

HEALTH AND STRESS

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HEALTH CARE- MORE FOR PROFITS THAN PATIENTS?

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It certainly seems that way. Premiums for health insurance have soared due to the steady rise in treatment costs, without any concomitant improvement in patient care. Deceptive drug company advertising and manipulation of clinical trials have been major contributors to this escalating crisis. A prime example is their ability to turn healthy people into patients by exaggerating the significance of minor complaints. This has been greatly facilitated in the U.S. by TV and other media hype that is banned in other countries.

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Take the case of a patient with a thickened, yellowish toenail due to a fungus infection. What the TV ads don't tell you is that Lamisil treatment only cures 38% of patients, and that this takes an average of ten months. The need for liver function tests and to avoid alcohol is mentioned, but not that 16 cases of liver failure and 11 deaths were reported to the FDA.

Costs are never mentioned, but a cure will set you back more than \$2,500. With respect to profits, **the price for a three-month supply of Lamisil here is \$850, compared to \$180 in Canada for the identical product.**

The cost for statins, the best selling class of drugs, is four times higher in the U.S than the U.K. for both brand names and generics. One explanation for this may be that pharmaceutical companies here spend more on advertising than they do on research and development. Small wonder that we spend so much on medications but have so little to show for it.

Erectile Dysfunction, Obesity And Insomnia – To Treat Or Not To Treat?

Another ploy is portraying normal, age-related changes or conditions as disorders that require treatment, even though they do not threaten health. Most people require glasses as they grow older and some need hearing aids, but these are merely appliances that increase our ability to enjoy life and have no effects on other body functions. Erectile dysfunction (ED) is another condition that increases as senior citizens age, and although it diminishes the quality of life, it is not a threat to health per se. This can be corrected in some instances by drugs that improve having satisfactory sexual relations, but they will not enhance health or prolong life. Nevertheless, TV ads portray erectile dysfunction as a disorder that is **"associated with an increased risk for heart attack."**

As a result, some viewers believe that taking Viagra or something similar will help to prevent heart attacks. The reality is that the reverse is much more likely to occur in patients with coronary disease, as well as elderly individuals who have not had sex for years. The highlighted statement above is not considered false advertising because no health claims are made. A statistical association is not surprising since both coronary disease and ED can result from diminished blood flow due to increased atherosclerotic deposits. But that does not mean that treating one condition will also benefit the other, as the term risk implies. A similar situation exists with cholesterol, which is always touted as a risk factor for a heart attack, when it is merely a risk marker, like a potbelly, deep earlobe crease, premature vertex baldness and over 200 other items that tend to be seen more frequently in patients with heart disease. However, although a tummy tuck, plastic surgery or a hair transplant can correct these risk markers, they will not reduce the likelihood of a heart attack, nor does lowering cholesterol.

As you might imagine, statin manufacturers were quick to exploit this potentially lucrative bandwagon by claiming that since statins lowered cholesterol, they would also reduce or even reverse atherosclerotic ED. Their early trials seemed to demonstrate this, especially in obese diabetics and patients with other manifestations of metabolic syndrome. It is more likely that many may have benefited from a placebo effect because of the strong influence of psychogenic factors on erectile dysfunction. One explanation of the difference between fear and panic is that fear is the first time you find that you cannot perform a second time, and panic is the second time you fail on the first attempt. Studies now show that statins lower testosterone levels and that spontaneous complaints of erectile dysfunction are 10 times more common in men taking statins than those taking other drugs. Over 50 percent reported recovery after the statins were discontinued. Although it has long been known, the FDA finally just mandated a warning label for all statins stating they can increase risk for diabetes and memory problems.

One study **reported a 50 percent increase in diabetes in longtime statin users. Current recommendations are that all diabetics should take statins regardless of LDL or cholesterol levels to prevent heart attacks!** This must be confusing to patients as well as physicians.

