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P.O. Box 127, Indian Rocks Beach, FL., 33785-

## NSAIDS

### ONCE CONSIDERED "SAFE" DRUGS, THE FDA RELEASED NEW WARNINGS IN 2015 RELATING TO DANGERS OF INITIATING HEART ATTACKS & STROKES.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are a drug class that groups together drugs that provide analgesic (*pain-killing*) and antipyretic (*fever-reducing*) effects, and, in higher doses, anti-inflammatory effects.

The term *nonsteroidal* distinguishes these drugs from steroids, which, among a broad range of other effects, have a similar depressing, anti-inflammatory action. First used in 1960, the term served to distance new drugs from steroids.

The most prominent members of this group are aspirin, ibuprofen and naproxen, all available over-the-counter. Acetaminophen is generally not considered an NSAID because it has only little anti-inflammatory activity. It treats pain mainly by blocking COX-2 mostly in the CNS, but not much in the rest of the body.

Most NSAIDs inhibit the activity of cyclooxygenase-1 (COX-1) and cyclooxygenase-2 (COX-2), and thereby the synthesis of prostaglandins and thromboxanes. It is thought that inhibiting COX-2 leads to the anti-inflammatory, analgesic and antipyretic effects and that those NSAIDs also inhibiting COX-1, particularly aspirin, may cause G.I. bleeding.

**Aspirin (ASA), the only NSAID able to irreversibly inhibit COX-1, is also indicated for inhibition of platelet aggregation. This is useful for the management of arterial thrombosis and prevention of adverse CV events. ASA inhibits platelet aggression by inhibiting the action of thromboxane A2.**

Prostaglandins basically are a family of chemical that are produced by the cells of the body and have several important functions. They promote inflammation that is necessary for healing, but also results in pain and fever, support the blood clotting function of platelets and protect the lining of the stomach from the damaging effects of stomach acid.

Prostaglandins are produced within the body's cells by the enzyme cyclooxygenase (COX). There are two COX enzymes. COX-1 and COX-2. Both enzymes produce prostaglandin that promote inflammation, pain and fever. However, only COX-1 produces prostaglandins that support platelet and protect the stomach. NSAIDs block the COX enzymes and reduce prostaglandins throughout the body. As a consequence ongoing inflammation, pain and fever are reduced. Since the prostaglandins that protect the stomach and support platelet in blood clotting also are reduced, NSAIDS can cause ulcers in the stomach and promote bleeding.

**Contraindications:** NSAIDs may be used with caution by people with: Irritable bowel syndrome, persons over 50 who have a family history of GI problems, person who have had past GI problems from NSAID use.

NSAIDS should usually be avoided by people with: peptic ulcer or stomach bleeding, uncontrolled hypertension, kidney disease, Crohn's disease, ulcerative colitis, past TIAs, past strokes, past myocardial infarction, undergoing coronary artery bypass surgery, congestive heart failure, third trimester of pregnancy, persons who have undergone gastric bypass surgery, persons who have a history of allergic or hypersensitivity reactions.



### LATE BREAKING NEWS

**IT's Official...Marco Annual Meeting in Orlando,** February, 8th through February 11th at the Hilton Garden Inn Orlando Airport, 7300 Augusta National Drive, Orlando, FL. 32822, Phone 1-407 240 3725. Special rate for MARCO, make your reservation by Feb. 9th. Directors mandated to attend. Visit the Cape and DisneyWorld along with Orlando's fine HamCation which rivals Dayton in attendance.

**Arnold Kalan WB6OJB,** Marco MediShare Director, is reported "at home" recuperating from recent surgery. Danny Centers W4DAN reported talking to him on a land line recently. We miss him.

### NEED CATEGORY I CME?

Go to [www.mpmcme.org](http://www.mpmcme.org) enter; go to "medical surgical archives" and a list will pop up...pick the lecture you want (includes mandatory ones) & when completed take the simple test and submit it to "Lee" for accreditation. When your medical license is up for renewal, notify Lee & she will submit the papers required. Tell her you affiliated with the Morton Planthospital through MARCO and Dr. Warren Brown.

(Txn to Morton Plant Hospital, Clearwater, Florida, an associate of the University of South Florida medical school.

**WRITE TO US!**  
We welcome your comments.  
Mail to Marco, P.O. Box 127,  
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33785. Email to  
warren.brown1924@gmail.com  
Letters may be edited for  
brevity & clarity.

## MARCO NET SCHEDULE

<u>DAY</u>	<u>EASTERN</u>	<u>FREQ.</u>	<u>NET CONTROLS</u>
Any Day	On the Hour	14.342	Hailing Frequency
Sunday	10:30 a.m. Eastern	14.140	CW Net, Chip, N5RTF
Sunday	11 a.m. Eastern	14.342	Warren, KD4GUA

(Alternate confidential Grand Rounds frequency—  
on or about 14.344 or as announced on the air.)

**MARCO'S CW  
NET IS NOW  
CALLED THE  
"Bob Morgan  
Memorial  
Net"**  
Sundays, 10:30 am,  
14.140 MHz

## Page 2

**MARCO Grand Rounds is held Sunday at 11 a.m. Eastern Time; 10 a.m. Central; 9 a.m. Mountain, and 8 a.m. Pacific Coast time on 14.342. You qualify for one hour Category II CME credit with your check-in.**

If a COX-2 inhibitor is taken, a traditional NSAID (Motrin, Naproxin, aspirin) should not be taken at the same time. In addition, people on daily aspirin therapy (for reducing CV risk) must be careful if they also use other NSAIDs, as these may inhibit the CV effects of aspirin.

**NSAIDs aside from aspirin, both selective COX-2 inhibitors and traditional anti-inflammatory increase the risk of myocardial infarction and stroke. This occurs at least within a week of use.** They are not recommended in those who have had a previous heart attack as they increase the risk of death or recurrent MI. Evidence indicates that naproxen may be the least harmful.

NSAIDs aside from low-dose aspirin are associated with a doubled risk of heart failure in those without a history of heart disease. In people with such a history, use of NSAIDs was associated with a more than 10-fold increase in heart failure. If this link is proven, researchers estimate that NSAIDs would be responsible for up to 20% of hospital admissions for congestive heart failure. In those with heart failure, NSAIDs increase mortality risk by about 1.2-1.3 for naproxen (Naprosyn, Aleve, Anaprox) and ibuprofen, (Motrin, Advil) 1.7 for rofecoxib and celecoxib (Celebrex), and 2.1 for diclofenac (Voltaren, Cataflam)

**On 9 July 2015, the FDA toughened warnings of increased heart attack and stroke risk associated with nonsteroidal anti-inflammatory drugs. Aspirin is an NSAID but is not affected by the new warnings.**

The main adverse drug reactions associated with NSAID use relate to direct and indirect irritation of the GI tract. NSAIDs cause a dual assault on the GI tract: the acidic molecules directly irritate the gastric mucosa, and inhibition of COX-1 and COX-2 reduces the levels of protective prostaglandins. Inhibition of prostaglandin synthesis in the GI tract causes increased gastric acid secretion, diminished bicarbonate secretion, diminished mucus secretion and diminished trophic effects on the epithelial mucosa. Clinical NSAID ulcers are related to the systemic effects of NSAID administration. Such damage occurs irrespective of the route of administration of the NSAID, i.e., oral, rectal or parental, and can occur even in patients with achlorhydria.

NSAIDs are also associated with a fairly high incidence of adverse drug reactions on the kidney and over time can lead to chronic kidney disease.

Photosensitivity is a commonly overlooked adverse effect of many of the NSAIDs. NSAIDs are not recommended during pregnancy, particularly during the third trimester. While NSAIDs as a class are not directed teratogens, they may cause premature closure of the fetal ductus arteriosus and kidney problems in the fetus. They are also linked with premature birth and miscarriage. In contrast, acetaminophen is regarded as being safe and well-tolerated during pregnancy,

**Drug interactions:** NSAIDs reduce kidney blood flow and thereby decrease the efficacy of diuretics, and inhibit the elimination of lithium and methotrexate. NSAIDs cause decreased ability to form a blood clot, which can increase the risk of bleeding when combined with other drugs that also decrease blood clotting, such as warfarin. NSAIDs may aggravate hypertension and thereby antagonize the effect of anti-hypertensives such as ACE inhibitors. NSAIDs may interfere and reduce efficiency of SSRI antidepressants.

**Mechanism of action:** Most NSAIDs act as nonselective inhibitors of the enzyme cyclooxygenase (COX), inhibiting both the COX-1 & COX-2 isoenzymes. This inhibition is competitively reversible as opposed to the mechanism of aspirin, which is irreversible inhibition. COX catalyzes the formation of prostaglandins and thromboxane from arachidonic acid. Prostaglandins act as messenger molecules in the process of

inflammation.

COX-1 is a constitutively expressed enzyme with a "house-keeping" role in regulating many normal physiological processes. One of these is in the stomach lining, where prostaglandins serve a protective role. Preventing the stomach mucosa from being eroded by its own acid. COX-2 is an enzyme facultatively expressed in inflammation, and it is inhibition of COX-2 that produces the desirable effects of NSAIDs.

