

The Medical News Report for August, 2012 #7

Sam La Monte, M.D., FACS (fellow of the American College of Surgeons)

Outline of subjects: 1. Continuing to look at Autoimmune Diseases—Lupus and Sjogren's Disease

- 2. Tumors of the brain—benign and malignant*
- 3. The sign and symptoms of an acute myocardial infarction*
- 4. Depression—the signs, symptoms, and treatment*
- 5. The Pharmaceutical industry*
- 6. Late breaking medical information*

As a generalist at heart, I want to remind you that I am reporting on medical information that I read in journals and websites. I am not intending to act like any kind of an expert in any field, but want to give you some pretty detailed information that any of you could access on the web. Trying to educate readers on a variety of subjects is my way of empowering you with medical information that is not meant to scare you but to stimulate you to learn more if the particular subject hits home for a variety of reasons. I reporting, not giving medical advice, and is meant for you to discuss this with your personal doctors. I hope this medical news report is beneficial to you. That is my desire. Dr. Sam

1. General information about Autoimmune Diseases Continued—Lupus and Sjogren's Disease

General information-- All **autoimmune** diseases have at least 4 things in common: 1. the disease manifestations of these illnesses are caused by our own body's immune system turning against certain tissues of our body, the cause of which is unknown. 2. The joints, skin, eyes, mouth, esophagus, lungs, heart, bowel, and brain are the most common organs involved. 3. It is a chronic incurable disease that can and go. 4. There is frequently overlap of these diseases.

It is unknown why one organ system is chosen over another in these individual disease. There is probably some predisposing factors that make one organ or another more vulnerable. Our own immune system is a wonderful defense against infection, cancer, disease, and foreign materials when it is working well. How we take care of our bodies has a lot to do with how well that system works, but not always. Diet, exercise, not smoking, not over-drinking, maintaining a healthy weight for our height, and managing our stress are the most important factors to consider. They all influence our immune system. Yes, I have repeated myself many times, AND I WILL CONTINUE TO, because, it is our **responsibility** to maintain our living body in its best condition. If we expect doctors to do all the work, we are delusional. We are the most important member on our team of doctors, dentists, and other healthcare providers. Without us doing our part, we are in for a rough time with our health.

Last month, I reported on two autoimmune bowel diseases (Crohn's and Ulcerative Colitis). This month, I will report on Lupus (Systemic Lupus Erythematosis-SLE), and Sjogren's (sounds like show-gren's) Disease. Like many of the autoimmune diseases, these both have arthritis in common. Any of the symptoms of any of these diseases can run the gamut from mild to severe and can come and go. Next month I will report on Rheumatoid Arthritis.

I. LUPUS

a. The name means "wolf", and is manifested by a "butterfly rash" on the face across the cheeks and bridge of the nose. It can be mistaken for acne rosacea, a not uncommon dermatologic disease. The connective tissues of the joints, muscles, skin, pleura (covering) of the lungs, pericardium (covering) of the heart, kidneys, medium and small vessels, and brain all can be involved. Raynaud's syndrome (I will describe in the next paragraph) is seen in severe cases of Lupus.

b. The disease affects women 90% of the time most common at ages of 15-45. There are various other factors: genetic, hormonal, and environmental. The disease like the others is characterized by remissions and exacerbations. It is aggravated by stresses to the system-physical and emotional— infections, over-exposure to the sun, certain blood pressure medications (esp. hydralazine), arrhythmia meds (procainamide), pregnancy, and any type of emotional event.

c. The usual PRESENTATION—butterfly facial rash, fever, joint pain, kidney damage (nephritis), ankle swelling, fatigue, painful fingers and blanching from exposure to cold with or without finger ulcers due vascular compromise of the middle and small vessel involvement (Raynaud's Syndrome). Other symptoms include shortness of breath, mouth and nose sores, hair loss, even seizures.

d. LABORATORY abnormalities include a positive ANA (anti-nuclear antibody test-specific only to autoimmune diseases but not diagnostic of any one autoimmune disease), the RF test (Rheumatoid Factor), elevated white blood cell count, anemia, platelet abnormalities (increased platelets can cause deep vein blood clots in the legs—DVT, and stroke), EKG evidence of heart arrhythmias, and heart failure. Your doctor may hear a "pleural rub" in your lungs with a stethoscope—from the thickening of the lining of the lungs. Kidney malfunction will show protein in the urine, and the blood tests will show various degrees of kidney failure—BUN and creatinine increases). When the kidney is involved, this is a very serious condition and may be accompanied by seizures, stroke, and even spinal cord abnormalities (numbness and weakness).