Obesity and insomnia are also very lucrative markets, since any FDA approved weight loss drug is guaranteed to be an instant blockbuster. It is well established that obesity is a risk factor for diabetes, heart disease, stroke and certain types of cancer, so unlike ED, there is a medical need for such drugs. However, this has little to do with their popularity, which is the desire to shed a few extra pounds, especially for women. But the public is also wary because of the stigma of older habit-forming amphetamines that frequently caused cardiovascular problems. There have been approved drugs like fenfluramine (Pondimin) but most were not very effective and any benefits were outweighed by numerous side effects like drowsiness and memory loss. It was later found that when fenfluramine was given with phentermine, another diet drug, not only did this combination cause greater weight loss, but that there were fewer side effects. In one study, subjects weighing an average of 200 pounds lost an average of 34 pounds. In the early 1990's, doctors began prescribing this fenfluramine-phentermine "Fen Phen" cocktail as an "off-label" combination, meaning it was not approved by the FDA. However, physicians are free to prescribe any FDA approved drug for any condition for which they feel it might be helpful, as long as it has not been specifically contraindicated in a warning notice.

Since sales for Fen Phen were steadily increasing, despite evidence of harm, and the patent for Pondimin was about to expire there was an urgent need to find a new weight loss drug the FDA would approve. The solution seemed to be Redux (dexfenfluramine). Redux was simply Pondimin from which levofenfluramine had been removed, leaving only dexfenfluramine as the active agent. Redux had been approved in Europe, but there were disturbing reports that it and all fenfluramine drugs caused pulmonary hypertension, a fatal disease due to thickened capillaries in the lung that make breathing difficult. This and other problems such as brain damage were brought up at the initial FDA meeting, where the vote was 5-3 against approval based on safety concerns. The session was characterized as "stormy" with three of the eight panel members walking out in protest. For reasons that are not clear, but are likely related to drug company pressures, a few months later the FDA convened a "reconstituted" panel. It voted 6-5 for approval, despite additional damning testimony from two neurotoxicity experts. While this should have raised red flags, Redux was approved as the first weight reduction drug in 20 years in April 1996. In its "The New Miracle Drug?" cover story, *Time* Magazine reported, "Just three months after the

introduction of Redux, doctors are writing 85,000 prescriptions a week."
Over 18 million prescriptions were written over the next 8 months.

Because of the risks associated with Fen Phen and Pondimin, doctors warned that Redux should only be taken by patients who were moderately or severely obese. But these recommendations were drowned out by the ensuing \$52 million Redux marketing campaign, and the *Wall Street Journal* projected that Redux sales could easily gross \$1 billion in the coming years. Weight loss clinics were springing up nationwide and both drugs were readily available via the Internet. However, the honeymoon didn't last very long. In August 1997, a *New England Journal of Medicine* article written by a Mayo Clinic cardiologist reported 24 cases of pulmonary hypertension in women due to "unusual valvular disease" in patients taking Fen Phen. In some patients, symptoms appeared after only a month. As a result of this and another 75 cases of heart valve disease that were reported, both Pondimin and Redux were withdrawn from the market in September 1997. There is no cure for pulmonary hypertension and surgical correction of the heart valve abnormalities is hazardous. By 2003, Wyeth had **paid out \$13 billion in claims** related to Redux and Pondimin, **which represented only a third of the 37,000 most serious claims** addressed by the compensation trust it had created. The vast majority of claims were from non-obese people who wanted to lose weight for cosmetic reasons. Unfortunately, taking Redux resulted in only a 3 percent average weight loss.

A few months after Redux and Pondimin were withdrawn in 1997, Meridia (sibutramine) was approved. As with Redux, a prior FDA Advisory panel had rejected it because its potential benefits did not outweigh its risks, which included significant increases in blood pressure and heart rate. In addition, obese patients taking Meridia for a year lost only 6½ pounds more than controls on a placebo. Like Redux, the best way to circumvent this is to pick another panel. Public Citizen, a consumer advocacy group, petitioned the FDA in March 2002 to have the drug banned because of 397 reported adverse reactions, including 29 deaths due to stroke and heart attacks. Meridia patients were three times more likely to show abnormal ECG findings and 143 patients developed significant arrhythmias. No action was taken. A second petition was made in September 2003, citing evidence from the FDA's own database of 49 cardiovascular deaths and 124 adverse cardiovascular reactions. In addition, there was strong evidence of Meridia's serious adverse effects on fetal development. In 2004, Dr. David Graham, an physician in the FDA's safety division with 20 years experience also told a Senate committee that Meridia should be banned. The petition was denied in 2005 and the FDA said it would reserve a decision pending the outcome of an ongoing post marketing study called SCOUT that had been mandated by concerned European regulators.