When nonselective COX-1/COX-2 inhibitors (such as aspirin, ibuprofen, and naproxen) lower stomach prostaglandin levels, ulcers of the stomach or duodenum internal bleeding can result. The discover of COX-2 led to research to the development of selective COX-2 inhibiting drugs that do not cause gastric problems characteristic of older NSAIDs.

**Antipyretic activity...**NSAIDs have antipyretic activity and can be used to treat fever. Fever is caused by elevated levels of prostaglandin E2, which alters the firing rate of neurons within the hypothalamus that control thermo regulation.

**Classification:** NSAIDs can be classified based on their chemical structure of mechanism of action. Older NSAIDs were known long before their mechanism of action was elucidated and were for this reason classified by chemical structure or origin. Newer substances are more often classified by mechanism of action.

Chemical types:

**Salicylates:** Aspirin, Salsalate (Disalcid).

**Propionic acid derivatives:** Ibuprofen (Motrin), Naproxen (Naprosyn), Fenopropfen.

**Acetic acid derivatives:** Indomethacin, Sullindac

**Enolic acid (Oxicam) derivatives:**

**Fenamates**

**Selective COX-2 inhibitors (Coxibs) Only one available, Celebrex, (reduces gastric bleeds).**

The following list is an example of NSAIDs:

Aspirin, celecoxib (Celebrex), diclofenac (Cambia, Cataflam, Voltaren-XR, Zipsor, Zorvolex), diflunisal (Dolobid—discontinued brand), etodolac (Lodine, discontinued brand), ibuprofen (Motrin, Advil), indomethacin (Indocin), ketoprofen (Active-Ketoprofen), ketorolac (Toradol, discontinued brand), nabumetone (Relaven, discontinued brand) naproxen (Aleve, Aaprox, Naprelan, Naprosyn), oxaprozin (Daypro), piroxicam (Feldene), salsalate (Disalsate), sulindac (Clinoril, discontinued brand), tolmetin (Tolectin, discontinued brand).

Some types of opioid drugs: codeine, fentanyl (Actiq, Duragesic), hydrocodone/acetaminophen (Lorcet, Lortab, Norco, Vicodin), hydromorphone (Dilaudid, Exalgo), meperidene (Demerol), methadone (Dolophine, Methadose).

**The above is complicated and difficult to read. However, it contains important information that necessitates a second read. Much of the information concerning these drugs is new and may be life-saving.**

**Getting struck by lightning will only kill 10% of those struck whereas a bullet will kill only 20%. Less than 10% of those shot in the heart & 5%, in the head will survive**

**HISTORIC APPROVAL FOR  
1ST GENE THERAPY IN  
THE U.S.A.**



The FDA has approved tisagenicelucel (*Kymriah*) for certain pediatric and young adult patients with a form of acute lymphoblastic leukemia (ALL).

The historic action makes Novartis Pharmaceutical's CAR-T cell treatment the first gene therapy available in the U.S. (Gilead just negotiated to buy Kite Pharma, which also has a CAR-T therapy under review). The announcement ushers in a new approach to the treatment of cancer and other serious and life-threatening diseases by using the patient's own modified T-cells to fight diseases.

"We're entering a new frontier in medical innovation with the ability to reprogram a patient's own cells to attack a deadly cancer," said FDA Commissioner Scott Gottlieb, M.D. "New technologies such as gene and cell therapies hold out the potential to transform medicine and create an inflection point in our ability to treat and even cure many intractable illnesses."

The therapy is approved for patients up to 25 years for ages with B-cell precursor ALL that is refractory or in second or later relapse.

Each dose is a personalized treatment using the patient's own T-cells. After being collected, the T-cells are genetically modified to include a new gene that contains a specific protein that directs the T-cells to target and kill the leukemia cells that have a specific antigen on the surface. Once modified, the cells are infused back into the patient to kill the cancer cells.

The treatment has an overall remission rate of 83 percent within three months of treatment.

Though effective, tisagenicelucel has the potential to cause several side effects. According to the announcement, it carries a boxed warning for cytokine release syndrome (CRS), which is a systemic response to the activation and proliferation of CAR-T cells causing high fever and flu-like symptoms, and for neurological events. Both CRS and neurological events can be life-threatening. Other severe side effects of tisagenicelucel include serious infections, low blood pressure, acute kidney injury, fever and decreased oxygen (hypoxia).

Most symptoms appear within one to 22 days following infusion of tisagenicelucel. Since the CD-19 antigen is also present on normal B-cells, and tisagenicelucel will also destroy those normal B cells that produce antibodies, there may be an increased risk of infections over a prolonged period of time.

The FDA also expanded the approval of ACTEMRA (tocilizumab) to treat CAR T-cell-induced severe or life-threatening CRS in patients 2 years of age or older. In clinical trials in patients treated with CAR-T cells, 69% of patients had complete resolution of CRS within two weeks following one or two doses of Actemra.

Because of the risk of CRS and neurological events, tisagenicelucel is being approved with a risk evaluation and mitigation strategy (RMES), which includes elements to assure safe use. The FDA is requiring that hospitals and their associated clinics that dispense tisagenicelucel be specially certified. As part of that certification, staff involved in the prescribing, dispensing, or administering of tisagenicelucel are required to be trained to recognize and manage CRS and neurological events. Additionally, the certified health care setting are required to have protocols in place to ensure that tisagenicelucel is only given to patients after verifying that tocilizumab is available for immediate administration.

The FDA granted tisagenicelucel FAST TRACK, Priority Review and Breakthrough Therapy designations.

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**There are two ways to be fooled. One is to believe what isn't true. The other is to refuse to accept what is true.**

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**MARCO GRAND ROUNDS ON HERPES.** called our attention to the combination drug **Truvada** which is indicated for HIV prevention that is now questionably being used to prevent Herpes infection. Note is made that once you have HIV you are more prone to contact Herpes 2 since you are immune compromised. so if you can prevent HIV you may have a stronger immunity against Herpes infection. Truvada is not indicated for syphilis or gonorrhea..



**POX & THE HERPESVIRUSES**

(As presented on MARCO Grand Rounds of the Air, Oct. 22nd, 2017)

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Eight types of herpesviruses infect humans. After the initial infection, all herpes viruses remain latent within specific host cells and may subsequently reactivate or be shed. Herpes viruses do not survive long outside a host; thus transmission usually requires intimate contact, although the chicken pox-shingles virus may spread by aerosol. Because the virus remains latent, transmission sometimes occurs from asymptomatic infected people. The Epstein-Barr virus and type 8, also known as Kaposi's sarcoma-associated herpesvirus, are tightly linked with cancer.

The names of the herpesviruses are:

Type 1	Herpes simplex	herpesvirus 1	Gingivostomatitis.
Type 2	Herpes simplex 2	herpesvirus 2	Genital herpes
Type 3	Varicella-Zoster	herpesvirus 3	Chicken pox; shingles
Type 4	Epstein-Barr	herpesvirus 4	Infectious Mono.
Type 5	Cytomegalovirus	herpesvirus 5	Mono, hepatitis
Type 6		herpesvirus 6	Roseola infantum
Type 7		herpesvirus 7	Roseola infantum
Type 8	Kaposi's Sarcoma	herpesvirus 8	Causative role in Sarc.

**CHICKENPOX...**is caused by the varicella-zoster herpesvirus type 3. Chickenpox being the acute invasive phase of the virus and herpes zoster (shingles) representing reactivation of the latent phase. Chickenpox, which is extremely contagious, is spread by infected droplets and is most communicable during the prodrome and early stage of the eruption. It is communicable from 84 hrs before the first skin lesions appear until the final lesions have crusted.

In immunocompetent children, chickenpox is rarely severe. In adults and immune-compromised children, infection can be serious. Papules appear in crops not all at once like in smallpox usually on the face and trunk. New lesions cease to appear after the 5th day, become crusted by the 6th day and disappear by the 20th day. Encephalopathy occurs in less than one in a thousand cases.

**Infection provides lifelong protection. All healthy children and susceptible adults should receive doses of live attenuated varicella vaccine.** In children between ages of 12 months and 18 months. If not given earlier it can be used at 2, 5, 12, 18 years of age. Vaccination is important especially in women of child-bearing age and adults with underlying chronic medical conditions. Serologic testing to determine immune status before vaccination in adults is usually not required.

Vaccination should not be given to moderately ill patients, immunocompromised, pregnant women, patients on high doses of systemic corticosteroids. Although the vaccine may cause chickenpox in immunocompetent patients, disease is usually mild.

Following exposure, chickenpox can be prevented or attenuated by IM administration of varicella-zoster immune globulin prepared from pooled plasma containing high titers of specific antibody. Candidates include those with leukemia, immunodeficiencies, or other severe debilitating illnesses. susceptible pregnant women and newborns whose mothers developed chickenpox within 5 days before or 2 days after delivery.

If the diagnosis is in doubt lab confirmation by way of the immunofluorescent detection of viral antigens in lesions or cultures or serologic findings.

