THE DANGER WITHIN US, By Jeanne Lenzer
Book Report and Comment, by David G. Schwartz, M.D.

Millions of people in this country are implanted with medical devices every year. More than 32 million, about 1 in 10, already have devices in their bodies, thinking that they have been tested and vetted properly, for safety and efficacy by the FDA. Appallingly, they don't get nearly the rigorous testing that drugs do before being approved by the FDA. That is not much to compare to, considering that many dangerous drugs are approved and have to be removed from the market after many thousands of people have died years later. Post marketing surveillance (monitoring the performance after approval) is poor for drugs, but for devices, it is almost non-existent.

Jeanne Lenzer, award-winning medical investigative journalist, portrays the shocking dangers of a failed regulatory system that allows sloppy science and faulty technology to experiment with unwitting patients for the profits of industry. She details thoroughly the dramas of medical corruption, influence peddling, deception, kickbacks, punishing of whistle-blowers, redaction and censorship of peer-reviewed journal articles, all for keeping patients in the dark about the objects placed in their bodies. This is a part of a larger whole medical-industrial complex that considers health care to be a commodity, not a basic human right. She weaves the sad story of Dennis Fegan throughout the book, injured by a device that almost killed him, turned off but never removed because of the dangers of surgical removal. She tells of his frustrating attempts to get information about it, to warn others about the dangers, and to have the device removed from the market, meeting legal and bureaucratic obstacles at every turn. At the printing of this book in 2017, the VNS device was still being implanted in people.

She receives high praise for her book from former editor-in-chief of the New England Journal of Medicine, Marcia Angell, M.D., Shannon Brownlee, author of Overtreated, and Bernard Lown, M.D. cardiologist, emeritus professor, Harvard School of Public Health, and Nobel Peace Prize recipient, among many others.

Some considerations about medical devices that many people may not be aware of is that a metallic object in the body prevents a person from being able to have an MRI, which may be vital necessity some day. Some devices cannot be removed, because of the scar tissue formed, and the consequent dangers of surgical removal from delicate tissues. Many devices use the cyberspace in order to function, and the can be hacked into, especially hazardous for people in the public eye. Dick Cheney had his pacemaker disconnected from the internet for that reason. If a device malfunctions and causes patient harm, the manufacturer will usually say it was the fault of the doctor who put it in. Then the patient can sue the doctor, but the manufacturer cannot be sued. If an adverse event takes place, often the manufacturer's manager can write the report and decide whether or not the adverse event was related to the device used. The FDA reports numbers of deaths, but does not track the total number of devices, so we don't know the % of the devices have deaths associated with them. Drugs are dated and tracked, and a batch of lettuce sold at a supermarket can be tracked from where it came and its destination, but there is no adequate tracking system for these devices. The Government

Accountability Office analysis found that the FDA reported 16,000 deaths in 2015, but that an estimated 99% of device-related adverse events are never reported to the FDA.

The "revolving door" involves people leaving the device industry to work for the FDA, which gives them an industry-favored bias. Then the regulators leave the agency to take lucrative jobs in industry, as a reward for serving the industry well while at the agency. The agency can be "captured" or controlled by the industry it is supposed to police, defending the industry over the public interest, thus, the term, "regulatory capture."

It is up to cabinet officials to craft policies that minimize regulatory capture of the agencies. When industry gives generous campaign contributions to Congressional and Presidential candidates, it is no surprise that administrations of both parties are business-friendly and pressure the FDA in favor of the device industries. My comment is that in many other countries corruption involves direct bribes, but in this country, it is honed to a very subtle fine-tuned art, crafty and legal. This is not likely to change as long as enormous sums of money are needed for campaigns and are readily available from corporations that want their money's worth in return.

Before 1968, the FDA Commissioner was a civil servant. Then Richard Nixon changed it to a political appointee. Since then FDA commissioners have all been industry-friendly, with the exception of Dr. David Kessler, who courageously battled the tobacco companies and recently is campaigning against the marketing of sugar-laden junk food to young children.

Many times the FDA commission will approve a drug or device against the overwhelming opinion of its own scientists. When a device runs into opposition, the manufacturer can call its Congressperson to whom it has given campaign contributions. Then the legislator calls the FDA with threats to cut off funding from Congress. The FDA bends to industry pressure to approve a dangerous device or drug that should never be on the market.