e. The TREATMENT includes corticosteroids, non-steroidal anti-inflammatory meds-NSAIDS (i.e. Aleve, Ibuprofen, etc). Anti-malarial meds, and.) disease modifying rheumatic disease meds (Methotrexate, etc and biologic therapies (Enbrel, etc.), avoidance of the sun, stress, and over-exercise are all used to treat these patients, even kidney dialysis. This is a difficult disease (if severe) to control, and kidney failure may lead to death. When I report on rheumatoid arthritis next month, I will describe these classes of medications above.

f. **COMPLICATIONS OF TREATMENT**--The treatment can be a problem too. Most of you know that taking corticosteroids can cause all kinds of problems like hypertension, elevated blood glucose, weight gain, osteoporosis, and fractures. Biologic therapies for any of the autoimmune arthritis including that in Lupus can lower the immune system so much that it can increase the likelihood of re-activating tuberculosis, other infections, and cancer of the lymph nodes (lymphoma). Reference—MedPage, WebMD, 2012. There are many good references for these autoimmune diseases, and the national associations of these diseases are good reliable places to learn more.

II. **SJOGREN'S DISEASE**

- a. **FACTS**—Sjogren's is an autoimmune disease that affects 4 million Americans, and nine out ten are women. Half of these patients go six and one half years on an average to be finally diagnosed. This disease can be mild to severe, just like the other autoimmune diseases. Also, half of these patients have another superimposed autoimmune disease with the diagnosis of Sjogren's, such as Rheumatoid Arthritis, Lupus, or Scleroderma, Mixed Connective Tissue Disease, Chronic Active Hepatitis, or Vasculitis, to name a few. These diseases will be described in future reports.
- b. **SYMPTOMS**—The *classic triad* of dry mouth, dry eyes, and swollen parotid glands (the "mumps glands" in front of and below the ear—par-otid means around the ear)) should alert the physician to this diagnosis. With dry mouth, dental decay is a big problem, so the dentist may be tipped off to refer you for this diagnosis. The patient may also complain of a sore tongue, dry throat, or change in taste. Eye symptoms include a constant foreign body sensation in the eyes, itchy eyes, redness of the whites (conjunctiva) of the eyes or eyelids with mucus drainage. The parotid and other salivary glands frequently get recurrent swelling, are painful, and can easily become infected because the saliva is so thick and blocks its release, when eating. The patient may think she has the mumps.
- c. **PATHOPHYSIOLOGY** of the disease—Because the immune system sees these exocrine* glands as foreign, an infiltration of lymphocytes attack the lacrimal, and salivary glands creating inflammation. This inflammation leads to dysfunction of these glands and thus decreased secretion of tears and saliva. *exocrine glands are those that secrete fluids to lubricate like sweat and saliva glands whereas endocrine glands secrete hormones, like the thyroid, testicle, and ovary.
- d. **LABORATORY TESTS**--like all the other diseases in this category, the ANA (antinuclear antibody) and RF (rheumatoid factor) test is positive, but there is an actual Sjogren's test fairly specific to this disease (anti-Ro and anti-LA tests). An important and easy way to diagnose this syndrome is with a biopsy of the minor salivary glands, rather the lacrimal or parotid glands. There are thousands of these little glands in our cheeks and throughout our mouth. A simple office procedure of (a tiny incision is made inside of the mouth and some of these little salivary glands will allow the pathologist to see a heavy infiltration of lymphocytes with at least 50% loss of the little gland cells. At least 3 of these tests (TEAR TEST, BLOOD TEST, BIOPSY) must be positive for a definitive diagnosis. In my practice, I was able to diagnose a high percentage of Sjogren's with this simple biopsy. Also, an ophthalmologist should be seen for the tear test and slit lamp exam to test for corneal staining because corneal abrasions occur due to dryness. Other types of eye disease must

also be ruled out (allergic conjunctivitis, ocular rosacea, blepharitis, foreign bodies, herpes infection of the cornea, etc.)

- e. **COMPLICATIONS**—the more severe cases may have corneal ulcers from dryness, severe redness, and inflammation of the eyelid margin, and severe infection in the parotid gland (parotitis), ultimately necessitating surgical removal of the parotid glands.
- f. **CONTRAINDICATIONS**--No one with **SIGNIFICANT** dry eyes should have cosmetic eyelid surgery or Lasik surgery to correct vision without very careful consideration.
- g. **TREATMENT**—oral omega-6 fatty acids may help to stimulate saliva and tears. Medications include corticosteroid eye drops, and anti-inflammatory drops, saline drops for comfort and hydration, cyclosporine (Restasis—you have seen the commercials on TV), biotene mouth rinse to help dry mouth, prescription fluoride treatments nightly (to combat the increased amount of bacteria in the mouth (saliva has many enzymes that kill bacteria in the mouth, which is lost with decreased or no saliva), and Evoxac to increase salivation. Like LUPUS, anti-malarials (Plaquinal), corticosteroids by mouth and in the eye, and cancer drugs like the biologics such as methotrexate, Cytoxan, Imuran and biologics like Rituxin and Enbrel may have to be resorted to in severe cases, especially with other superimposed autoimmune diseases.