**Varivax** is a live attenuated varicella virus. Children 12 months to 12 years should receive one dose subQ .5 ml (*If a second dose is given it should be 3 months later.*) Children over 13 and adults should receive two injections one to two months apart.

**HERPES ZOSTER...**is infection that results when varicella-zoster virus reactivates from its latent state in a posterior dorsal root ganglion. Treatment: Gabapentin, cyclic antidepressants and topical capsaicin or lidocaine ointment.

A vaccine is now available to boost the immune response in elderly patients who previously had chickenpox.

Diagnosis can be confirmed by the Tzanck test. Herpes simplex virus may produce nearly identical lesions but unlike zoster, it tend to recur and is not dermatomal. Viruses can be differentiated by culture. Antigen detection from a biopsy sample can be useful.

**Zostavax...Merck**, an attenuated live vaccine works best in those 60-69 and is less effective in the younger patients. Contraindicated in those immunocompromized, those allergic to neomycin. **This is not a substitute for VARIVAX and should not be used in children.** Duration of effectiveness is not known past 4 years. Transmission of the vaccine virus has not been reported. Indicated only for those 60 years or over.

## LETTERS TO THE SOCIETY:

**Kudos from** (No luck this issue).

From **Ian Kelleman, K3IK, Shavertown, PA...** (regarding the no-eat till 12 theory)... We have to stop making ourselves crazy. It's only partly what and when you eat. It's how you burn it off that counts. My Dad loved his salami on chaliah late at night and his egg salad for lunch...lived to 94 with a little breakfast—who knows?

From **Dave Justis KN0S, Virginia...** (regarding physician retirement) Retirement is a real fascinating concept. I have decided to wait until I reach 70.5 years to collect full social security benefits in early 2019. Interestingly, Nuala who is 64.5 now can take half of my SS benefits until she too reaches 70.5—I think according to SS.. Still working 3 days a week—seeing a mixed bag of ages from the very young to the very old in urgent care..... I am currently training the next generation of nurse practitioners, medical students, EMTs and paramedics as this does keep one up to date answering questions and learning along with my students.

**Bob K4RLC, Raleigh, N.C.** writes: Great net on retirement, Chip's (N5RTF) internet service was great. I'm 67 and plan on retiring at 69. I downsized the practice and attempting to transition and work less, but my patients and referral sources won't let me, plus, still 2 kids in grad school. My health is excellent, just ran 3 miles on the beach at low tide so that's not an issue. The issue is I enjoy writing professional articles and teaching and still want to do that. Also will do volunteer work probably with the Red Cross.

**Paul Lukas N6DMV, Torrance, CA** reports on his recent trip to Hungary: "A friend, professor Andrew Gschwindt PhD, head of the Budapest University of Technology & Economics' Space Program, asked me to make a presentation of my involvement with the American Space Program, NASA, and my experience in Amateur Radio. The one-hour program was a mixture of both with a picture show. At the end of the presentation I was taken up to the top of the building where the satellite control antennae were located. This group, the students were responding a few years before to a program to build a satellite by the name of Masat-1—Magyar Satellite-1 which would circle the Earth for at least 3 months. It lasted from Feb. 13, 2013 to Jan. 10, 2015.

The satellite size was a 10 x 10 x 10 cm, -4 inch cube, not exceeding 1000 grams, 1 kg-2.2lbs. Seven countries entered the project, but only one of them worked—the Hungarian one. After the assembly of the cube, they found that there were a few grams left over. They went to a toyshop, bought a cheap tiny camera and built it into the cube. It supplied remarkably nice sharp images of the Earth—I have some."

Paul goes on to explain the group is getting ready to launch another satellite—Smog-1—an UHF-band spectrum monitoring system. The launch is either this year or 2018.

Where I am, there is fun. I told them that in my age I have to be cognizant of my advanced age and the 31,577,600 seconds of a non-leap year expressed in years in 32 decimals remind me to hurry and get things done—the end is approaching fast. (still in the dash between birth and demise.)

**Bruce Small KM2L** reports he has been able to get good flight tickets to Orlando for the M/EXO HamCation annual event. Plan to join him.

**EDITOR'S NOTE:** Walter Winchell began broadcasting in 1933 to an audience of 25 million people. The Winchell style was unmistakable. He talked rapidly at 197 words per minute...the voice was high-pitched and not pleasant to the ear; but it was distinctive. The staccato quality made every item compelling. He claimed he talked so fast because if he talked more slowly people would find out what he was saying...he began his radio program with a series of dots and dashes operating the key himself. Telegraphers throughout the country complained that what Winchell tapped out made no sense. He realized he hadn't the faintest knowledge of Morse code but he refused to have an experienced telegrapher provide the sound effects for him. He wrote like a man honking in a traffic jam.



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**Tesla has a really major problem in the future...** If you really intend to adopt electric vehicles, you have to face certain realities. For example, a home charging system for a Tesla requires 75 amp service. The average house is equipped with 100 amp service. On the average small street there are about 25 homes, the electrical infrastructure would be unable to carry more than 3 houses with a single Tesla each. For even half the home to have electric vehicles, the system would be wildly overloaded. This is the elephant in the room with electric vehicles. Our residential infrastructure cannot bear the load. So as our genius elected officials promote this nonsense, not only are we being urged to buy the things and replace our reliable cheap, reliable generating systems with expensive, new windmills and solar cells, but we will also have to renovate our entire delivery system. This latter investment will not be revealed until we're so far down this dead end road that it will be presented with an oops and a shrug. What is your opinion?

**If all the people in the world were divided up proportionately,** 57% would be Asians, 21% Europeans, 14 % North & South Americans and 8% Africans. 52% would be women & 48% men. 30% Caucasians and 70% non-Caucasians; 30% would be Christians and 70% non-Christians. Six people would own 54% of the world, 80% would live in poverty and 70% would be illiterate, 1% would be dying and 1% being born. 1% would own a computer and 1% would have a college education.

**A must read...** Shell Oil comments: Here are some reasons why we don't allow cell phones in operating areas, propane, gas and diesel refueling areas...three incidents in which mobile cell phones ignited fumes during fueling operations: the phone was placed on the car's trunk lid during fueling; it rang and the ensuing fire destroyed the car and the pump. In the second, an individual suffered severe burns to their face when fumes ignited as they answered a call while refueling their car. In the third, a individual suffered burns to the thigh as fumes ignited when the phone, which was in their pocket, rang while they were fueling their car. **Mobile phones should not be used in filling stations, or when fueling lawn movers, boats, etc.**

**Worth a look...** People who drink diet soda daily are almost three times as likely to develop dementia or stroke as those who rarely drink them. Researchers at Boston Univ. School of Medicine used MRIs of about 2,886 volunteers age 45 and older over a 10-year period to monitor the development of stroke and an additional 1,484 volunteers age 60 and older for dementia. Even after excluding diabetics from the study because they are believed to be at increased risk for dementia, the risk for dementia was still higher in those who drank diet sodas.

**Keep it gray...** Women who dye their hair dark brown or black increase their risk for breast cancer. Rutgers Cancer Institute found that white women who used dark hair dyes raised their overall risk by 75%..

**The first oral treatment for women with fibroids** could be available as soon as summer 2018, with two others in the pipeline. In October the U.S. accepted Allergan's new drug application for ulipristal acetate to treat abnormal uterine bleeding caused by uterine fibroids. The company expects a decision by May. The drug has been available in Europe and Canada for several years.

**The new female Viagra** "Addyl" by Sprout Pharmaceuticals approved by the FDA.

## QUICK TUTORIAL ON THE HUMAN IMMUNE SYSTEM & CANCER RX.

5

More than 90% of pediatric patients with acute lymphoblastic leukemia recently went into remission after being infused with CAR T-cells (Chimeric Antigen Receptor) which are acquired by using modified HIV cells as a tool to alter the DNA of T-cells which prevented the virus from replicating. It is called "an anti-HIV cut-and-paste job—an anti HIV molecular scissors." (Confusing? Yes, bear with us.....)



There are two major cell types in our acquired immune systems that distinguish us from flies, and those are B-cells and T-cells. T-cells are a sort of offensive weapon, destroying viruses and bacteria. B-cells are more like a shield. They produce antibodies that detect and swat down foreign invaders based on unique molecular characteristics. A CAR T-cell is a "chimera"—Greek for a fusion of two animals. It combines the "killing machinery" of T-cells with the precise antibody targeting of B-cells.

A CAR T-cell binds to the target, the immune system responds the same way it does to a virus: T-cells kill the cancerous cells and then proliferate. Once all the cancer is destroyed, CAR T-cells remain on "memory level;" they are on surveillance, we now know, for at least seven years.

There is, however, a hitch or two. After being cured, patients must receive blood infusion every few months to prevent their immune systems from killing off their B-cells. And about a third of patients undergoing treatment with CAR T-cells experience a violet immune-system reaction known as *cytokine-release syndrome*. When cancer cells die, they release inflammatory proteins called *cytokines* that can cause high fevers and leave patients comatose.

