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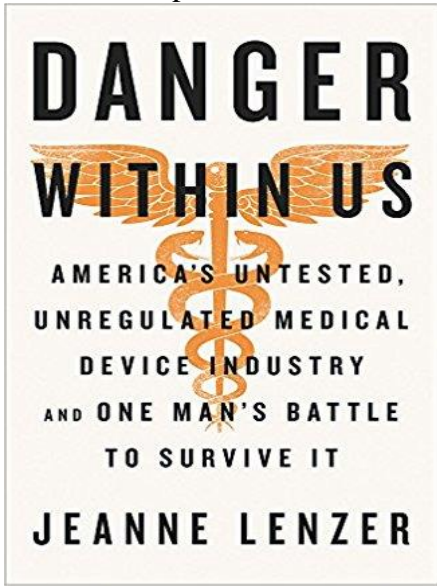
John T. James, Ph.D.

*Question: Between 2011 and 2016, how many U.S. physicians were disciplined by one state medical board, and yet were able to hang their shingles out in a new state with a "clean" license?*  
 a) 100      b) 200      c) 300      d) 400      e) 500

**Book Review: The Danger within Us – America’s untested, unregulated medical-device industry and one man’s battle to survive it.**

By Jeanne Lenzer

Ms. Lenzer, a medical journalist, tells her tale at two levels, as her subtitle suggests. She begins with the story of Dennis Fegan, a Texan harmed in an automobile accident as a boy, and who eventually developed disabling seizures. He is duped into trying an implantable contraption called a vagus nerve stimulator ([VNS](#)) in his neck to ward off seizures. As the story goes, the device nearly kills him because of its ability to stop his heart. Woven beautifully into this personal story is that of how the device industry came to be much more focused on profits than helping patients. That industry was aided by a secretive, overwhelmed, weak, and industry-favoring Food and Drug Administration (FDA).



The reader becomes acquainted with a few terms that could easily affect his life, yet are largely unknown outside the mafia-like world of medical device marketing and FDA acquiescence. Medical devices are the beneficiary of the “preemption doctrine,” leaving harmed patients largely powerless to sue for harm caused by any device. The FDA is the victim of “regulatory capture” by the device industry. The reader discovers how “current political realities” poison the chances for consistently safe and effective devices.

Most folks know what an “end run around” is in football, but now the reader learns how this works within the marketing strategies of the device industry. An end-run is instigated with the poorly defined term “substantially equivalent” backed by massive lobbying efforts from the device industry, and by “paying kickbacks” to physicians who become the front-line marketers of the substantially equivalent devices. Learn how the “revolving door” enables industry to weaken the effectiveness of the FDA. Learn how the FDA gives conditional approval, and then never follows up on whether the device-maker in question actually meets the conditions. Side effects may be “deemphasized” and hidden “under the rug.”

In other terms, the reader learns the difference between clinical significance and “statistical significance.” This forms the backdrop for “medical illusions” that distort the thinking of physicians. These are enhanced with aggressive “marketing tactics” often based on “biological plausibility.” The goal here is to capture a “key opinion leader” to be paid to promulgate the company’s marketing strategies. “Perverse incentives” are widespread in the medical industry. This may lead to the interesting term called “cure as cause,” meaning that the intent to cure with some device actually becomes the cause of harm.

The reader discovers how the FDA’s 510k process for clearing devices for marketing fails to protect patients like Mr. Fegan from harm, but makes it easy for device makers to ply their contraptions. “Off label” marketing is yet another ruse the device industry uses to enhance sales to the detriment of patients. Fines for such practices are

simply “part of doing business.” Elicit promotions are sometimes hidden behind the wall of “commercial trade secrets.”

In the end, the reader comes away with a troubling sense that he had better be careful when any device is recommended for treatment. As for Mr. Fegan, he continues to try to change the system that led to his harm. One might deduce that by being the subject of Ms. Lenzer’s book, he may have accomplished change, at least in the individuals that read the book, if not in the money-driven medical-industrial complex. The book is a remarkably easy and informative read. I noted that Amazon reviews are highly polarized - 21% give it a 1 and 63% give a 5. It seems that those associated with the device industry do not like her analysis, which is backed up by 396 reference notes. She is not the first writer to attack the way medical devices are regulated. Those who are critical of her writing might want to know that the Institute of Medicine declared that the 510k process used to clear devices is so flawed that it should be replaced. It has not been. I give this book 5 stars. About \$16 on Amazon.