2. **BRAIN TUMORS**-*benign and malignant*

a. 22,020 brain tumors were reported in 2010 and there were 13,140 deaths. Nothing gets your attention more when you hear someone has a brain tumor. Even though benign tumors are not cancerous, they can still cause death just the same because they are a space-occupying lesion in a contained space that can press on vital brain tissue and cause disability and death. Remember, if you get a headache, thinking it is a brain tumor should not even enter your mind, but this subject is scary, and I realize could make you worry. Try to realize these tumors are very uncommon, but there are signs and symptoms that might alert you to see a specialist.

b. **BENIGN** tumors can occur anywhere, but they are very slow growing and can be overlooked for some time before symptoms of headache, double vision, seizure, dizziness, drowsiness, etc. can occur. The most common type is meningioma (25%), pituitary gland adenomas (8%), vestibular schwannoma also called *acoustic neuromas* (9%), *neuroectodermal tumors/cysts* (1-3%), and *vascular masses* (less than 1%). *Fortunately the lion share of brain tumors are benign and even these are pretty rare considering the above number of tumors reported.*

c. *Meningiomas are the most common and occur between the two sides of the brain in the middle (parasagittal)-25%, on the surface of the skull-18%, above the deepest paranasal sinus in the skull-sphenoid-17% and other positions. These are slow growing and until they cause symptoms or are accidentally found when doing sinus CTs, they are not found early. These can usually be completely removed, but not always. If they are large, radiation treatments can be used to shrink them before surgery as well. The results are usually pretty good.*

d. *Schwannomas (Acoustic neuromas) are usually found by ENT doctors or neurologists because they cause hearing and balance problems. These can be removed through the back of the ear (mastoid) or*

more frequently through a posterior approach. As an ENT/Head and Neck surgeon, I assisted the neurosurgeons in removing them as well as the pituitary tumors, which are most commonly removed through the nose (because the pituitary is just behind and above the sphenoid sinuses). Many surgeries require more than one specialty surgeon.

*e. **MALIGNANT** tumors must be graded to know what kind of chance you have of beating this cancer. All tumors are from normal cells in the brain, lining, or the structure that makes spinal fluid. How they turn malignant is still unknown. 85-90% of all malignant brain tumors start primarily in the brain. That means 10%-15% are metastatic usually from the lung (50%), breast (15-20%), unknown (10-15%), melanoma (10%), and colon (5%). Cancers can even spread to the brain stem (oldest part of the brain responsible for vital organ functions like breathing).*

f. The 3 most common primary brain tumors are astrocytoma and glioblastoma multiforme account for 38%, and meningiomas (benign) account for 30%, so that means almost 70% of tumors are from these 2 sources, one malignant and the other benign. After that, there are 30% of these tumors like medulloblastoma (more common in children), and oligodendrogliomas. The difference between the growth of the benign and malignant tumors is that benign tumors push normal brain tissue out of the way, and malignant tumors infiltrate the surrounding tissue making it much harder to remove all of the tumor without causing major physical deficits. So many of the malignant tumors are partially removed and then radiation therapy and chemotherapy are used to hopefully either control or kill the part of the tumor left behind. The younger the patient is, the more likely the cancer can be completely removed. In children 70% of these tumors can be removed but cause long term side effects, like learning and development issues. From 20-44 years of age, 50% can be removed giving about that same survival rate, but after 65, only a small percent survive. Obviously, other diseases superimposed on the cancer has a lot to do with that low survival rate. There are places in the brain, brain stem, and spinal cord that prevent neurosurgeons from removing them, because the deficits would be severe. Fortunately, radiation and chemotherapy can keep these tumors from growing or at least slow the progression.

g. There are different forms of radiation therapy and chemotherapy that can be used. I will not discuss them now, rather, I will have a report on the use of these modalities in general in the near future.

h. Clinical trials are a very important thing to consider with these brain tumors. The National Cancer Institute has a fine website to explore these options. www.cancer.gov/clinicaltrials. The NCI has a call center for information---1-800-4-CANCER. The American Cancer Society's website is www.cancer.org/clinicaltrials a great site too. You also can call the ACS and talk to a specialist about any cancer and any treatment as well as clinical trials. Call 1-800-ACS-2345

