To Your Health

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Reflections on Autumn

Dear Friends,

Welcome to the November issue of *To Your Health.* In this issue we expose the FDA drug safety cover up. Also presented are safe, non-toxic supplements to relieve stress, one of the major complaints of my clients.

To your health!
Lita

Anti-Stress Program: Nutritional Support for Mild Panic, Depression, Anxiety, Hyperactivity, Insomnia and Nervousness

Take your appropriate multiple digestive enzyme — usually PAN (sugar intolerance) is indicated, 2 caps with each meal 3x/d. But, sometimes additional formulas are required. The Loomis 24-hour urine test will determine the exact formulas needed.

Enzymes for nutritional support of stress

- **Thera-zyme SvG** — take with meals (2 caps) to for carbohydrate cravings. Take 4 caps 3x/d between meals to relieve a racing mind, can't sleep because can't stop thinking, relax, become serene or meditate.
- **Thera-zyme Adr** — digests sucrose and puts glucose into the brain. Take 2 caps with meals to digest sugar AND take 4 caps between meals 3x/d to help relieve depression, stress, panic, moodiness, anger and when you wake up at night.
- **Thera-zyme CLM** — for nervousness and emotional upsets and severe emotional, mental or physical stress. Take 4 caps as needed.
- **Thera-zyme TRMA** — for anxiety, sighing a lot and immune system problems. Take 4 caps between meals 3x/d.

Anti-stress adaptogen: Rhodiola rosea

Rhodiola relieves depression and increases stamina. Rhodiola rosea has been used for centuries in the traditional medicine of Russia and Scandinavia. Rhodiola has a positive nutritional effect on the mitochondria (the "lungs" of the cell) and may also increase metabolism and improve overall brain metabolism. By providing this energy boost, Rhodiola appears to help cells function better under stress. As well, antioxidants in this herb help protect cells and DNA from peroxidative (free radical) damage. The mechanism by which Rhodiola reduces depression has not been proven. (*Alternative Medicine*, January 2005.)

Here is a summary of clinical benefits reported with Rhodiola:

- Decreases fatigue whether from illness, jet lag or hard work
- Improves physical performance
- Eases mild to moderate depression
- Nutritional support for the immune system
- Improves mental performance and rate of learning.

Hormonal Balancing

- **Pregnenolone** — anti-panic, pro-memory formula. Stops chemical cascade in the brain that leads to panic attack. This is a great formula for the "pre-performance jitters".
- **Thyroid** — a major anti-stress glandular. The need for thyroid will increase with stress (any kind, physical, emotional, mental, and spiritual).
- **Progesterone** in vitamin E oil for women.

Healthy Reading

Dr. Lee's book,

***The Enzyme Cure*,**

is available from her office or her website

Call 503-775-2251 to order or visit: www.litalee.com

This newsletter is provided courtesy of Lita Lee, Ph.D.

Newsletter Editor Michelle Nicolson

Next Newsletter: January 2013

Please send your comments, recipe ideas, email address and suggestions to:

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How the FDA is Recklessly Abandoning Drug Safety

August 13, 2012
By Dr. Mercola
http://articles.mercola.com/sites/articles/archive/2012/08/13/drug-safety whistleblower.aspx?e_cid=20120813_DNL_artNew_1

The FDA once more stands accused of being little more than a rubber-stamping agency for Big Pharma.

Explosive revelations of an intensive spy operation by the FDA on its own scientists emerged last month. Using sophisticated spy software, the agency tracked and logged every move made by the targeted individuals. The targeted scientists had expressed concern over the agency's approval of dangerous medical imaging devices for mammograms and colonoscopies, which they believe expose patients to dangerous levels of radiation. Now, another whistleblower has stepped forward, and what he has to say about the agency's drug safety reviews is shocking even to the jaded.

Former FDA Reviewer Speaks Out About Systemic Suppression of Safety

In a recent interview Robert Kavanagh reveals how the FDA bypassed or ignored safety issues on major drugs approved during his employment. In an interview for the online news magazine Truth-Out he tells Martha Rosenberg:

"In the Center for Drugs [Center for Drug Evaluation and Research or CDER], as in the Center for Devices, the honest employee fears the dishonest employee.