SCOUT (Sibutramine Cardiovascular Outcomes Trial) was a 6-year study designed to evaluate the cardiovascular safety of Meridia in 10,744 obese patients over age 55 with preexisting cardiovascular disease, diabetes, or both. Based on the results, which showed a 16% increase in significant cardiovascular side effects, the drug was banned in Europe in January 2010. The FDA did nothing until August 2010, when it simply added a new contraindication for patients over age 65. An Advisory panel was split on whether it should be banned, but because of mounting criticism, it was voluntarily withdrawn in October 2010. Numerous lawsuits have been filed by patients and relatives of those who may have died due to Meridia.

We now have Qnexa, a combination of two drugs: the amphetamine phentermine, which is approved for short-term weight loss, and topiramate (Topamax), an approved anti-seizure drug. Phentermine helps to suppress appetite, while topiramate allegedly makes patients feel more satiated. Qnexa was also rejected by the FDA in 2010 because of safety concerns, including elevated heart rate, psychiatric problems and birth defects, which occur twice as often in pregnant women taking Topamax. Nevertheless, an FDA Advisory panel just voted 20-2 to approve Qnexa as the first new weight loss drug in 13 years. This overwhelming endorsement was largely because most patients lost nearly 10 percent of their overall weight **after a year** on the drug, and that save for surgery, there is nothing to offer the 75 million obese adults in the U.S. It was felt that the weight loss benefits outweighed any safety concerns, although the latter required careful monitoring. Since conducting such a study prior to market approval would cost millions of dollars and take at least three more years, the panel agreed that the company could conduct the **cardiovascular safety study after FDA approval**. While the FDA does not always follow its Advisory panel's recommendations, most authorities agree that Qnexa is likely to be approved next month. As an old saying warns, "Those who do not learn from the mistakes of history are doomed to repeat them." I doubt that Qnexa will prove to be the answer to obesity, and drug company sponsored clinical trials can be manipulated in so many ways that most are worthless.

Another example of the danger in approving drugs without long term safety data is illustrated by a recent report showing that **sleeping pills may be responsible for up to 4.6 times higher death rates as well as an increase in cancer**. Insomnia is much more frequent than commonly appreciated and is also a growing problem. Sleeping pill prescriptions rose 23 percent from 2006 to 2010, during which they grossed \$2 billion in annual sales. Some of the most frequently used hypnotics are Ambien, Restoril, Lunesta, Sonata, Halcion and Dalmane. These have largely replaced older barbiturates and antihistamines that had drowsiness as a side effect. Because drugs like Ambien and Restoril have a shorter window of action,

they were thought to be safer than older medications, but the study did not support this. **The top third of sleeping-pill users had a 5.3-fold higher death risk as well as a 35% higher risk of cancer.**

What was shocking was the 3.6 times higher death rate for patients who **took only 1 to 18 sleeping pills a year**, compared to people who took none. In addition, the senior author, Emeritus Professor of Psychiatry at the University of California, had noticed a link between sleeping pills and **increased death risk back in 1975**. Although he and others have published 18 studies confirming this since then, they have not attracted much public awareness of this important problem. Certain types of insomnia, such as sleep apnea increase risk of heart disease, and this is often emphasized in sleeping pill ads. However, like drugs for ED, hypnotics will not help to prevent a heart attack. As noted in prior *Newsletters*, insomnia is a major source of stress, and conversely, stress is the main cause of insomnia. Hypnotics can help people who have a hard time falling asleep due to some stressful situation, but only for a few days or a week. As one expert warned, "These sleeping pills are mostly for short-term use, so the ideal patient would be someone with a very high stress level for some reason, such as the recent loss of a loved one or a divorce, or for a traveler adjusting to a new time zone. This should be for a limited time period, and only as needed, not on a nightly basis."

Another authority also emphasized that hypnotics affect the quality of sleep, and that when used too often, "people don't feel as restored after sleeping with them." In addition, many hypnotic sleeping pills are habit forming. For those with other addictions, they can be particularly dangerous, and most of these drugs increase the effects of alcohol. There are other non-pharmaceutical approaches that are much safer since they have no side effects and are not habit forming. Cranioelectrical therapy stimulation, which was originally called "electrosleep", has been cleared by the FDA for the treatment of insomnia for over 30 years. It has also been similarly approved for the treatment of pain and depression, both of which are frequent causes of sleep problems. Its efficacy and safety have been confirmed in over 140 papers published in peer-reviewed journals, and it is extremely cost effective in chronic insomnia, where long term use of hypnotics is contraindicated.