3. SIGNS AND SYMPTOMS OF A HEART ATTACK (MYOCARDIAL INFARCTION)

*a. **Heart attacks kill more Americans than any other disease. There are 1 million heart attacks per year. Heart attacks imply some death of heart tissue. Add all vascular disease, and it is the number one disease in Americans. It is also the most preventable disease of all. 11-25% die when they have their first heart attack. About 6% of deaths are prevented by aspirin, beta blockers, and rapid***

perfusion therapy (clot busters). \$273 billion or 17% of the healthcare spending is created by cardiovascular disease, and heart attacks account for \$96 billion.

b. Emergency rooms are different when it comes to treating heart attacks. The best ones have a lower mortality rate because 1) the staff has frequent meetings with the emergency room service providers to review care of patients 2) There is cross-training of nurses in critical care to cover cardiac cath labs where the vascular studies and angioplasty and stents are performed and cardiac emergencies can occur. Coordinated care is always important and rapid response of the staff is a must. Pick your hospitals wisely!

c. The signs/symptoms of a heart attack are many: 1) pain the mid-chest (30% of men do not have pain) 2) This pain or discomfort can spread into the back, the jaw, the neck, the left arm 3) Nausea and vomiting in women is not uncommon even without pain 4) indigestion, which can be gastric reflux or esophageal spasm or a heart attack 5) weakness, anxiety or shortness of breath is also more common in women 6) palpitations—a rapid heartbeat or an irregular heartbeat. 7) women also are more likely to feel weakness, loss of appetite, tiredness, or coughing without chest pain (40%) and have a higher mortality because of a delay in diagnosis. The younger the woman, the more likely not to have chest pain. Angina needs to be differentiated from a heart attack, as angina occurs with exertion, not at rest. There are more heart attacks in the early morning hours than any other time. That is why, if your doctor suggests you take a daily aspirin, you should take it at night, so that it will be working well in those same hours. When in doubt CALL 911. Don't mess around....CALL. 14.6% of females and 10.3% of men die in the hospital from heart attacks (Journal Of The American Medical Association-2012).

d. Sudden cardiac death is different from a heart attack. This is caused by an acute arrhythmia or electrical abnormality that leads to ventricular fibrillation. The heart quivers and does not pump the blood causing death. I hope you watched the separate email about AEDs to shock a heart back to a normal rhythm.

e. How does a heart attack cause death? Depending where the heart muscle is damaged (from lack of coronary blood supply), arrhythmias (irregular heartbeats), heart failure and pulmonary edema can cause low cardiac outflow and blood pressure drop with resultant shock. Meds are given to maintain the efficiency of the heart, blood pressure, and allow the damage to begin to heal. If that does not occur, intervention of the coronary arteries is a must with angioplasty, stenting, or coronary bypass surgery. See below!

e. Being admitted to an emergency room with chest pain is a priority evaluation, requiring quick action, immediate examination including an EKG and heart monitoring, blood tests for enzymes, and fluids started in your vein (if the EMS personnel has not already done so). An enzyme (clot buster) might be recommended to dissolve the clot in the coronary artery.

f. Again depending on the severity of the situation, you will be transferred to a coronary care unit or sent directly to the cath lab to do coronary arteriography to see if there is a blockage of one or more arteries. If it is felt that a dilation procedure can be done, angioplasty (balloon) and/or a stent will be placed. If the disease is more extensive, an emergency coronary bypass procedure may be necessary.

The procedure for cardiac catheterization is usually performed through the main vessel in the groin. 40% of patients 5 years after a stent show perfusion defects showing that the disease progresses. Once you have a heart attack, you are more likely to have a second one. Stents in a stable disease state have not shown much more benefit more the medical treatment (BP meds, aspirin, statins, management of diabetes, and overweightness).

*g. **Cardiac rehabilitation** is a must after a heart attack, and carefully adhering to the recommend life-style changes. Post-MI (myocardial infarction) depression is very common and must be managed. The resting heart rate correlates with increased risk of heart attack and death. If your resting rate is greater than 70-85 beats per minute, there is increased risk and if over 90 beats per minute, you better get personal trainer.*

*i. The American Heart Association tells you 7 ways to a **healthy heart**: 1) no smoking 2) be physically active 3) maintain normal blood pressure 4) normal cholesterol 5) normal blood glucose 6) normal weight for height 7) eating a healthy diet will **prevent** 59% of all deaths, 64% of all cardiovascular disease, 63% of ischemic heart disease (MI) over a 20 year period.*