Medical devices didn't come under regulatory control by the FDA until 1976, when Congress passed the Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938. So all devices, including high-risk devices on the market before 1976, may continue to be sold under the 510(K) provision of the Act. Then, any new device that the manufacturer considers to be "substantially equivalent" to an old device, can also be approved. Added to that, any other device substantially equivalent to another new device previously cleared under 510(K), can also be approved, without any clinical trials. On and on the iterations continue, until the current iteration bears little resemblance to the original, like the old game of "telephone." Three decades after 1976, only 16% of the highest-risk devices underwent clinical trials.

Even when devices did undergo testing, a 2009 study found that only 27% were randomized, 14% blinded, and 88% used only surrogate markers as endpoints. A surrogate marker is an intermediate health measure (such as heart rhythm or Hemoglobin

A1C) that shows the effect of the intervention but does not reflect overall survival or mortality. Reported in JAMA, from 2008-2012, the FDA approved 400 high-risk implanted medical devices without requiring clinical testing.

The information doctors receive is tainted by manufacturers' bias. University medical research is highly funded, designed, and monitored by industry, so data can be manipulated in any number of ways, to make the outcome appear favorable to the manufacturer.

After the uproar about the military-industrial complex during the Vietnam War, universities were prohibited from accepting funding from industry. Then during the Reagan years, that was reversed. The Bayh-Dole Act created academic-industrial partnerships, and allowed universities and their researchers to own patents for their innovations. By 2014, 86% of clinical trials were funded by industry. So all medical education based on this research should be suspect.

Dr. Marcia Angell, former editor-in-chief of the New England Journal of Medicine wrote, "Let me tell you the dirty secret of medical journals: It is very hard to find articles to publish. With a rejection rate of 90%… you end up publishing weak studies because there is so much bad work out there."

Medical illusions often drive the thinking and evaluations of devices and drugs. Dr. Jerry Hoffman, after 3 ½ decades of medical practice and as professor of Medicine at UCLA, saw a lot of wrong medical thinking, and he has lectured around the world about medical illusions. He discusses how we use medical language that can leave a different impression on the public than is factual. The word "significant" in a study means that there is a real effect of the intervention, drug, or device that has a 95-98% certainty that the effect is not do to chance. The effect may be too small to be of importance or practical or cost-efficient, but it is statistically significant, not medically or "clinically" significant. Thus, something may be approved because studies show it to be "significant." The word "benefit" can be assumed to be "net benefit" when it is not. There may have been adverse effects that, on balance, decreases the value of, or negates the benefit, and yet it is recorded as a benefit.

Sometimes devices are approved on the basis of impressive case studies or anecdotes. Manufacturers may bring patients to give dramatic testimony to the FDA about how a device has done wonders for them. How were the patients selected? The phenomenon of "regression to the mean," occurs as chronic conditions wax and wane. Some patients are more likely to volunteer for a study when they are in a worse phase, and then when the symptoms wane, it may coincide with the intervention used. Was it the drug or device, or was it a part of the natural cycle? There is also spontaneous remission that occasionally occurs and can coincide with the treatment. Also there is the placebo effect, which is a real improvement that always has to be accounted for. Then what is not reported is as important as what is reported. Many clinical trials that show negative results for a drug or device are not reported and kept sequestered as "trade secrets."

Another ominous aspect of medical devices is the way doctors are manipulated to support the device industry against the best interests of patients. Often the surgeon who implants the device depends on a manufacturer's representative to help with the technical procedures in the operating room. That promotes a cozy relationship between the doctor and the manufacturer. The industry funnels large sums of money to doctors who use the device or who lecture to other physicians about the devices. Money is sometimes "laundered," sent through third parties, sometimes, patients' advocacy organizations, which are really fronts for the manufacturers.

Often manufacturers promote devices for conditions for which they are not approved, make false claims, fail to report adverse events, pay kickbacks to doctors, etc., all illegal acts. They pay millions of dollars in fines regularly and continue to violate laws, as "just the cost of doing business." Recall Peter Gotzsche's book, Deadly Medicine and Organized Crime, about pharmaceutical industry corruption. My report on it is in the archives. Many if not most companies do this. Seven (a few among many) fines paid by Medtronic are itemized on page 146, with the comment, "Medtronic is no exception."