Cytokine-release syndrome almost ended the therapy in its infancy. In 2012, one of the first pediatric patients, a 6-year old girl developed a 106-degree fever and experienced multiple organ failures. A blood analysis showed high levels of the cytokine *interleukin-6*, or *IL-6*. Fortunately. The children's hospital where she was being treated had the drug, *Tocilizumab*, on hand.

Within hours of receiving the drug, the patient awoke from her coma. Eight days after receiving the CAR T-cell injection, she went into remission. Two weeks later, she was cancer-free. She's now 12 and thriving.

Tocilizumab saved the field as well as the girl. If the first patient dies on a protocol and nobody's been cured, the protocol is finished. Regulators always err on the side of caution. Our FDA regulations are made so that you can never have more than about 30% of people get sick with serious side effects to be approved.

Glioblastoma, the brain cancer with which Sen. John McCain was recently diagnosed, is also challenging. A recent protocol targeting a receptor on brain tumors showed that the CAR T-cells successfully crossed the blood-brain barrier but then it was found the target was gone. That's called tumor editing. Patients still had a tumor but it no longer had that target. In other words, the tumor mutated as bacteria do in response to antibiotics.

Since a glioblastoma often consists of many different tumors, the difficulty is designing a T-cell that targets them all—or alternatively, devising a cocktail of T-cells. That's what we've done with HIV—people take three or four drugs, and then the virus can't mutate and be resistant.

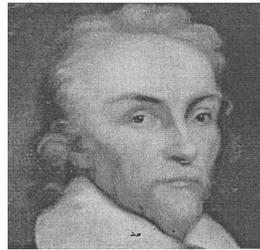
Currently, each patient requires a team of highly trained specialized scientists and technicians to re-engineer T-cells. If you have 100,000 lung-cancer cases each year, there aren't 100,000 Ph.D.s to grow the cells, so it will need to be done with robotics to get the price down. This will take anywhere from 10-20 years to happen.

There are now over 200 trials going in the world trying to treat cancer with CAR T-cells.

Manufacturing T-cells at the moment is extremely expensive and it's unclear whether and how insurance companies will cover the costs. But the question may be whether the regulatory approvals will keep up with the technology.

(Information for the above was taken from an article by Allysia Finley with appeared in the Aug. 19, 2017 edition of the Wall Street Journal.)

## MARCO'S HEROES Sir William Harvey, 1578-1657



William Harvey was an English physician who discovered how blood circulates in the body. His discovery became an important foundation of medicine. Harvey's book, *An Anatomical Treatise on the Motion of the heart and Blood in Animals*, appeared in 1628. It was considered the most important single volume in the history of physiology. In it, Harvey showed the heart, by repeated contrac-

tions, produces a continuous stream of blood throughout the body which continually returns to its source.

Although his theories were severely attacked by followers of the ancient Greek physician Galen, they were based on first hand observation and experiment. Harvey lived to see his discovery widely accepted, although full credit for it came after his death.

Harvey was born April 1, 1578, in Folkestone, England. After graduation from Caius College, Cambridge, he studied medicine at the University of Padua in Italy. He returned to London in 1602 to practice medicine.

Harvey became a member of the Royal College of Physicians and served as physician to James I and Charles I.

In 1651, he published his second great work, *Exercitationes de Generatione*, considered the basis for modern embryology. It deals with reproduction, particularly the part that the egg plays in fertilization.

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### HIGHLIGHTS FROM QRZ

**The EZ Hang Square Shot Kit...**(submitted by *wb8imy*) For the last 20 years I've gazed longingly at the uppermost branches of a Fir tree in my back yard. At about 50' those branches would be the ideal perch for the apex of an 80 meter inverted-V antenna, but unless I resorted to hiring a bucket truck, or otherwise alarming my neighbors, the perch would remain out of reach...until now.

I unzipped the plastic bag that held the EZ Hang Square Shot Kit. The kit consists of a heavy-duty slingshot with a unique square yoke and a foldable wrist support. Attached to the arm of the EZ Hang is a spin-casting fishing reel containing 300' of light monofilament line. Also included is a collection of yellow 1-ounce weights and the EZ Winder with 500' of 155-pound—test orange line.

I unfolded the EZ wrist support and sighted the gap in the branches and fired. I watched as the yellow ball soared into the air and neatly threaded the gap in the branches. The monofilament line played out and then stopped.

Following instructions I soon had the copper wires of my 80-meter inverted V dipole antennas gleaming in the morning sunlight.

(Manufacturer: EZ Hang, 75 Goldfinch Way, Capon Bridge, WV 26711; [www.ezhand.com](http://www.ezhand.com). Price: \$99.95)

**Antennas and Radios are usually compatible.** KD2GMX asks: I'm a new ham. I have a 2-meter handheld transceiver and would like to expand my station. If I get a new antenna and transceiver, how can I tell if a new antenna will be compatible with a new radio?

A. Fortunately things are pretty standard between antennas and radios. There are a few considerations to keep in mind. They need to be designed to operate on the same frequency range. They need to have the same nominal impedance—this is almost always 50 ohms for coax-fed antennas. They need to be interconnected by cables with the correct connectors—one that matches the antenna on one end and the radio on the other. Fortunately, there are connector between-series adapters that can be used to solve compatibility problems. The usual connectors encountered on VHF antennas and radios are: UHF, Type-N, BNC, and SMA on some handheld transceivers. For proper performance on VHF or UHF they need to be of the appropriate polarization.

**KEEP MARCO PERKING !**

**Pass this copy to a friend OR send us a \$15 membership**



Probiotics contain microorganisms, most of which are bacterial similar to the beneficial bacteria that occur naturally in the human gut. They are available over-the-counter or by prescription and in a variety of forms, such as capsules, packets, or food supplements. Although most probiotics are available without a prescription there may be an advantage to patients with prescription drug coverage because probiotics may be a covered benefit. Probiotics have been widely studied in a variety of gastrointestinal diseases and one in five Americans take probiotics for digestive problems. The most studied probiotics for human use belong to the *Lactobacillus*, *Bifidobacterium*, or *Saccharomyces* species.

The intestinal microbiome is composed of microbes that reside in the gut and may be altered by diet, lifestyle, exposure to toxins, and antibiotic use. There is a relationship between disease, health, the immune system, and changes in the microbiota. Probiotics have an important role in the maintenance of immunologic equilibrium in the GI tract through direct interactions with immune cells. The microbiome diversity is likely important in health maintenance, and is likely that broad-spectrum probiotics may increase the effectiveness of treatment.

**Key recommendations for practice:** Probiotic use reduces the risk of antibiotic-associated diarrhea in children and adults.

**Probiotic use** may reduce the incidence of *Clostridium difficile* associated diarrhea .

**Probiotic use** significantly reduces the risk of hepatic encephalopathy but there is insufficient evidence regarding the effect on nonalcoholic fatty liver & nonalcoholic steatohepatitis.

**Probiotic use** increases remission rates in adults with ulcerative colitis.

**Probiotic use** improves abdominal pain and global symptom scores in children and adults with irritable bowel syndrome.

A recent review found that a dosage of 5 billion colony-forming units or greater per day was significantly more effective than lower doses.

Probiotics are effective for acute infectious diarrhea caused by bacteria, but there are inconsistent result for the effectiveness of probiotics for diarrhea caused by viruses. Probiotics do not reinoculate the gut microbiome and are recoverable only in stool samples for one to two weeks.

**Conditions for which Probiotics are ineffective...**Probiotics are not effective for acute pancreatitis or Crohn’s disease. Probiotics are generally considered safe but caution is advised in immunologically vulnerable populations. A review of 24,615 participants did not find a significant increase in the number of adverse events in individuals treated with short-term probiotics (*less than one month*) or in the number of adverse event incidents reported in probiotic vs control groups based on another study. The long term effects of probiotics are largely unknown, and additional randomized trials are needed to address this question.

(The above includes excerpts from the paper “Probiotics for Gastrointestinal Conditions,” by Thad Wilkins and Jacqueline Sequoia” which appeared in the Aug. 1, 2017 edition of “American Family Physician.”)

**A NOTE ON THE Grand Rounds PROBIOTIC LECTURE OF OCT. 15TH**

**FOOD IS FUEL for the human body engine...**I remember getting some bad gas in Beckley, West Virginia and then getting stuck on the Pennsylvania turnpike and then again right in the middle of Wall street when some 30 busy bystanders helped actually pick up my Buick and move it from blocking traffic. Bad fuel can make your car stutter and stop—bad biome (*body gut bacteria*) may make the body engine stop in the form of constipation or diarrhea or IBS (*Irritable Bowel Syndrome*.)

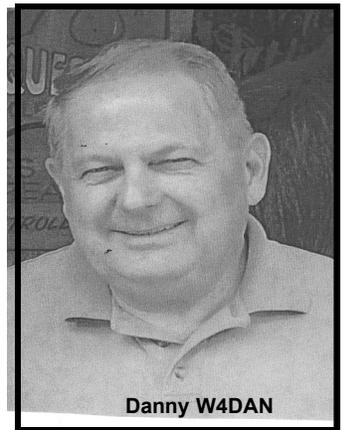
Someone mentioned about the skin biome being just as important NO, after all you can have a bad car body yet the engine of the car will continue to run.

