs Herbert Schneider, a chemist who is a recognized expert in quality control manufacturing to oversee the quality of melatonin (and other products).

THE FOUNDATION'S EXPERIENCE WITH MELATONIN

Foundation Vice-President William Faloon states that: *"If people have been 'wrapping their cars around telephone poles' as a result of taking melatonin, how come we haven't heard about it? We've sold pharmaceutical-grade melatonin to tens of thousands of satisfied customers from around the world for the past 3 years, and have never had any complaints about side effects. It's clear that Dr. Wurtman has an agenda which is not in the best interests of the American people, unless they happen to be stockholders of his company, Interneuron Pharmaceuticals. We deplore the unobjective news reporting of the NBC Nightly News."*

[Back to the Magazine Forum](#)

All Contents Copyright © 1995-2009 Life Extension Foundation All rights reserved.

LifeExtension®

These statements have not been evaluated by the FDA. These products are not intended to diagnose, treat, cure or prevent any disease. The information provided on this site is for informational purposes only and is not intended as a substitute for advice from your physician or other health care professional or any information contained on or in any product label or packaging. You should not use the information on this site for diagnosis or treatment of any health problem or for prescription of any medication or other treatment. You should consult with a healthcare professional before starting any diet, exercise or supplementation program, before taking any medication, or if you have or suspect you might have a health problem. You should not stop taking any medication without first consulting your physician.