4. DEPRESSION-DIAGNOSIS AND MANAGEMENT

a. I have consulted a lifelong friend and former medical school classmate, who is a psychiatrist, and has sent me special reading material to prepare for this huge subject. There is no way I can do this subject justice, but I hope to bring up some thoughts for you to consider and discuss with your doctor.

b. The most important question is: when does a person go from sadness, grieving over a loss, helplessness, hopelessness to a true diagnosis of clinical depression. We all have times of sadness, loss, disappointment, frustration, anxious times, and even periods of feeling like a person just wants to hide in a dark place and never come out. To say that is normal is a mouth full, BUT, when these symptoms continue over time with worsening, it is time to consider talking to your doctor. Obviously, ventilating to a friend or loved one can help, but when even that doesn't help, get some professional help. The stigma should not exist. They are doctors best trained to help!

*c. Dr.Kubler-Ross many years ago described the **STAGES OF GRIEF (Bereavement)***

*1. Denial, 2. Anger, 3. Bargaining, 4. Depression, and 5. Acceptance. Some feel, if you don't go through these stages, there could be unresolved grief. How long it takes to get through these stages is dependent on many variables, but it is best to understand these stages as the individual or family and friends, because resolution takes time. Of course, if already depressed, the stages could be greatly magnified (New England Journal of Medicine, 2012). The American Psychiatric Association is currently considering bereavement as a mild depressive disorder. But, one must go on with life regardless of a serious illness, loss of a loved one, loss of a job, retirement, loss of income, etc. We are resourceful people and should look at any negative experience as a challenge to **OVERCOME**. We have all had*

experiences in our lives that test our core, and for those that can't cope, DON'T BE AFRAID TO REACH OUT FOR HELP!

d. CLINICAL DEPRESSION is a serious disease in this country. 14 million have depression, and 2.5 million die each year as a result of this disease. Suicide, reckless behavior, drug and alcohol addiction, and neglecting themselves are the cause for the death rate. Depressive symptoms of grief last a finite time, and depression continues, is unrelenting, with impairment of functioning, delusional or suicidal ideation. Depression is more severe with underlying brain disorders. It is twice as common in women, and genetics do play a role in certain cases. Depression is clearly made worse by traumatic events, medications, alcohol, substance abuse, hormone levels, the season of the year, postpartum and pre-menopausal women. (Psychosomatic Medicine, April, 2012)

e. One can diagnose clinical depression if one has a depressive mood with 4 or more of the following associated symptoms 1) loss of appetite 2) loss of pleasure 3) insomnia or excessive sleep 4) psychotic changes of personality 5) diminished concentration 6) fatigue 7) low self esteem 8) recurrent thoughts of death or suicide (even threatening to hurt others) ----that last over 2 weeks. Other symptoms include a sense of guilt, loss of hope, aches and pains, cramps, and digestive symptoms. Careers, marriages, relationships, hobbies, and sex are at risk with untreated depression. Sometimes, it takes a caring family member or friend to persuade a depressed person to seek help.

f. Can you demonstrate differences in the brain with normal vs. depressive patients? There are studies to show the contrast in imaging (PET scans) between a normal brain and a depressed individual. Studies have also substantiated that the serotonin level in the brain has a delicate job of communicating one brain cell to another, and if there is not enough serotonin, normal amounts of activity do not occur vs. too much serotonin can create hyper-excitability (serotonin syndrome). Certain areas of the brain (the raphe nucleus, the locus coeruleus, hippocampus to name a few) are involved with the release of serotonin. Now, if you are still with me (and I know some of you aren't), the amount of serotonin release and degradation, play a key role in depression, and is part of the mechanism for how the serotonin reuptake inhibitors help depression (a major group of anti-depressants) (Journal watch of Psychiatry, Jan 12, 2012).

g. SEROTONIN influences mood and pain. That is why medications like Cymbalta are frequently considered for patients in chronic pain, because those individuals tend to have depression because of the pain or vice versa. Chronic pain itself can affect serotonin levels. That also brings up chronic fatigue syndrome and fibromyalgia, for these disorders may play a role in some of these patients. When you are dealing with psychosomatic illnesses, it is hard to categorize these patients because of overlap. We all know about mind-body connections, and it is this connection that creates many disorders that require medical and psychological treatment.

h. If a person is referred by their doctor to a psychiatrist, it should not be seen as anymore than a referral to any specialist. They are the experts, and they can make the most accurate diagnosis. These disorders should not be taken lightly, so get the best diagnosis and treatment.