It all adds up to bad fuel—lactobacillus is an additive you use to get a smooth running body engine. Don’t add a bad additive—just as you would use only a good additive in your car oil

We have vocal anesthesia—”It won’t hurt”, then we have local anesthesia, like Novocain, then we have Bulgarian anesthesia—a blow to the head—now we have Bulgarian and Romanian food additives—why? Because Bulgarians and Rumanians are the longest living people in the world....In summary, the human engine isn’t a car engine—but it is similar, so why not mimic the long-livers?

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**By Danny Centers W4DAN**



**Danny W4DAN**

Many radio amateurs have never operated during a radio contest because they either don’t want to be involved in the “madness,” or they feel their operating skills are not sufficient. The fast pace can be intimidating, and the frustration of not understanding rapid exchanges, whether in SSB, or CW mode can sometimes be enough to discourage some seasoned contest operators.

Participation does not mean that one must remain in the contest for an extended time. Short periods of operation can be fun. As a matter of fact, after making a few initial contacts, you may begin to enjoy it. If frustration sets in, take a break and start again later.

My initial reason to begin contesting was to increase DXCC, WAS, IOTA, and grid locator numbers on more bands and modes. At that time, I had interest in neither making large numbers of contacts, nor racking up high scores. My modus operandi at that time was to listen and tune the bands to find new states, countries, and entities. It was a long time after first participating in a contest that I considered soliciting for contacts.

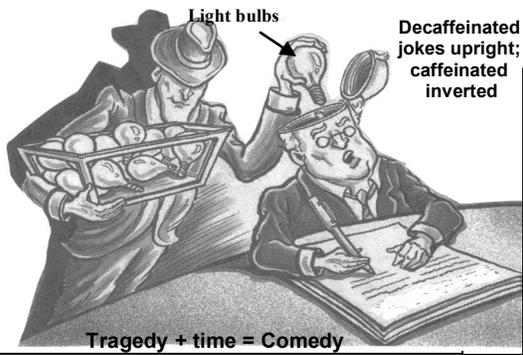
There seems to be some conflicting opinions about whether contesters are fair to non-contesters. Many non-contesters feel that the bands are too often taken over and limits their “rag chewing” time, especially on weekends. Some claim that the only time they have to operate is on the weekends. When contesting crowds the conventional bands, this allows a good opportunity to explore the WARC bands for those not participating. For years, I have tried to promote the idea of regular group schedules and nets having alternate frequencies to stay clear of the QRM. Of course, like much of my advice, it is shed like water off a duck’s back. Local groups that I have regular skeds with have much success by setting aside alternate frequencies to avoid QRM.

Major contests do not occur every weekend, and hardly ever through the week. Most of the biggest ones have separate weekends for phone, CW, and other digital modes. Something to ponder is the thought that if “rag chewers” and contesters alike were all on the same bands at the same time every day and every evening, the congestion would be much worse. What chaos! In other words, most contesters and DX chasers usually do a small amount of “rag chewing” and most “rag chewers” do very little contesting and DXing, if any. Even net operations are only occasionally interfered with on weekends. This allows each group to take their turn sharing bands.

A big benefit of contesting is to increase CW skills and speed while enjoying equipment operation. Antenna testing can easily be performed during casual contesting because numerous stations at varied locations and distances can be observed. Switching between antennas will usually reveal some surprising results. I have personally found that different antennas can produce better results at different times on the same bands due to propagation changes. This can result in interesting studies of antennas versus ionospheric conditions and can be achieved without actually working toward scoring, or preparing logs for submission.

Serious participants will be glad to receive contacts that will help them increase their score, even if the contacts are a little slower, and take a little longer. Don’t be intimidated if they try to rush you. Mistakes and errors shouldn’t be taken too seriously because everyone is just trying to make a contact and move on to the next one. “Good luck in the test.”

LIGHTEN UP...



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### GOLFER'S LAMENT

**Golfer to caddy:** How do you like my game? **Caddy:** Very good sir, but personally I prefer golf. **Golfer to caddy:** Do you think it is a sin to play on Sunday? **Caddy:** The way you play, sir, it's a sin to play on any day. **Golfer to caddy:** Do you think my game is improving? **Caddy:** Yes sir, you miss the ball much closer. **Golfer to caddy:** This is the worst course I've ever played on. **Caddy:** This isn't the golf course, we left that an hour ago. **Golfer to caddy:** This isn't my ball, it's too old. **Caddy:** It's been a long time since we teed off, sir. **Golfer to caddy:** I think I'm going to drown myself in the lake. **Caddy:** Think you can keep your head down that long? **Golfer to caddy:** I'd move heaven and earth to break 100 on this course. **Caddy:** Try heaven, you've already moved most of the earth.



**Signs outside a Scotch Pub:** "Helping ugly people have sex since 1864." "Drink triple, See double, Act single," "Buy one beer for the price of two and receive a second beer absolutely free." "Come in and meet your future ex-wife."

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"I changed my car horn to gunshot sounds. People get out of the way much faster now."  
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**An Englishman, a Scotsman, an Irishman, a Latvian, a Turk, a German, an Indian, an American, an Argentinean, a Dane, an Australian, a Slovak, an Egyptian, a Japanese, a Moroccan, a Frenchman...** all walk into a fine upscale restaurant. **"I'm sorry"** says the maitre d after scrutinizing the group. **"You can't come in here without a Thai."**

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**W. C. Fields said...** A woman drove me to drink and I didn't even have the decency to thank her.... **I cook with wine some-times...I even add it to the food.** *Start every day with a smile and get it over with.* Always carry a flagon of whiskey in case of snake-bite and furthermore always carry a small snake. **I am free of prejudice. I hate everyone equally.** *Once during prohibition I was forced to live for days on nothing but food and water.* A rich man is nothing but a poor man with money. **Never try to impress a woman, because if you do she'll expect you to keep up the standard for the rest of your life.** *I'd rather have two girls at 21 each than one girl at forty-two.* Some contemptible scoundrel stole the cork from my lunch.. **I spent a year in Philadelphia, I think it was on a Sunday.** The only thing a lawyer won't question is the legitimacy of his mother. **Christmas at my house is always at least six or seven times more pleasant than anywhere else.** **We start drinking early, and when everyone else is seeing only one Santa Clause, we'll be seeing six or seven.**

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**TWO MEN DRESSED PILOT'S UNIFORMS** walk up the aisle. Both are wearing dark glasses, one is using a guide

A salesman rang the bell and the door was opened by a nine-year old boy puffing on a cigar. "Is your mother in?" asked the salesman. "The boy took the cigar out of his mouth, flicked ashes on the carpet and asked, "What do you think?"

dog, and the other is tapping his way along the aisle with a cane. Nervous laughter spreads through the cabin, but the men enter the cockpit, the door closes and the engines start. The passengers begin glancing nervously around, searching for some sign that this is a joke but none is forthcoming. The plane moves faster and faster down the runway and the people sitting in the window seats realize they're headed straight for the water at the end of the runway. As it begins to look as though the plane will plough into the water, **panicked screams fill the cabin.** At that moment, the plane lifts smoothly into the air. The passengers relax and laugh and soon all retreat into their magazines, secure in the knowledge that the plane's in good hands. In the cockpit, one of the blind pilots turns to the other and says, **"You realize John, one of these days, they're gonna scream too late and we'll gonna die."**

# MEMORIES OF YEARS AGO IN MARCO

Our History Book

## Fifteen years ago in MARCO

December 2002... "GAS" was the headlines of Marco... What is it and where does it come from? A good topic we will have to go back to. **Danny Centers W4DAN** has a good article in the NL entitled, "While Shopping at the Dayton Hamvention" and **Arnold Kalan WB6OJB** wrote about his "African Adventure" in Tswalu. **Ellen KC9ARN** told about her recent holdup during which "the assailant had a weapon pointed at me." Her purse was stolen and she urged all Marco members to have duplicate photo copies of all important papers as if they are taken away they are very, very difficult to replace.

## Ten years ago in MARCO

December 2007... "Was Sputnik a "German Satellite?" That was page one a decade ago. **Paul Lukas N6DMV**, who had the unique opportunity of having lived through the Nazi occupation of Hungary, the Soviet occupation and the Hungarian Revolution of 1956, wrote about his attendance at the Atoms for Peace Conference in Geneva on behalf of the American Atomic Energy Commission in the early 1960s at which time he reported seeing German emblems on Sputnik which was on display. The late **Sister Mary Emanuel KC5AQ** sent Marco a very nice Thanksgiving card which read "Thanks for sending me the Marco Newsletter. It just keeps getting better and better. A real delight to read. I don't get too much mail anymore because so many of my contemporaries are getting to Heaven before me. I hope that's where they are going. Keep up the good work and have a very Happy Thanksgiving Day." Sister became a silent key two years ago.