There is also irrefutable evidence that managers at CDER have placed the nation at risk by corrupting the evaluation of drugs and by interfering with our ability to ensure the safety and efficacy of drugs. While I was at FDA, drug reviewers were clearly told not to question drug companies and that our job was to approve drugs. We were prevented, except in rare instances, from presenting findings at advisory committees.

In 2007, formal policies were instituted so that speaking in any way that could reflect poorly on the agency could result in termination. If we asked questions that could delay or prevent a drug's approval — which of course was our job as drug reviewers — management would reprimand us, reassign us; hold secret meetings about us, and worse. He points out that human studies are typically too short and contain too few subjects to get a clear picture of potential risks.

FDA Actively Thwarts Serious Safety Investigations

There's no telling how many ineffective and/or dangerous drugs and medical devices have been approved and ushered into market through sheer intimidation and bullying, either by pharmaceutical companies or FDA management. Perhaps even more shocking are the revelations that some of the internal rules and regulations of the FDA are clearly designed to *thwart* serious safety reviews from the get-go.

Examples of Dangerous Drug Approvals

In his interview, Kavanagh discusses some of the dangerous drugs that were approved in the face of safety concerns. One is the nerve gas drug pyridostigmine — a prophylactic drug against the nerve agent Soman. The drug was approved under the "Animal Rule," which allows drugs to be approved based on animal data alone. There were multiple problems with this approval. First, the animal studies did not reflect how the drug would be used in humans. Second, the drug actually *increases* lethality if nerve agents *other* than Soman are used.

According to Kavanagh:

"This information was not secret — both FDA and DoD public documents acknowledge increased lethality with other nerve agents such as Sarin, and DoD and other government documents that are public also document that Saddam Hussein was not using Soman and was instead using these other nerve agents exclusively.

Yet because I raised this as an objection, I was immediately replaced as the primary reviewer so that I could not document my concerns and so that pyridostigmine could be approved. It's since been proposed that if we ever face the prospect of nerve agents in the future, that this approval will be used as a justification to convince the President at that time to waive informed consent without presenting a full picture."

Pediatric drugs also end up posing unnecessary risks due to the FDA's failure to adequately review safety risks, and the many scientific loopholes employed by pharmaceutical companies. For example, the following flawed parameters are typically used in pediatric drug studies:

- Dosages are based on approved adult dosages, without regard for metabolic differences between a developing child's body and an adult.
- Exposure studies oftentimes use overweight children, and include too few children to adequately evaluate risks.
- No allowances are made for race, age, puberty, or actual weight.
- Dangers to pregnant women and their developing fetuses are also frequently ignored.

"FDA's response to most expected risks is to deny them and

(Continued on page 3)

wait until there is irrefutable evidence postmarketing, and then simply add a watered down warning in the labeling. In fact, when patients exhibit drug toxicity, it is usually attributed to an underlying condition which we know is likely to make the drug toxicity worse. This also allows the toxicity to be dismissed as being unrelated to the drug in any way.

Consequently, toxicities are only attributed to the drug when the evidence is irrefutable. Thus the majority of cases where there is a contributing factor are simply dismissed. When you do raise potential safety issues, the refrain that I heard repeatedly from upper management was, 'Where are the dead bodies in the street?' Which I took to mean that we only do something if the press is making an issue of it."

FDA Safety Reviewers Made to Fear for Their Lives?

Kavanagh gives several examples of how he was personally intimidated, to the point of fearing for his life, and the safety of his children!

"After FDA management learned I had gone to Congress about certain issues, I found my office had been entered and my computer physically tampered with," Kavanagh tells Rosenberg.

"... After I gave Representative Waxman's (D-CA) office a USB drive with evidence, FDA staff was admonished that it was prohibited to download information to USB drives. Then, after I openly reported irregularities in an antipsychotic drug review and FDA financial collusion with outsiders to Senator Grassley's office and the House Committee on Oversight and Government Reform, I was threatened with prison if I should release trade secret information to Congress... [T]he Food Drug and Cosmetics Act explicitly allows communication of trade secrets by FDA employees to Congress, but since most people are unaware of this, FDA management can use the threat of jail for violation of the Trade Secrets Act, not only to discourage reviewers, but in my case they got Senator Grassley's staff to destroy the evidence I provided them.