*i. The differential diagnosis must be considered with depression just like any illness. **Bipolar disorder** is a good example because the manic-depressive symptoms certainly overlap in the depressive phase. Also there is true **psychotic depression** that must be considered. Genetics and family history may play a role in depression and certainly these problems tend to show up more commonly in families with mental illness.*

i. Considering the multitude of options for treatment (talk therapy, cognitive behavioral therapy, psychotherapy, electro-shock, group, and medications), one should not look at an anti-depressant as the only treatment anymore than insulin is the only treatment for diabetes. Psychological therapy (of which there are many), individual and family counseling all can be very valuable.

j. Seeing a psychiatrist or a psychologist is something that should be considered by the patient and the primary care physician. Milder depression may be something that is really situational and talking to a counselor may be all that is necessary. If more serious symptoms of depression are superimposed by other diseases (addiction, cancer, heart disease, chronic pain, other brain disorders, etc.) it might be better handled by a psychiatrist. But that decision is not mine, it is the primary doctor and the individual.

*h. Finally, when you get medical treatment (anti-depressants), over weeks to months, a person should expect improvement in their symptoms. The anti-depressants have many side effects and must be defined for each patient. Anti-depressants take 6 weeks or more to work, so be patient. **NEVER ADJUST YOUR OWN DOSEAGE OF ANTI-DEPRESSANTS**). I WILL RESEARCH THE MAJOR ANTI-DEPRESSANTS ON THE MARKET WITH CONSULTATION FROM MY PSYCHIATRY FRIEND and report on some tips regarding these medications.*

i. ALTERNATIVE THERAPY is frequently used by patients as well. Scientific proof may not be great, but anything a person believes in may help even as a placebo effect. Light therapy, acupuncture, aromatherapy, chiropractic, visualization, massage, meditation, relaxation, yoga, and music therapy. And for most of us, asking for help from a Higher Power may be the best medicine. Just be sure and never do anything your treating doctor doesn't know about.

Probably the safest thing to consider is EXERCISE, EXERCISE! Releasing endorphans will make anyone feel better. Supplements may help but the evidence is weak. I have reports that Omega-3 fish oil can help boost serotonin levels, but all of these alternatives should be discussed with your doctors. Don't be discouraged with "hills and valleys", as this is similar to addiction....good days and bad days can be expected and don't get discouraged....keep on trying!!

5. The Pharmaceutical Industry—'Big Pharma'

This subject is so huge, but it is a hot topic that deserves attention. I have consulted with a retired executive from a Big Pharma company. His articles helped me understand both sides. Reading about the FDA was painful, since that agency is clearly lacking in their ability to do all that is asked of them.

The problem we all have with big business is that they are big targets for ridicule, jealousy, suspiciousness, and it is easy to not like them because they make so much money. It is just saying we all hate lawyers til we need one. Where would we be without the investment of billions of dollars to find cures for disease?? Those dollars come from the federal government, charitable organizations, and, yes, Big Pharma. The interplay between the federal government and Big Pharma leaves a lot to be desired, when discussing the cost of medicine. The brand name vs. generic name medications must also be looked at. Also lawsuits are a necessary evil in many cases to get the industry to play fair. But is there a balance with all these factions.

As a physician, I could not have been an effective clinician without BP (BIG PHARMA). In 30 years, I never took a bribe, kickbacks, or any trips, gifts (yes, lunch for the staff was routine), or any inducements to prescribe one “brand” drug over another. There is information out there that physicians, pharmacies, and hospitals are being “bought” by BP (Big Pharma). Paying a doctor to lecture on a drug by a particular drug company has gone on forever, and I have never heard a lecture where the doctor said that you need to use a particular drug over another just because that pharmaceutical company paid the doctor to give the lecture. It would cheapen the doctor and his credibility, so my experience tells me that over 30 years of practice doctors are not on the take. So, reports about hospitals, doctors, and others taking money from BP even though true, is not widespread. Still, when a report that Big Pharma has paid millions of dollars in fines for fraud, it really makes news. If the system wasn’t corrupt to some extent, they wouldn’t be happening. That is what reform needs to do.....stop the fraud, corruption, and undo influence by special interest groups.

Now, I wasn’t born yesterday!! Of course, the BP expects to get a return on their investment and paying doctors to talk about their drugs is not a crime. But, without the BP paying for a lot of continuing education for physicians, CME lectures would drop significantly. Now, if a doctor is getting a kickback for writing prescriptions for a certain drug, he must be reported and dealt with. Shame on those professionals, and they should be punished accordingly. The regulations on Big Pharma are numerous, but their influence on the FDA is well known, with one of the most powerful lobbies in Washington DC. You must realize they had a lot to do with writing a lot of those over 2000 pages of Obamacare. You think congressmen had time to write it? There will never be a squeaky clean system for healthcare or any other industry. But corruption and fraud must be sought out and dealt with harshly. The public trust is at stake and as a physician, I pray that the new system (whatever it is) is fair to your doctor and you. Getting the federal government out of bed with Big Pharma is a must. I will have a lot to say about this subject now and in future reports. Of course, politics stink, no matter what.