Pharmageddon – And Why Sales Of Statins Bring In \$35 Billion Annually

Other than the popular 1998 movie starring Bruce Willis, most people don't know what Armageddon is or refers to. Some believe it is a battle between good and evil that will occur before Judgment Day, or that it is the site where this battle will take place. Others view it as a synonym for the end of the world. Armageddon is an Anglicized form of the Hebrew *har megiddon*, (hill or mountain of Megiddo) which is found only once in the Bible at

Revelation 16:16. Megiddo was a strategic site in Israel south of Haifa, where many decisive battles were apparently fought. However, there is no actual "mountain" near Megiddo, and it is believed that this reference was used figuratively to describe an eventual war that would be waged between God in the person of Jesus Christ and all the evil forces and nations that opposed him (led by the "Anti-Christ"). *Revelation*, the final book of the New Testament was written by Saint John the Divine and is sometimes cited as the *Book of the Revelation of St. John*, since he did not give it a title. It is called *Revelation* because the first word in the book is *apokalupsis*, which in ancient Greek meant an "unveiling" or "revelation". *Apokalupsis* is also the origin of apocalypse, which refers to a war or some catastrophic event that ends life on earth. However, a "battle of Armageddon" does not appear in *Revelation*, or anywhere else in the Bible and it is not clear whether Armageddon refers to such a conflict, the site where it takes place, or a metaphor to describe the constant clash between good and evil.

Since some of this confusion may carry over to pharmageddon, a blend of *pharmaceutical* and *Armageddon* it is important to understand what this neologism signifies. Although pharmageddon has been in use for over a decade, appears in the titles of three books and numerous articles published in the last two years, I doubt that it will be found in any dictionary. The web definition is "A dystopian scenario wherein medicine and the pharmaceutical industry have a net detrimental effect on human health and medical progress does more harm than good." Dystopia ("bad place") is the opposite of utopia. It is an imaginary place where everything is as bad as it can possibly be. Perhaps the best description of this scenario can be found in David Healy's just published PHARMAGEDDON. It is an insightful and incisive indictment of the pharmaceuticalization of medicine by an eminent psychiatrist who was the first to warn about the suicide inducing effects of antidepressants in prior books such as *Let Them Eat Prozac: The Unhealthy Relationship Between the Pharmaceutical Industry and Depression*. This new book explains why other **drugs also promote sickness rather than health and so-called medical "progress" does more harm than good.**

Healy traces our present problems to three crucial regulatory changes: expanded patent protection changes for branded pharmaceutical products; restricted prescription drug privileges for doctors only; and especially a requirement for industry-controlled clinical trials that demonstrate a benefit over placebo. These were all introduced in 1962 following the thalidomide disaster to protect the public by curbing deceptive drug company practices. A double blind placebo controlled trial in which neither the patient nor the doctor knows whether the test medication or something inactive is being administered is considered to be the gold standard. This is particularly true if the study is conducted by a respected authority at a distinguished medical

facility and is then published in a prestigious medical journal. However, there are numerous ways to influence or report the results of these trials, as explained by Dr. Marcia Angell, former editor-in-chief of the *New England Journal of Medicine* in *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*. As she notes in the following excerpts:

Before a new drug can enter the market, its manufacturer must sponsor clinical trials to show the Food and Drug Administration that the drug is safe and effective, usually as compared with a placebo or dummy pill. The results of all the trials (there may be many) are submitted to the FDA, and if one or two trials are positive—that is, they show effectiveness without serious risk—the drug is usually approved, even if all the other trials are negative.

In view of this control and the conflicts of interest that permeate the enterprise, it is not surprising that industry-sponsored trials published in medical journals consistently favor sponsors' drugs—largely because negative results are not published, positive results are repeatedly published in slightly different forms, and a positive spin is put on even negative results. A review of seventy-four clinical trials of antidepressants, for example, found that thirty-seven of thirty-eight positive studies were published. But **of the thirty-six negative studies, thirty-three were either not published or published in a form that conveyed a positive outcome.**

Thus, if only 2 out of 100 trials showed statistically significant improvement for a drug compared to a placebo, it can be approved, even if there was no evidence of clinical improvement and more people on the new drug died than those in the placebo group. It is necessary to demonstrate that there are no increased health risks, but these can easily be disguised. Healy shows how the first blockbuster drugs, Zantac for ulcers and Prozac for depression attained that status by aggressive advertising hype that exaggerated their efficacy despite poor performance in clinical trials. Internal company records later made available showed that their potentially lethal hazards had been concealed for decades, and this has also been found true for other drugs.