## Five years ago in MARCO

December 2012... "Doctor, I want my young face back!" 3-D printing in the future will allow one to either replace an aging face with a younger face mold made earlier or by replacing it with a face from the internet—perpetual youth?" There was a photo of actor Clark Gable on the front page with the comment, "My face doesn't come cheap." This was the time of the "Terrorist" who was destroying our Marco Grand Rounds of the Air with bad language and musical sounds. (He died recently after being fined \$25,000 which he is reported not to have paid.) Marco was requesting its members to complain to the FCC (to no avail—we had to move frequency to 14.342 MHz). **Mary Favaro AE4BX** was President of Marco and she commented about Hurricane Sandy skipping Myrtle Beach, SC and colliding with the northeastern States. She requested all members to attend the upcoming Annual Meeting in Myrtle Beach this coming April.. (Many of us did and we had a wonderful time.)

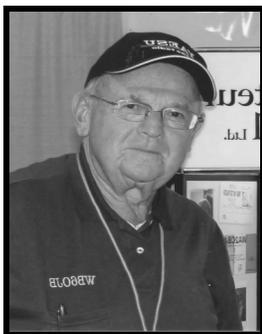
## MARCO'S HEROES

His name is Arnold Kalan, M.D., WB6OJB and he lives in Pacific Palisades, CA. He is our MediShare Director and a loyal MARCO ham.

Arnold is a big-game hunter to Africa but he doesn't shoot animals with a gun—but with a camera. Arnold and his wife Joan systematically return to Africa each year to visit, learn and Dx with the world.

Arnold is a man of STEEL having annually undergone heroic surgery that would dent any man—except him. Throughout these adventures he returns with a big smile as if to say, "I did it again!"

Today, Arnold is recuperating from another surgical adventure and reportedly doing "well." Let's all give this man a pat on the back for teaching us a lesson on just how to successfully respond to adversity—he is our real



MARCO teacher and role model.

# BOB CURRIER MARCO GRAND ROUNDS OF

## THE AIR. (Corrections to Marco)

14.342, Sundays, 11 am Eastern, One Hour Cat. II CME

CALL	HRS.	NAME	QTH
N5AN	38	Bud	Lafayette, LA
KD4GUA	36	Warren	Largo, FL
KC9CS	35	Bill	Largo, FL
NU4DO	34	Norman	Largo, FL
N5RTF	34	Chip	New Orleans, LA
N2JBA	34	Ed	Amenia, N.Y.
W4DAN	33	Danny	Cleveland, TN
WB6OJB	31	Arnold	Pac.Pal., CA
KK1Y	31	Art	Seminole, FL
N4TSC	31	Jerry	Boca Raton, FL
WB9EDP	31	Harry	Batavia, IL.
K9QA	30	Rich	Knox, IN
KNOS	29	Dave	Virginia
N9RIV	29	Bill	Danville, IL.
KM2L	29	Bruce	Clarence, N.Y.
WB1FFI	28	Barry	Syracuse, N.Y.
KE5SZA	27	John	Marietta, OK
KE8GA	26	George	N. Carolina
N6DMV	26	Paul	Torrance, CA
WA3QWA	26	Mark	Chesapeake, VA.
WORPH	25	Tom	Denver, CO
N2OJD	25	Mark	Sydney, Ohio
W8LJZ	25	Jim	Detroit, MI
NOARN	25	Carl	Denver, CO
K6JW	24	Jeff	Palos Verges, CA
W6NYJ	23	Art	Beverly Hills, CA
W0UNZ	23	Paul	Warsaw, MO
K4RLC	22	Bob	Raleigh, NC
WB2MXJ	21	Joe	St. Metairie, LA
WA1EXE	20	Mark	Cape Cod, Mass.
N8CL	19	Chuck	Albany, N.Y.
N9GOC	19	Pat	Champagne, IL
K3IK	16	Ian	Shavertown, PA
WA1HGY	16	Ted	Massachusetts
KD5QHV	15	Bernie	El Paso, TX
W6BPP	14	Susan	Colorado
N4MKT	13	Larry	The villages, FL.
K9YZN	13	Mike	Crystal Lake, IL
W1RDJ	13	Doug	Cape Cod, Mass.
K0FS	13	Fred	St. Louis, MO
N9HIR	10	Bill	Berwyn, IL
KB5BQK	9	Linda	El Paso, TX
W4MEA	9	Max	Tennessee
KC9ARP	9	Michelin	Batavia, IL
K1WDR	6	Wayne	Parish, FL
AE4BX	6	Mary	Myrtle Beach, SC
W3PAT	6	Marvin	S. Carolina
N4DOV	5	David	Ft. Lauderdale, FL.

YEAR	TOTAL CHECK-INS	AVERAGE PER SUNDAY
1998	694	14.46
1999	766	15.95
2000	1,035	20.29
2001	1153	22.60
2002	1383	26.15
2003	1489	28.63
2004	1534	29.50
2005	1517	29.17
2006	1531 (one extra Sunday)	28.89
2007	1591 (one extra Sunday)	30.02
2008	1524 (Only 46 nets)	33.14
2009	1533 (46 nets)	33.32
2010	1591 (44 nets)	36.22
2011	1514 (44 nets)	34.41
2012	1602 (44 nets)	36.41
2013*	1400 (44 nets) (New Freq)	31.82 (Year of Terrorist)
2014	1756 (47 nets)	37.36
2015	1722 (49 nets)	35.14
2016	1687 (46 nets)	36.67
2017	1294 (38 nets)	34.05

Record number of stations checked-in was 51, on Feb. 24, 2013

## BLOOD DISORDER COULD EXPLAIN ORIGIN OF “Vampires.”



Blood-sucking vampire or blood disorder? A new study from Boston’s Children’s Hospital has uncovered a genetic mutation that triggers a disease linked to vampire folklore.

Porphyria is a group of eight known blood disorders which affect the body’s ability to produce **heme**, which is a component of the oxygen transporting protein, **hemoglobin**.

It’s the different genetic variations that affect heme production that give rise to different clinical presentations of porphyria. One, erythropoietic protoporphyria (EPP), shares symptoms—and even treatments—with legendary vampire lore. EPP causes people’s skin to become very sensitive to light, and in some cases, prolonged exposure can lead to painfully, disfiguring blisters

People with EPP are chronically anemic, which make them feel very tired and look very pale with increased photosensitivity because they can’t come into the daylight. Even on a cloudy day, there’s enough ultraviolet light to cause blisters and disfigurement of the exposed body.

Today, treatment of the disease includes blood transfusions containing sufficient heme levels to alleviate symptoms as well as the avoidance of ultraviolet light by staying indoors during the day. But in earlier times, treatment consisted of drinking animal blood and avoiding daylight—linking the condition to the vampire myth..

Research on some genetic pathways leading to build-up of protoporphyrin IX have already been described but many cases of EPP remain unexplained. For their research, the team performed deep gene sequencing on members of a family from France with EPP of a previously unknown genetic signature. They discovered a novel mutation of the gene CLPK, which plays a role in mitochondrial protein folding.

The lead professor hopes his work leads to therapies that could correct the faulty genes, adding, “Although vampires aren’t real, there is a real need for innovation therapies to improve the lives of people with porphyria.”

### **PORPHYRIA**

**Porphyria** is a group of diseases in which substances called porphyrins build up, affecting the skin or nervous system. The types that effect the nervous system are also known as **acute porphyria**, as symptoms are rapid in onset and last a short time. Symptoms of an attack include abdominal pain, chest pain, vomiting, confusion, anxiety, confusion, hallucinations and rarely overt psychosis. Also, constipation, fever, high blood pressure, and high heart rate. The attack usually lasts for days to weeks. Complications may include paralysis, low blood sodium levels, and seizures. Attacks may be triggered by alcohol, smoking, hormonal changes, fasting, stress or certain medications. If the skin is affected, blisters or itching may occur with sunlight exposure.

**Treatment** depends on the type of porphyria and a person’s symptoms. It involves the avoidance of sunlight and giving I.V. heme or a glucose solution. Rarely a liver transplant may be carried out.

The frequency of porphyria is unclear but it is estimated that it affects 1 to 100 per 50,000. Porphyria cutanea tarda is the most common type and it is often confused with Guillain-Barre syndrome and porphyria testing is commonly recommended in those situations.

**Acute porphyria can be triggered by a number of drugs**, such as Sulfonamides, Sulfonylureas (exception is glipizide), Barbiturates, antifungals, ketamine, certain antibiotics (rifampicin, isoniazid, nitrofurantoin and possibly, metronidazole.), Ergo derivatives, antiretroviral meds, anti-convulsants, antidepressants (imipramine, trazodone), antipsychotics (ripiperidone, ziprasidone). **Causes** are considered genetic.