The threats, however, can be much worse than prison. One manager threatened my children — who had just turned 4 and 7 years old — and in one large staff meeting, I was referred to as a 'saboteur.' Based on other things that happened and were said, I was afraid that I could be killed for talking to Congress and criminal investigators."

FDA Failures Place Health of Americans and Nation at Grave Risk

The FDA's mission statement reads as follows: *"The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health."*

In 2007, a report bearing the revealing title "FDA Science and Mission at Risk" by the Subcommittee on Science and Technology, detailed how the FDA *cannot* fulfill its stated mission because:

- Its scientific base has eroded and its scientific organizational structure is weak
- Its scientific workforce does not have sufficient capacity and capability
- Its information technology (IT) infrastructure is inadequate

Furthermore, the report found that "the development of medical products based on "new science" cannot be adequately regulated by the FDA, and that the agency does not have the capacity to carry out risk assessment and analysis. Additionally, the agency's science agenda "lacks coherent structure and vision, as well as effective coordination and prioritization."

"Make up your mind that nothing is more important than how I feel now, because now is everything. Now is the whole enchilada. Now is the power of me. Now, now, now, now, now... You might as well start somewhere, and it might as well be now. Why not start improving your life now, now, now?"

— Abraham

(FDA, Continued from page 3)

The fact that the FDA does not have its ducks in a row; has sorely misplaced its priorities; and is not working to fulfill its mission is clearly evidenced in the numerous cases where hundreds and sometimes thousands of complaints about dangerous drugs (like Vioxx and Avandia), vaccines (like Gardasil), and additives (like aspartame) are stubbornly ignored, while SWAT-style teams armed to the teeth are sent to raid supplement makers, whole food businesses, organic farmers, and raw dairies when oftentimes not a single incidence of harm can be attributed to their products.

According to the Science and Technology Subcommittee's report, the failures of the FDA is placing the health of Americans, and indeed the economic health of the entire nation, at grave risk:

"The FDA constitutes a critical component of our nation's healthcare delivery and public health system. The FDA, as much as any public or private sector institution in this country, touches the lives, health and wellbeing of all Americans and is integral to the nation's economy and its security.

The FDA's responsibilities for protecting the health of Americans are far-reaching. The FDA protects our nation's food supply through regulatory activities designed to cover 80 percent of the food consumed in this country. The FDA also regulates all drugs, human vaccines, and medical devices, and hence plays a critical role in ensuring the appropriate safety and efficacy of rapidly emerging medical products.

... The FDA is also central to the economic health of the nation, regulating approximately $1 trillion in consumer products or 25 cents of every consumer dollar expended in this country annually.. Thus, ***the nation is at risk if FDA science is at risk****. The Subcommittee concluded that science at the FDA is in a precarious position: the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities."*

Final Thoughts

One of the root causes for their utter abandonment of public safety is that the majority of the FDA's funding comes from the very companies that it is seeking to monitor and evaluate. The FDA has progressively morphed into a mere pawn and instrument of the drug industry, which has little to do with drug safety, and everything to do with maximizing profits.

As Dr. David Graham — another prominent FDA whistleblower who blew the lid on the Vioxx scandal — stated in a 2005 interview:

"As currently configured, the FDA is not able to adequately protect the American public. It's more interested in protecting the interests of industry. It views industry as its client, and the client is someone whose interest you represent. Unfortunately, that is the way the FDA is currently structured.

Within the Center for Drug Evaluation and Research, about 80 percent of the resources are geared towards the approval of new drugs and 20 percent is for everything else. Drug safety is about 5 percent. The 'gorilla in the living room' is new drugs and approval. Congress has not only created that structure, they have also worsened that structure through the PDUFA, the Prescription Drug User Fee Act, by which drug companies pay money to the FDA so they will review and approve its drug."

The only real solution isn't minor changes to the existing structure, but a complete reform of the FDA. But until then, please, don't risk your money or your life on a paradigm designed to profit from your ill health. Instead, switch to natural methods that will allow your body to heal itself without the need for the deadly drugs being pushed on you by the drug companies and the FDA.