Statins are the biggest blockbusters ever, but their \$35 billion in sales/year are mostly to people without heart disease whose lipid levels are arbitrarily designated as at "increased risk", even though statins have never been shown to prevent heart attacks in healthy people. Manufacturers have also been successful in concealing side effects such as memory loss and other cognitive problems, peripheral neuropathy, diabetes and Lou Gehrig's disease. It was not until last month that the FDA mandated placing a warning label on all statins for some of these safety concerns. Other blockbuster drugs that are now banned include Vioxx for arthritis and several beta agonists used to treat asthma. Avandia, a popular diabetes drug was banned in Europe, Canada, China and other countries in 2010 because of evidence that it caused heart attacks and liver disease. A 2008 FDA panel strongly urged its removal for similar reasons, and although a watchdog group later showed this would prevent 500 heart attacks a month,

it is still available on a "restricted" basis. Company documents revealed that the manufacturer was well aware of these problems and deliberately concealed them. Some other highlights of Healy's book are that:

- The number of deaths or serious adverse events reported to the FDA is increasing by 5% to 10% annually, mostly from heavily promoted blockbuster drugs with dubious efficacy. Although these side effects reported by patients and doctors are discounted as "anecdotal", four out of five have been shown to be legitimate. **Adverse drug events** are currently the fourth leading cause of death in the US and **the leading cause of death in patients with mental health problems**. The reported price tag for treating serious adverse drug effects is over \$100 billion annually, but is undoubtedly much higher, since **95% of serious side effects are never even reported**.
- We spend over 20% (\$743 billion/year) of our national budget on health care, which is more than we devote to defense and security, and this does not include 10% of the U.S. military budget that also goes to health care. Drugs are one of the biggest factors and are responsible for up to 20% of insurance expenses.
- Studies are cited documenting that 30% of clinical trials are never reported because companies want to hide any negative results. Almost half of those that are published are ghostwritten by drug company employees and 25% of published trials misrepresent the evidence. (Dr. Ionnidis had previously determined that half of all published medical articles misrepresent the evidence.)
- Only 1 in 7 new drugs are superior to existing ones, and millions of people take the other 6, even though they have not been adequately tested for harmful effects. As a result, at least 1.5 million US hospitalizations a year and about 129,000 hospital deaths a year are caused by serious drug reactions. As Healy noted, "We are in a world where increasingly we need protection from the latest miracle cure to ensure we do not die prematurely." Direct to consumer drug advertising is so successful, that **Americans consume almost 40% of all pharmaceuticals sold in the world**.
- We spend an estimated \$2 trillion annually on healthcare expenses, 2 1/2 times more per capita than any other industrialized country. However, save for Turkey and Mexico, we are the only nation without universal health insurance and things are getting worse. 40 million Americans had no health insurance in 2000, but now it is closer to 60 million, or one in four people living in the U.S. As Big Pharma's influence has grown, **our health care ranking among developed countries has plummeted from #1 in the 1960s to #72 in 2000**. Reversing the trend of past centuries, life expectancy in the US has already dropped compared to other advanced countries. As noted in a prior *Newsletter*, Starfield's 2000 article found that that of 13 countries, the United States ranked 12th (next to last) for 16 leading indicators of health, including projected life expectancy.

Dr. Healy is heading up a free website for patients and physicians to research and report drug side effects. WWW.RXISK.org will provide a medical timeline chart that captures important information on symptoms so that patients can have a more informed discussion with their physicians. This will allow patients to not only "Ask your doctor if this medication is right for

you", but also "Please explain the reasons for your recommendations", and "Are there any safety concerns I should be aware of?"