### *Restasis – My Eye!*

When I was a kid some in my family used to reply “My eye” to some of the tales I told. This indicated that there was doubt in the veracity of what I was saying. And, so it is with Restasis, a medication for dry eye. Two MDs trace the widespread use of this drug in the U.S. despite any convincing evidence that it is effective in treatment of [chronic dry eye](#). The authors point out that \$8.8 billion in sales happened from 2009 to 2015, and of this \$2.9 billion came from Medicare part D. How does a company achieve such success with a marginal drug?



In the American system, this is not too difficult. The drug is not approved in the European Commonwealth, Australia, or New Zealand. It is approved in Canada, but no provincial health insurance pays for it. Here is brief history of how this stuff was approved by the FDA. In 1999 the

FDA rejected the drug for treatment of chronic dry eye. Allergan, the manufacturer, cooked the data over and over again, finally winning FDA approval in 2003 for increasing tear production.

In 2010 Canada approved the drug for moderate, but not severe chronic dry eye. The means of selling this stuff was to coin a new illness “chronic dry eye *disease*.” From 2007 to 2016 the manufacturer spent \$645 million on advertising the drug. I remember multiple TV advertisements featuring a doe-eyed clinician giving the stuff to a young woman. This campaign was enhanced with an on-line Dry-Eye questionnaire designed to convince the person taking it that Restasis was the answer to this pseudo-condition because it increases tear production. The company paid doctors \$9.1 million from 2013 to 2015, presumably to promote and prescribe Restasis.

That’s how marginal drugs and devices are marketed in a free-enterprise healthcare industry. The authors point out that a deeper dive into the data may have convinced American doctors against the use of this stuff. It is expensive. Sixty [restasis](#) vials of 0.4 ml each (about half the size of a small pencil erasure) cost at least \$525 with discounts. At a dose every 12 hours in each eye, this will last for a month at best. Apparently, dry eye is perceived to be a huge medical problem by some.

### *Medical Overuse in 2017*

It is an open secret, to doctors at least, that overuse of medical treatments is widespread and drives up the cost of U.S. medical care. This is no surprise in a system that is based on free-market principles – basically – sell customers what they think they need, or if they don’t need anything, throw in a little fear to modify their thinking. I just talked to a colleague in San Antonio who was the intended victim of fear mongering by doctors. He was smart enough not to bite.

A team of MDs searched the literature published last year to glean which procedures were being performed as part of the overuse landscape. [Medical overuse](#) was obvious in many cases, but the 10 most influential articles were selected for documentation. Some procedures were simply inappropriate, whereas others were deemed to be more likely to harm the patient than to help.

The procedures that may harm more than help included the following: treatment of early-stage

prostate cancer, oxygen for patients with moderate obstructive pulmonary disease, surgery for meniscal tears in mechanical symptoms, and nutritional supplements for people with malnutrition. As possible solutions to overuse, the authors point to shared-decision making with patients and peer-feedback on potential overuse. It seems to me that the role of patients in such conditions is to ask for the demonstrated, quantitative benefits and risks of any proposed procedure.

While I am on the subject of overuse, let me remind my reader of ongoing overuses that seem to hang on unabated. These include the insertion of cardiac stents in patients with stable angina when they should be treated with optimal medications first. It seems that even in patients with some pain, the insertion of stents is of no help. Dr. Rita [Redberg](#) has campaigned against this overuse for years.



One of the more harmful [overuses](#) is that of advanced imaging. An MD points out the harms that may occur from advanced imaging – radiation exposure, incidental findings, and patient anxiety. Radiation exposure is associated with a few percent of cancers, and incidental findings may lead to unnecessary invasive procedures. Anxiety occurs when a scan discovers a “suspect” lesion that has nothing to do with the original purpose of the scan. The author argues that overuse of advanced scans is not going to be easy to stop. She proposed decision-support tools for doctors to guide away from overuse. **The patient’s role in this is to ask what a scan is going to reveal that is going to change the course of treatment.**

## *Bariatric Surgery and Obesity*

In my September 2017 newsletter, I summarized an article critical of gastric bands for treatment of obesity. It seems that re-operations are extremely common. In this month’s collection of articles, I came across one that describes the [long term outcomes](#) of a multi-center experience with gastric-bypass and gastric-band, bariatric surgery. The study included about 1700 patients that had a Rou-en-Y gastric bypass and 600 who had laparoscopic adjustable gastric banding. The 7-year weight loss from the first procedure was 28 percent and from the latter was 15 percent. Operative revisions were about 1/800 for the bypass surgery and 30/700 for the gastric band operation. The authors discuss various barriers to the use of surgery to relieve obesity. If I were considering such an operation, I’d make sure I knew the risks, and then choose a hospital and surgeon with lots of experience and an excellent track record.