I am fully aware that patents for BP’s drugs have 7 plus years in which they could recoup their investment. When you consider the average cost of R&D (research and development), facilities, employees, manufacturing, taxes, production, distribution, marketing, lobbying costs, sales staff (pharmaceutical representatives), the company spends an **AVERAGE OF \$4 BILLION DOLLARS to get a new drug to clinical human trials** (Bernard Munoz—Forbes magazine). In fact, there has been as much as \$18 billion dollars spent on development of a few drugs that required several clinical trials and years to get to the desk of the FDA for approval.

Now there is a little “trick” that Big Pharma does not tell you when they announce how much R&D costs. They take the cost of all their failed drugs into consideration when reporting the cost. **One in ten drugs is approved for clinical trials. THE AVERAGE ACTUAL EXPENSE IS APPROXIMATELY \$55 MILLION DOLLARS, not \$ 4 billion. They need to recoup their investment on the failures and should report just what they spend on the particular drug in question.**

Some drug companies have been more fortunate than others to have a better average in bringing drugs to market, and therefore their expenses are lower when you average out the failures. Astra Zeneca from 1997-2011 spent \$59 billion on drug development compared to GlaxoSmithKline of \$81 billion, or Pfizer \$108 billion. A single human clinical trial costs an average \$100 million, and they may have to conduct several to get approval of the drug by the FDA. There are big stakes here, and I can know how cut-throat the industry is. Without BP willing to invest, we would be back in the early 1900s as far as new drug therapies. Why, then, are we surprised that they make so much money. It is a lucrative business, but if it wasn't, they wouldn't be in the business.

The Fortune Global 500 provided us with the total annual revenues. Johnson and Johnson took in \$63 billion in 2009, with a net profit of \$8 billion employing 118,700 people. Pfizer-\$48, net-\$8.4 billion employing 81,800, Lilly-\$20 billion, net-\$2 billion, employing 40,500.

Now, that I have defended BP, it is time, to report on the other side of the coin. You must know, that the FDA (FEDERAL DRUG ADMINISTRATION) is an enormous agency, and has been under attack constantly by everyone. After reading a huge amount of material for this report, I am very concerned about the federal government's capability to run an organization to protect the American public from unsafe or ineffective drugs. It is just too massive of a job. They must depend on organizations to help them make decisions. The FDA does little research, and in fact, they are a **reviewing agency**, requiring hundreds of experts to carry out the reviews. Whe they make mistakes, people die, and THEY HAVE. There is some fraud and corruption in research as well. I said it! So has 60 minutes, the NY Times, the Wall Street Journal, etc. That is why independent labs must verify results of a drug before we should believe it is safe and effective.

Could it be that Big Pharma controls the FDA?? Some say yes, and there are numerous examples of this. The FDA has delayed pulling a drug from the market (sometimes years) while the poor patients are being harmed by them. I will give specific examples and a lot more information on this next month, but this month, I wanted to provide you with an overview, and get some reactions from a few friends of mine who were in Big Pharma and health insurance companies, before I continue. I have no ax to grind, no money to make, and nothing but a desire to understand the trouble about our government as they try to convince us they can do things better than the private sector. **WE ALL DESERVE THAT!** Big government breeds beaurocracy, reams of regulations that hamper the system, create unnecessary jobs that do little, and create huge delays in progress. I know there is a place for both government and the private sector. I am just trying to figure out who will “screw us “ the least. It is a shame, but that it is my opinion. You know I promised to report, not pontificate, but when it comes to the welfare (bad choice of words) of this country from a healthcare standpoint, I want to see both sides of the coin, and make informed decisions upon which to report on. We have an election

ahead of us that gives us a clear picture of the different direction of our 2 parties in this respect. Your vote will never be more important than in this election....not in your lifetime!

We have the players 1. The **FDA**, 2. The **Federal Healthcare** System (Medicare and Medicaid), 3. The **Health and Welfare** Federal Agency, 4. **Big Pharma (and their lobbyists)**, 5. The **Naturalists and Health Food** Industry, 6. The **Watchdogs and Activists**, 7. The **Private** Healthcare Insurance Industry, 8. The **Food** Industry, 9. The **Media** 10. The **Congress** and the **White** House (Obamacare) (who have miles of difference in ideology), 11. Those that **have insurance** and those who **don't** or don't have enough, or won't buy it, 12. The **Charity** organizations (who have more influence than you think), 13. The **illegals** 14. The **Health Providers**, and yes.... 15. The **legal profession** ready to pounce when any of the above screw up. Did I miss anyone?? How do 15 entities work together to come up with a system that is fair and equitable, without bias? Get off the floor from laughing and admit, like me, there is no way!! That is what the USA is facing! I think we can all agree on one thing.....help everyone equally if we can afford it.....but can we??? How we do that is the big question! Do you want a socialized system or a capitalistic system. We can't have both. Look how most socialist systems are doing in Europe!