The enormous sums of money in the sales of these device is staggering. Why does a hip replacement in this country cost 3-5 times that done in some European countries? Hospitals can pay $4,500-7,500 for a hip implant that costs $350 to manufacture. Hospitals sign confidentiality agreements to not reveal the purchase price. How can patients exercise their "free market" powers as consumers when there is little price transparency?

The book tells the narrative of Dennis Fegan, who had severe, frequent seizures and had a device, VNS (Vagus Nerve Stimulator) implanted around the vagus nerve in his neck to decrease seizures. After a while he began having "drop attacks," which were called seizures, even though they did not resemble the symptoms he had had with the seizures previously. The episodes became more frequent. When a severe episode occurred, he went to the hospital by rescue squad. Then it was discovered that his heart would stop long enough for him to pass out. He had had several fractures from previous falls. Every 3 minutes his EKG would flat line in asystole (no electrical activity). When finally someone suspected the device, the device was turned off, and he had no more episodes. He had nearly come to the end of his life on earth. If he had died, it probably would have been diagnosed as SUDEP (Sudden Unexpected Death in Epilepsy), which does occur with some people with severe epilepsy.

Dennis wondered how many other patients had been killed by this device, diagnosed as SUDEP? He met with his neurologist and a manufacturer's representative, who would not say whether this incident would be reported to the FDA, and there was no offer of compensation. The representative denied that he knew of any other case like this, which was a lie, discovered later. His neurologist then refused to see him any more.

In 2010 Fegan discovered through the MAUDE (Manufacturer and User Device Experience) web site sponsored by the FDA, where patients reported experience with the VNS device, 800 device-related deaths among approx only 50,000 patients with the

device. Yet Cyberonics, the manufacturer, declared that all these deaths were SUDEP. Fegan explored the FDA's website and found that Cyberonics had earlier failed to report 60 deaths. The FDA had sent a warning letter to Cyberonics back in 2001 about it.

When Fegan tried to sue Cyberonics, he was not allowed, due to a U.S. Supreme Court decision in 2008, Riegel vs. Medtronic, that no one could sue a manufacturer over a device if the device had been approved by the FDA. The false assumption the court made was that the FDA was doing its job. The FDA has to recall about 1100 class I (high-risk) devices annually. In the 1997 pre-market deliberations, the FDA knew there were a large number of deaths associated with VNS, Medtronics' original approval for it was then conditional. The conditions were never met. In an FDA advisory meeting, the sum of the Cyberonics data regarding the VNS showed that 18% of subjects improved over the short term, most patients failed to improve, some experienced worsening of their condition, and many died.

Fegan tried contacting the FDA directly, and got many rebuffs and runarounds. He contacted his Congressman, Ortiz, who could not get a response from the FDA. The author contacted the FDA, whose representative would not confirm or deny that there was an investigation of the VNS. So the author states that 11 years after Fegan's near death experience and 8 years after Ortiz' letter, any information about an FDA investigation "is locked up so tight that even my Freedom of Information Act requests have failed to unearth it."

Fegan found through other sources that nearly 1000 VNS patients had died in one decade, yet the FDA still insists that the VNS is safe, and this author, on emailing the FDA, found that the FDA never required Cyberonics to count the actual numbers of deaths, but only to "characterize" mortality. The FDA ignored its own demand for safety studies, when the VNS was first approved. So many patients may still be dying as a result of the VNS, and with no recourse to valid information or justice.

Dennis Fegan's experience is not atypical. The author recounts other patients' stories, one of which is about an orthopedic surgeon who had his own hip replaced with a metal-on-metal device, that caused massive tissue damage and cobaltism, and had to have it replaced, all without his being informed properly in advance. A Medtronic representative had a device implanted into her neck without being informed about it properly, and suffered scarring and pain, and got fired from her position. These are only a few stories that exemplify the problem of patients being harmed unwittingly by these devices, often with no recourse to justice.