Medicalization Masquerading Under The Mantra Of Preventive Medicine

"If You Feel O.K., Maybe You Are O.K." was the title of a recent article in *The New York Times* by Dr. Gilbert Welch, a professor of medicine at Dartmouth. As the article points out, early diagnosis is one of the basic precepts of modern medicine. Everyone knows that the earlier you can diagnose a disease, especially cancer, the more successful the chances for a cure or minimizing further damage. And the best way to insure this is by doing screening tests on healthy people before they develop symptoms or signs to suggest they might have some problem. When I entered practice all adults, and especially older ones, were urged to have an annual checkup, which in addition to taking a history and performing a physical examination, included blood tests to rule out diabetes or anemia, as well as a chest X-ray that might detect lung cancer or tuberculosis. All hospitalized patients routinely had chest X-rays on admission regardless of their diagnosis. As other screening tests became available, middle-aged and older women were told to have annual mammograms and men were advised to have a blood test for prostate cancer along with their yearly physical. March is National Colorectal Cancer Awareness Month to remind us that everyone should have a colonoscopy. It is no coincidence that a *New England Journal of Medicine* article published last month found that removing polyps during colonoscopy could reduce deaths from colon cancer. And, since you are already under anesthesia, why not take another 10 minutes or so for a "flip" endoscopy to detect any diseases that might be hiding in your esophagus and stomach.

Diagnosing asymptomatic cancer is what motivates most healthy people to undergo screening. The impetus for this was Nixon's 1971 National Cancer Act, in which he emphasized, "We need to work out a system that includes a greater emphasis on preventive care." To implement this, he gave the National Cancer Institute unprecedented power and funding. NCI's budget went from \$233 million in 1971 to \$815 million in 1977, and is **now over \$5 billion**. Yet, despite this 25-fold increase over the past forty years and a decline in smoking, we are losing the war on cancer as indicated by the escalation in rates of many malignancies during this period, including liver (165%), thyroid (145%), non-Hodgkins's lymphoma (82%), childhood (24%) and breast (19%). Nixon's project was doomed from the start, since there was no financial gain in finding preventable causes of cancer (not smoking, a healthy diet, exercise and reducing carcinogens). More importantly, preventing cancer would seriously threaten the income of members of the cancer cartel, an unholy alliance between NCI, the American Cancer Society, (ACS), chemotherapy drug makers, tobacco, automobile and

petrochemical companies responsible for carcinogenic pollutants, as well as prestigious cancer centers like Sloan-Kettering.

And there was a revolving door between NCI and ACS as well as other cartel members. Nixon appointed Benno Schmidt, a drug and chemical company executive, to head up his "War on Cancer". Schmidt was also Chairman of the Board of Sloan-Kettering, which had thousands of shares in chemotherapy drug companies. Like the ACS, its board also included top executives of drug, tobacco and petroleum companies. ACS, said to be "the world's wealthiest non profit organization" (over \$1 billion in profits), was largely responsible for Nixon's 1971 Act, and his promise that it would find a cure for cancer by the 1977 bicentennial. However, ACS has consistently opposed any attempts to improve the environment that might jeopardize chemical and automobile interests. The *Chronicle of Philanthropy* complained that it was "more interested in accumulating wealth than saving lives." NCI was similarly described by a former director as "a governmental pharmaceutical company." Support comes from a scathing analysis by the National Academy of Sciences requested by Congress, which stated, "the leadership of NCI is marked by pervasive conflicts of interest and a revolving door with the cancer drug industry." Their focus is on "screening, diagnosis and treatment" rather than prevention, and that "contrary to the requirements of the 1971 Act, NCI has still failed to inform the public of a wide range of avoidable causes of cancer. This denial of the public's right to know has even been extended to the withholding of readily available scientific information."

As noted, **instead of prevention, the ACS promoted screening, since this also brought in money.** In 1984, ACS created the industry-funded October National Breast Cancer Awareness Month to **falsely assure women that "early mammography detection results in a cure nearly 100 percent of the time."** The chief medical officer of ACS also boasted that his hospital could make around \$5,000 from each free prostate cancer screening, thanks to ensuing biopsies, treatments and follow-up care. Yet, as reorted in a prior *Newsletter*, mammography in asymptomatic healthy women not only does not seem to save lives, but is responsible for needless surgery, anxiety and medical expenses. And even the inventor of the PSA test for prostate cancer agrees it is worthless as a screening test, and leads to unnecessary surgical procedures, complications and costs. Chest x-rays are no longer advised for all hospital admissions and yearly routine physical examinations, even for those at high risk of developing lung cancer such as chronic smokers. The reason for this surprising change in recommendations is that the available evidence reveals that lung cancer is not detected early enough to affect survival rates. In addition, such routine screening procedures also result in unnecessary biopsies, chest surgery, disability and

other complications and costs. Some experts have also questioned the recent colonoscopy results because the study participants were probably not only much healthier than the general population, but also more intent on staying well by not smoking, eating sensibly, and other lifestyle habits that can reduce the risk for cancer. NCI's recent large study also found that no lives were saved from screenings for prostate and ovarian cancers.