## PORPHYRIA CUTANEA TARDA

**Porphyria cutanea tarda (PCT)** is the most common subtype of porphyria & makes up about 80% of cases of porphyria. It is found in about 1 in 10,000 people and is characterized by blistering of the skin in areas that receive higher levels of exposure to sunlight. It heals slowly and with scarring. Other skin manifestations are hyperpigmentation (as if they are getting a tan), and hypertrichosis (mainly on the top of the cheeks). Patients also often complain of voiding a wine-red colored urine.

Inherited mutations in the UROD gene cause about 20% of cases (the other 80% of cases do not have mutations in UROD, and are classified as sporadic). In the 20% of cases that is inherited, it is an autosomal dominant pattern. It is caused by a deficiency of uroporphyrinogen decarboxylase which participates in the formation of heme.

Excess alcohol abuse is frequently associated with both types. It is thought to do so by causing oxidative damage to liver cells, resulting in oxidized species of uroporphyrinogen that increases the uptake of iron in the liver.

Diagnosis is by the appearance of skin lesions and blistering along with high levels of uroporphyrinogen in the urine. Additionally, testing for common risk factors such as Hepatitis C and hemochromatosis is strongly suggested as their high prevalence in patients with PCT may require additional treatment.

Treatment consists of avoiding alcohol intake & iron supplements, excess exposure to sunlight as well as estrogens and the use of phlebotomy to reduce excess iron. Low doses of antimalarials can be used such as chloroquine which works by removing excess iron from the liver.

Porphyria cutanea tarda is implicated in the origin of vampire myths. This is because people with the disease tend to avoid the sun due to photosensitivity and therefore have a young complexion and pallor and require blood transfusions. Hypertrichosis, a full head of hair, will also give a young appearance.

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### **IMMUNOTHERAPY FOR CANCER GAINS MOMENTUM**

(From Thomas M. Burton’s fine article in the Wall Street Journal)

The science of using immunotherapy to treat cancer is advancing rapidly marked by the NCI’s recent disclosure that a metastatic breast-cancer patient is now cancer-free. Regulators’ are expecting approval of a major lymphoma treatment and the unveiling of a partnership between government, researchers and drug makers.

Immunotherapy describes a range of treatments that harness a patients’ own immune system to target cancer. The approach doesn’t work in all patients but its success against some hard-to-treat cancers makes it the most closely watched area in cancer pharmaceuticals.

Meanwhile a lymphoma drug, called **axi-cel** is expected to be approved soon, It would be the second immunotherapy drug of its type to get a green light from the FDA and has promise for thousands of patients with a type of lymphoma that resisted other treatments. The FDA recently approved a new gene-based immunotherapy, Novartis’s **Kymriah**, for a form of leukemia.

In a lecture at a Boston meeting, Dr. Steven Rosenberg, who head the immunotherapy lab at the NCI reported on the first patient with metastatic breast cancer who is disease-free nearly two years after her first immunotherapy treatment. In the therapy, a person’s own cells are multiplied billions of times and reinfused into the patient. Dr. Rosenberg’s lab has already reported successes in treatments of melanoma, lymphoma, colorectal cancer and bile-duct cancer.

The breast patient is Judy Perkins, a 51-year-old engineer from Port St. Lucie, FL. She was diagnosed with metastatic cancer—cancer that spread beyond the original location—in 2013. Then she underwent multiple regimes of chemo and other standard treatments to little avail. But she learned of the NCI research, and in Aug. 2015, doctors in Bethesda, Md., harvested her immune cells. In Dec. 2015, she got an infusion of her own, intensified immune cells. Driving home, she said she already could feel a tumor that had shrunk “*I thought this thing could be working.*” she said.

By May 2016, her scans at the NCI came back clean—no detectable cancer. They have stayed clean, including during a visit to the NCI recently.

Ms. Perkins is only one case but the fact that she had metastatic breast cancer that is no longer detectable make it very consequential.

Dr. Rosenberg’s interest in immunotherapy was piqued three decades ago, when he was struck by a chance encounter with a stomach-cancer patient who improbably recovered despite no treatment. It became a life long quest to discover how that patient had, in effect, cured himself.

Now his lab is exploring the promise of testing and accomplishing tumor regressions in far more common solid-tumor cancers of internal organs, including the breast, colon and bile-duct.

## IS STEM CELL THERAPY SAFE & EFFECTIVE OR IS IT A SCAM?

## 10 IS THIS A SCAM?

**Regenexx is the only stem cell treatment network to publish an analysis of patient stem cell procedure outcome data. The analysis is made possible thanks to the massive numbers that are compiled throughout the years in the Regenexx patient registry, which tracks patient outcome at regular intervals following all of the stem cell procedures offered.**

**This patient outcome data is not part of a controlled trial. Every patient however, becomes part of a registry to track outcome and any complications. This data is a compilation of patient input to the Regenexx Patient Registry at regular intervals following their Regenexx procedure.**

Regenexx procedures are known by many as some of the most advanced orthopedic injury treatments in the world. It involves using stem cells and blood platelets to treat a number of different conditions including arthritis, orthopedic issues and a variety of other degenerative ailments.

Since first being offered as a medical treatment option in 2005, almost 50,000 Regenexx procedure have been completed. They are considered pioneers in the field of orthopedic stem cell treatment and offer some of the most advanced procedures available..

**How does it work?** Stem cells are something that are found in all humans, and they typically serve as a repair agent when we get injured or hurt. As we get older, however, our body can't always supply enough cells to injured areas, which can result in lingering injuries, or an inability to fully recover.

Regenexx helps to solve this issue by hugely increasing your body's own natural supply of stem cells, which helps promote the healing process.

This is achieved by harvesting your own stem cells from areas in your body, such as the bone marrow, that have an abundance of them. The cells are then concentrated in a lab before being re-injected into whatever part of your body is in need of repair. The process is extremely precise and effective and has been used by thousands to overcome a variety of orthopedic injuries.

They call the process *same day* procedure because they harvest the stem cells and then re-inject them on the same day. The full process however typically takes about a week to complete and involves a number of different injections. Each situation will be different, so there really isn't an exact timeframe.

The Regenexx procedure is offered by close to 40 different providers around the world.

**How much will it cost?** Unfortunately, the Regenexx treatment isn't currently covered by insurance, so there will be a significant amount of out-of-pocket cost. Treatments run around \$6,000.

**Blood Platelet Treatments.** Platelet Rich Plasma (PRP) & Platelet Lysate injection treatments contain healing growth components from your own blood that increase your body's natural ability to repair itself. The use of PRP is becoming well known, since they have a stimulating effect on the stem cells within the targeted area, making those stem cells work harder to heal damaged tissues. Platelet procedure are commonly used for soft tissue injuries, mild arthritis and spine conditions.

**Why Regenexx is a better option than Fusion Surgery or Steroid Epidural injections.** Fusion surgery is a highly invasive procedure and is more likely to cause complications which occur in 36% of fusion patients. 76% still require narcotics for pain and patients missed 3X as much work as those who didn't have surgery. A steroid epidural is an injection that places steroid medication around irritated or inflamed nerves in the spine. While they do help patients avoid surgery, epidurals use very high-dose steroids that can cause severe side effects and actually reduce the body's ability to heal. Results: Of 147 patients Stem cells worked better and longer 5 to 1 over epidural injections.



The Justice Department and the FDA have ordered doctors from a Denver, Colorado company to stop performing a cultured mesenchymal stem cell-treatment. But physicians at its Southern California affiliate have gone ahead and announced recently that they are "*licensed and trained*" to perform a completely different procedure.

The FDA in 2010 asked a federal judge to stop doctors from Regenerative Sciences Inc from performing what it calls a "Regenexx-C" procedure marketed as "breakthrough" to prevent surgical treatment options for people suffering moderate to severe pain from joint, tendon, ligament, or bone injury.

The Regenexx-C procedure entails removing stem cells from a patient's bone marrow, propagating them in a special solution, then re-injecting the cells at the site of an injury. This is quite different from the procedure being offered by the California clinic, which is fully FDA compliant as it's a same day treatment without the propagation step (Regenexx-SD).

The federal lawsuit filed in Aug. 2010, was the first time the FDA took the stand in court that the Colorado company was producing a drug by culturing the patient's own stem cells to larger numbers. Prior to that, the FDA had argued in court that it had no formal position that the procedure the medical clinic was performing was not to be classified as a drug. In fact, the FDA was initially sued by Regenerative in Denver in 2008 and the case couldn't be heard because the agency claimed that it had no formal regulatory position on what Regenerative was doing. The Regenexx-SD procedure used in California is fully compliant with the FDA regulation allowing doctors to perform same day bone marrow stem cell procedures as in the "practice of medicine" governed by the states.

While promising stem cell treatments often hog the headlines, these are part of highly structured clinical studies conducted in major universities. Aimed to prove that new therapies are safe and to gather more evidence that treatments are more effective than placebos, such studies take years and cost millions. By contrast, the mesenchymal stem cells used in the Regenexx-C procedure are not the subject of an approved biologic license application or part of a clinical trial or an investigational new drug application in effect. However, the FDA neglects to note that about half of all medical care isn't developed in such settings but is instead is developed by doctors like those at Regenerative. These new therapies begin with doctors trying to help a unique individual lead to *small research studies*, and then finally advance to larger studies.