Next month, I will report on some evidence based information to the best of my ability about the FDA, Big Pharma, and HOW the cost of U.S. medications has to be reduced to keep our healthcare system afloat. If you have references for me to read, feel free to send them to me. Comments go on my blog, please. This subject is huge and contraversial, but trying to understand IT a little better is well worth it.

One last fact!! We are all aging and living longer, but we need more medical care than ever before. That costs, and WE BETTER BECOME PROACTIVE ABOUT OUR OWN HEALTH AND WELLNESS. I hope this medical news report is doing that in some small way.

6. THE LATEST IN MEDICAL INFORMATION

a. Physical Inactivity as bad as smoking?

5.3 million of the 53 million deaths in the world in recent years has come from physical inactivity. In fact, when you consider the obesity epidemic, cardiovascular disease, and type 2 diabetes it creates, it will rise over the years (Medical Wire News). 9% of deaths are premature worldwide, and according to the medical journal Lancet, inactivity is as bad as smoking. So get off your couch, America, and get active with moderate exercise 30 minutes 5x a week, according to the World Health Organization. With the elimination of inactivity, 10% of colorectal cancer, and 10% of breast cancer, 6% of cardiovascular deaths, and 7% of type 2 diabetes WILL BE PREVENTED.

b. Patient centered-care

This concept is being discussed widely with the new healthcare legislation (Obamacare). This means you will be at the center of decision making with your doctor about your healthcare. That is why I keep harping on all Americans becoming more proactive when it comes to an individual's healthcare. If

your doctor spends more time letting you be a bigger part of the decision making, insurance must reimburse them for this time. It is calculated, this CONCEPT OF PATIENT CENTERED CARE will cost primary care physicians \$28,000 each to provide this type of care. This is an attempt to reduce emergency room visits and hospitalizations. We will see!

c. Dehydration

Even 2% of body weight loss from dehydration will render you less effective at your task. Before going out in the heat, you should pre-hydrate with 7-20oz. of water or low sugar sports drink 2-3 hours before exercise. This will allow fluid absorption and urine output to return to normal levels. Additionally, 7-10 oz of fluids 10-20 minutes before exercise. Maintenance hydration during exercise should be considered based on the amount of sweat and urine lost during the exercise. Be careful drinking high sugar drinks, however 30-60gms per hour is needed to maintain blood sugar. Alcohol and exercise should be carefully considered, as it will cause dehydration by shutting off the pituitary hormone, ADH-anti-diuretic hormone, creating more urine loss than fluid intake. Without rehydration, muscle cramps and soreness will worsen. Sports drinks also have sodium and potassium necessary for hydration balance and cellular function. Weigh yourself before and after exercise, to see how much weight you lose, and calculate your fluids accordingly. 1 liter of fluid weighs 2.25 lbs.

While we are on hydration, the best thing you can do for your body as soon as you rise in the morning is drink an 8oz. glass of water. Everyone is dehydrated in the morning, so rehydrate and you will feel better. Remember drinking coffee will dehydrate you even more, if you are drinking caffeinated coffee.

d. 2 new diet medications have been approved

Belviq (locarserin hydrochloride) and Qnexa (phentaramine/topiramate). To qualify, you must have a desire to lose weight, diminish caloric intake 1200-1500 cal/24 hrs., have a BMI of 30 or higher (waist of 37 inches for women and 40 for men), have obesity related disease like hypertension, type 2 diabetes, or high cholesterol. You must have a negative pregnancy test (causes birth defects), a good birth control plan, not have hyperthyroidism or closed angle glaucoma, or recent unstable heart disease. These are FDA approved. Studies show with above requirements, a loss of 10% of body weight in a year was seen over placebos by reducing the activity of the hunger center in the brain. Side effects are dry mouth, constipation, tingling of the fingers and toes, but no increased heart attacks or strokes were seen in these studies. The drug contains some of the same chemical that was in phen-phen, which was removed by the FDA because of heart valve problems. However, these drugs do not show that complication.

As always, please talk to your doctor about these issues and consult some of my references on the website for more information.

STAY HEALTHY AND WELL MY FRIENDS!! Dr. Sam