Fegan continued to email officials at the FDA and got promises to investigate the situation, but that never materialized. Time after time, he ran into a brick wall. He found out later that when he had had his cardiac arrest incident in 2006, the X-Rays showed that one of the lead wires had migrated into his jugular vein, and that was confirmed again in 2010, and a clot was attached t it. As far is we know, he is still alive with the device still in place and no satisfaction that he could do something to prevent thousands of other

patients from suffering the fate he had. Maybe this book will make this situation more transparent.

What can be done? Dr. Bernard Lown referred to before, has been a medical activist for many decades. He and his Russian counterpart, Dr. Evgeni Chazov, shared the Nobel Peace Prize for their work toward nuclear disarmament and the Reagan-Gorbichov summit. Dr Lown founded the organization, Physicians For Social Responsibility, which raised health concerns about the danger of nuclear war.

Dr. Lown spoke at a forum of the Lown Foundation and the New America Foundation, where Shannon Brownlee was working. He said, "the underlying issues relate to essential moral principles. At the core … is a covenant of trust between health professionals and patients…[and] the expectation that the patient's needs will be placed first, over and beyond personal interests and the interest of any third party." He stated further, "There is a moral absolute in medicine to help and never to wrong the patient. No such moral absolute can be found in the marketplace." Furthermore he said, "The warm and fuzzy rhetoric that "patients come first," is a transparent marketing ploy. For-profit healthcare is essentially an oxymoron."

In my view, there are very few doctors who have a one on one relationship with the patient without considering the influence of a third party. In that rare situation, the potential benefits, harms, and costs are more transparent, and the free market can work, Patients can make informed choices, and many times the doctor does charity or pro bono care. The health professional can look the patient in the eye and honestly put the patient's needs first and follow the Hippocratic maxim, "First do no harm, " from a moral perspective.

That situation almost no longer exists. Recall An American Sickness, by Elizabeth Rosenthal, who concluded that the current system is not sustainable. See my article in the Archives. It is a whole medical care system that is treating the patient, driven by profits, accountable first to its shareholders and not legally bound to put the patient's needs first or to " do no harm." This whole medical system needs to take the Hippocratic Oath. This can only be done by eliminating the profit motive as the primary motivating factor for service. Health care must no longer be used primarily as a commodity but recognized as a basic human need, and the system should exist primarily for the patient. Health care must be a social business, generating enough income for its workers and professional to make an adequate living, but not to maximize profit. Health professionals are basically altruistic, and they must be allowed to work in an altruistic system. This could be done with tightly regulated social capitalism, or with a single payer, such as Medicare for all.

Patents on drugs and devices stifle innovation because most patents are only slight alterations on existing products, "me too" products, not for true innovations.
Many drugs are patented by private industry, after much of the basic research had already been done through public funding.

The author of this book proposes a single payer system, and she notes several polls showing that a majority of the public and doctors favor that.

The FDA needs to be reformed, stopping political appointments, doubling the budget, and stopping drug and equipment manufacturers from paying user fees to the FDA. Every high-risk implanted device should be subject to at least 2 randomized, placebo-controlled trials. The Bayh-Dole Act should be repealed.

Lacking those changes to public policy, what can you do? First, be proactive, preventive, with healthful lifestyle, so you are less likely to need medical devices and drugs. For health problems, except for emergencies, seek the least harmful treatments first, herbs, supplements, home remedies, chiropractic, homeopathy, acupuncture, etc. If worst comes to worst, and you think you need a device, exhaust every other option of dealing with the situation, including prescription drugs, if necessary. Ask plenty questions of the surgeon like, "What is the evidence that it has had proper studies of safety and effectiveness, and adverse effects, and how many deaths per thousand implants? Look up as much information as you can online that is not sponsored by the manufacturer. You can go to https://openpaymentsdata.cms.gov to find how much money the company has given your surgeon, and you can ask the doctor the same question. Don't do the surgery without your questions being answered. Of course, in an emergency, like a heart attack, go ahead and get a stent placed in your coronary artery without asking a lot of questions. Anyway, asking questions puts you in the driver's seat, and you will more likely get better monitoring and quality of care.

This book is a timely eye-opener and its warnings need to be heeded, as a window into how the whole medical industry operates. Caveat Emptor.