It is important to emphasize that there is no doubt about the value of periodic colonoscopy and mammography in individuals with a family history of colon or breast cancer. What is of concern are crowds flocking to mobile trailers around the country to have their bodies scanned by three-dimensional computerized X-rays. They don't need a physician's referral and few have any symptoms that would justify an exposure to radiation equivalent to up to 500 X-rays. The procedure is non invasive and painless and simply requires lying in a machine that takes high-resolution X-rays of hundreds of slices of the body. Promoters cite people with asymptomatic kidney cancers that were cured, although it is not clear if these were small tumors that were contained. CT scans were not developed for screening, but rather to assist in the diagnosis of unexplained symptoms, such as abdominal pain. Radiologists know where and what to look for, in contrast to screening films, where they never see the patient and have no clue as to where a problem might be. Nevertheless, what has been called "the worried wealthy", are willing to spend many hundreds of non reimbursable dollars on total body scans to be reassured that nothing is wrong internally. However, instead of this peace of mind, they are subjected to stress, since when any abnormality is reported, further testing or even surgery may be necessary. As one authority warned, "A negative total body C.T. scan does not provide reason to feel reassured, and a positive scan does not provide information that has been shown to improve life expectancy or quality of life."

People are also increasingly undergoing virtual colonoscopy to avoid anesthesia and hospitalization. This is a new test in which a CT scanner examines the colon for polyps, but it can also cause problems, as the Chief of Radiology at a leading medical school explained in a recent interview. His colon was normal but other parts of his body that showed up in the scan were not. "A renal mass was detected, as was a liver mass as were multiple nodules in the base of my lungs." He had another scan using a special dye to examine his kidney and learned that the lumps were renal cysts, which are found in half of everyone over 50. But the inch and a half lump on his liver was still a mystery even after another scan with a dye, so he had a biopsy. "The pathologist couldn't tell whether it was benign or malignant," he said. "Then we had the lung lesions, which looked as if they could be cancer." He had two options: he could wait to see what happened. Or he could have a major operation to find out what they were. If they were

cancer, however, the operation would not cure him because there were too many lumps and they were too large. "I didn't want to sit around thinking I had a malignant lesion. I was either normal or I was terminal. It's kind of tough going around for a couple of years thinking about that." His surgeon told him that they would have to collapse his lung and take out a piece, and "This is not trivial. You're going to be sick and have a lot of pain." The lung and liver nodules turned out to be scars from an old histoplasmosis infection, a common fungal disease that is of no consequence in healthy people. However, it took eight weeks before he felt normal again and his bill for surgery and hospitalization was \$47,000. A total body scan would not have been able to rule out cancer, because patients have to be prepped so their colons have no stool and are inflated with carbon dioxide. But a total body scan would still have found the same masses in his kidney, liver and lung.

Nevertheless, the screening juggernaut rolls on. Starting this year, all Medicare recipients can now obtain almost two dozen preventive services without owing co-payments or deductibles, including mammograms, annual flu vaccines, pap smears, PSA tests and an annual "wellness" examination. There is an Awareness Month, Week or Day for almost every disease. In addition to colorectal cancer, March is also the Awareness Month for Chronic Fatigue Syndrome, Hemophilia, Kidney Disease, Mental Retardation and Multiple Sclerosis, as well as Pulmonary Rehabilitation and Sleep Awareness Weeks and American Diabetes Alert and Tuberculosis Days. All do not have screenings to raise funds as well as awareness, but this may be short lived.

Screening does not insure prevention, but it does guarantee increased testing, which often results in overdiagnosis. Since the early 1990s, the Medicare per capita use of head scans has doubled, the rates of abdominal scans have tripled, chest scans quintupled, and brain MRI rates quadrupled. Many are concerned that DNA screening will add to this overdiagnosis problem, since everyone's genes will likely reveal an increased susceptibility to some disease, with little that can be done about it. This transformation of healthy people into patients trend has clogged clinics, emergency rooms, and doctors' offices because of the need to evaluate the worried well (via ordering more tests), at the expense of treating patients who are sick. The definition of healthy is no longer "A sound mind in a sound body". It is "Someone who has not had a complete medical workup". — stay tuned!

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