Another viewpoint by 2 PhDs examines the [social factors](#) associated with obesity. They note that there is some movement to accept fatness as OK. As norms drift to acceptance of fatness, as they have in the U.S., there seems to be a reduction in the stigma associated with obesity. Medical professionals must not stigmatize patients who need treatment for obesity. Instead, the focus should be on healthy behaviors – reasonable diet and some exercise.

Three experts ask the question – which matters [fitness or fatness](#)? They cite various studies that seem to favor fitness over avoiding obesity as being associated with longevity. But there are plenty of studies that do not support this conclusion. They note that cardiovascular fitness declines as we age and fatness tends to increase. In the end, they deduce that what matters most is physical activity. Guidelines recommend 150 minutes per week of moderate activity or 75 minutes of vigorous activity per week. So, go for a vigorous, 30-minute walk, and then come home and reward yourself with some ice cream – maybe it is a zero-sum game.

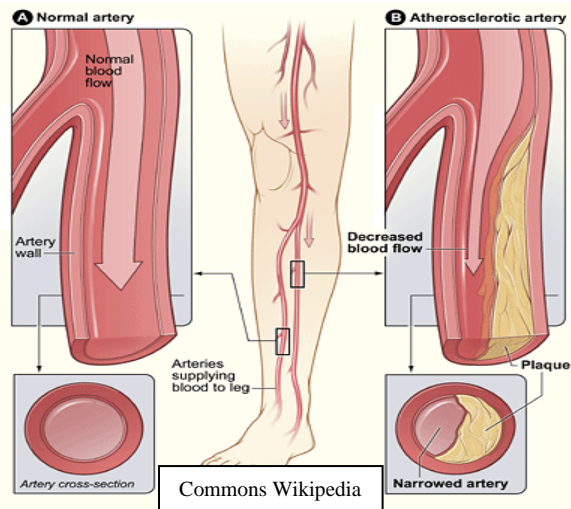
The *JAMA* periodically devotes an [entire issue](#) to the problem of obesity. The last of these was six years ago. The hope then was that something definitive would appear that really works to reduce obesity in the U.S. That has not happened. Perhaps the call to “reimagine” obesity is the way to go. The author notes that some communities have tried to control sugar consumption with warning



labels on high-calorie drinks. This did not go over well. Bariatric surgery does seem to diminish obesity and rates of diabetes, but there are concerns with applying this widely. It appears that a “new norm” of accepting obesity is underway in the U.S. The author concludes with a pessimistic view of our efforts to control obesity. A refocus on fitness may be our best bet.

### *Peripheral Artery Disease – Beware the Boomerang*

Pain in your legs may suggest that you have peripheral artery disease. There is a [decision aid](#) for this condition that you may want to review before you agree to undergo surgery. Approximately 8.5 million Americans have this condition. A recent



study published in the *Annals of Internal Medicine* has underscored the [high risks](#) associated with surgery for peripheral artery disease. The research team looked at the records of 62,000 people (median age 68 years) discharged from the hospital after surgery for peripheral artery revascularization in 2014. The major complications during the index hospitalization were as follows: vascular complication (22%), major bleeding (18%), acute kidney injury (11%), and heart attack (3%). Such surgeries must not be undertaken lightly.

The investigators discovered that almost 18% of the patients had an unplanned readmission (boomerang, if you will) to the hospital within 30 days of discharge. This return rate is third only to patients with heart failure or psychoses. The causes of unplanned readmission were as follows: procedure complications (28%, usually infection),

sepsis (8%), diabetes (8%), and gangrene (5%). The likelihood of readmission did not vary greatly among the 1,085 hospitals studied; it was from 16.6% to 18.8% at the 25<sup>th</sup> and 75<sup>th</sup> percentiles, respectively. The median cost of readmission was just over \$11,000. The authors recommend better post-discharge care to reduce 30-readmissions.

**Based on my look at the decision aid linked above, it seems to me that the informed patient should seek alternatives to revascularization of peripheral arteries for leg pain. These include lifestyle changes, medicines, and exercise.**

### *Fungal Infections of Toe Nails*

Many of us have toenail infections with fungi. One may paint contact remedies on the offending area, but these are often ineffective. Three experts published in the *JAMA* a summary of a [Cochrane Review](#) of 48 studies on the effectiveness of oral medications that treat toe nail fungi. These were generally grouped as terbinafine, or azole-based medications. The clinical cure rates, defined as achieving normal toenail appearance, were only 57% for terbinafine and 31% for azoles. The authors caution that clinicians should discuss these success rates with patients to keep expectations realistic. The prevalence of side effects from the medications was not statistically different from those reported by patients that received a placebo. The [Mayo Clinic](#) has some options for toenail fungus treatment.

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