Before the FDA filed its declaration, it asked an expert to review the studies that Regenexx had performed at its clinic. At that early date, the Regenexx procedures did not go through the kind of rigorous testing that leads to widespread acceptance in medicine, concluded George Muschler, an orthopedic surgeon and professor who reviewed several cases studies. However, Muschler had serious undisclosed financial conflicts of interests by owning shares in a company and the patents on a device that is marketed by that company, that is directly competitive with the Regenexx procedure.

These early studies by Regenexx merely reported the benefits of the treatments that meant to remedy unhealed fractures and torn muscles or tendons. These included x-ray evidence of healing of fractures as well as those consistent with healing of other tissues such as cartilage.

Meanwhile, "*stem cell tourism*" is a growing global industry that offers hope to people suffering from Parkinson's disease, amyotrophic lateral sclerosis, spinal cord injury, severe burns, heart disease, diabetes and other severely debilitating and disabling conditions. While some clinics are legitimate, many are not. Most of these procedures are conducted outside the U.S., in China, Russia, the Dominican Republic, Ukraine and other counties in Europe and elsewhere.

In legal documents reviewed by attorneys for Regenerative Sciences they say that the procedure falls under state powers because it "constitutes the practice of medicine." and this is overseen by the medical board. Medical practice isn't regulated by the FDA, they argue.

**IMPRESSION: The idea has merit and is relatively harmless and has had good results. The bad part being expensive and no coverage by insurance carriers**

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Psoriasis is a disabling problem that affects one's appearance, ego and a patient's life potential. Who would hire someone that has a face of blisters and plaques that resembles eczema and possibly leprosy. Now new hope has arrived: The FDA has approved **Siliq**.

**Siliq (brodalumab)** is now available to treat adults with moderate-to-severe plaque psoriasis. It is administered as an injection. The new drug is intended for patients who are candidates for systemic therapy who have failed to respond, or have stopped responding to other systemic therapies.

Psoriasis, present in 1.5 million Americans, is a skin condition that causes patches of skin redness and flaking. It is an autoimmune disorder that occurs more commonly in patients with a family history of the disease, and most often begins in people between the ages of 15 and 35. The most common form of psoriasis is plaque psoriasis, in which patients develop thick, red skin with flaky, silver-white scales.

Siliq's active ingredient binds to a protein that causes inflammation, inhibiting inflammatory response that plays a role in the development of plaque psoriasis. Siliq's safety and efficacy were established in three randomized, placebo-controlled clinical trials with a total of 4,373 adult participants with moderate-to-severe plaques psoriasis who were candidates for systemic therapy or phototherapy. More patients treated with Siliq compared to placebo had skin that was clear or almost clear, as assessed by scoring of the extent, nature and severity of psoriatic change of the skin.

Suicidal ideation and behavior have occurred in patients treated with Siliq during clinical trials. Siliq users with a history of suicidality or depression had an increased incidence of suicidal ideation compared to users without this history. As a result the labeling includes a warning and the drug is only available through a restricted program under a Risk Evaluation and Mitigation Strategy called the Siliq REMS Program.

Siliq is a medication that affects the immune system thus patients may have a greater risk of getting an infection, or an allergic or autoimmune condition. Patients with Crohn's disease should not use Siliq. Doctors should also evaluate patients for tuberculosis infection prior to initiating treatment with Siliq. Patients with active TB should avoid immunizations with live vaccines in patients being treated with Siliq.

The most common adverse reactions reported include joint pain, headache, fatigue, diarrhea, throat pain, nausea, muscle pain, injection site reactions, influenza, low white count and fungal infections.

**PHYSIOLOGY**

Your immune system is designed to help protect your body from infections and diseases. But in conditions like plaque psoriasis your immune system is not working properly. It can make too much of several proteins, including one called tumor necrosis factor, or TNF. The extra TNF can contribute to skin cells growing too quickly, and cause them to build up. When skin cells build up, they form raised red patches, known as plaques, which often have silvery tops.

**Enbrel**, for example, is a medicine that affects your immune system. **Enbrel** can lower the ability of your immune system to fight infections. Serious infections have happened in patients taking Enbrel. These infections include tuberculosis and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients have died from these infections. Your doctor should test you for TB before you take **Enbrel** and monitor you closely for TB before, during and after Enbrel treatment, even if you have tested negative for TB

There have been some cases of unusual cancers reported in children and teenage patients who started using tumor necrosis factor (TNF) blockers before 18 years of age. Also, for children, teenagers, and adults taking TNF blockers, including Enbrel, the chances of getting lymphoma or other cancers may increase. Patients with RF may be more likely to get lymphoma.

**What are the possible side effects of Enbrel?** It can cause serious side effects including new infections or worsening of infections you already have. Hepatitis B can become active if you already have had it; nervous system problems such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes, blood problems, new or worsening heart failure; new or worsening psoriasis allergic reactions autoimmune reactions including a lupus-like syndrome and auto immune hepatitis.

Psoriasis treatments reduce inflammation and clear the skin. Treatments can be divided into three main types: topical treatments, light therapy and systemic medications.

**Topical treatments: Topical Corticosteroids...** for mild to moderate psoriasis. They reduce inflammation and relieve itching and may be used with other treatments. **Vitamin D analogues...** These synthetic forms of Vit. D slow skin cell growth. Calcipotriene (Dovonex) may be used. **Anthralin...** This medication helps slow skin cell growth and can also remove scales and make skin smoother. However, it stains almost anything it touches. It's usually applied for a short time and then washed off. **Topical retinoids...** These are vitamin A derivatives that may decrease inflammation. These medications may also increase sensitivity to sunlight. **Calcineurin inhibitors...** tacrolimus (Prograf) and pimecrolimus (Elidel) —reduce inflammation and plaque buildup...not recommended for long-term use because of a potential increased risk of skin cancer. **Salicylic acid...** promotes sloughing of dead skin and reduces scaling. **Coal tar...** Reduces scaling, itching and inflammation. However, it is messy and stains clothing and has a strong odor. **Moisturizers...** Reduce itching, scaling and dryness.

**Light Therapy:** This treatment uses natural or artificial ultraviolet light. The simplest and easiest form involves exposing your skin to controlled amounts of **natural sunlight** but avoiding excessive exposure. **UVB phototherapy...** Controlled doses of UVB light from an artificial light source may improve mild to moderate psoriasis symptoms. **Narrow band UVB phototherapy...** A newer type of psoriasis treatment, that may be more effective than broadband UVB treatment. Usually administered two or three times a week until the skin improves and then weekly sessions. **Goeckerman therapy...** combines UVB treatment and coal tar treatment. **Psoralen plus Ultraviolet A (PUVA)...** This form of photo chemotherapy involves taking a light-sensitizing medication (psoralen) before exposure to UVA light. **Excimer laser...** treats only the involved skin with a controlled beam of UVB light.

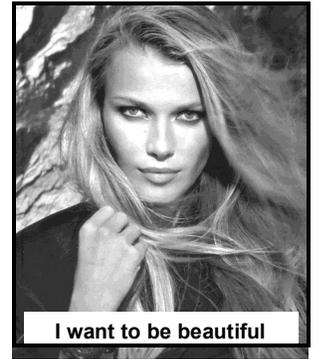
**Oral or injected medications:** If you have severe psoriasis or it's resistant to other types of treatment, you may then take oral or injected drugs. **Retinoids...(acitretin (Soriatane))** May help if doesn't respond to other therapies. Should not be taken by pregnant women for at least 3 years after taking the medicines. **Methotrexate...** taken orally (Rheumatrex) helps suppress inflammation. Should be taken only for short periods of time. **Cyclosporine (Gentraf, Neoral)...** suppresses the immune system and is similar to methotrexate in effectiveness, but can only be taken short-term.

**Drugs that alter the immune system (biologics)** that are flooding the TV advertisements... They include etanercept (Enbrel), infliximab (Remicade), adalimumab (Humira), ustekinumab (Stelara), golimumab (Simponi), apremilast (Otezla), secukinumab (Cosentyx) and ixekizumab (Taltz),

Most of these drugs are given by injection (apremilast is oral) and are usually used for people who have failed to respond to traditional therapy or who have associated psoriatic arthritis. Biologics must be used with caution because they have strong effects on the immune system and may permit life-threatening infections. In particular people taking these treatment must be screened for tuberculosis.

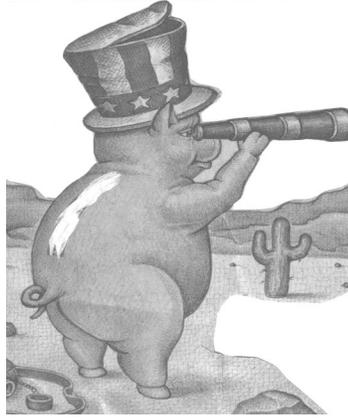
**Other medications:** Thioguanine (Tabloid) and hydroxyurea (Droxia, Hydrea) are medications that can be used when other drugs can't be given.

**Alternative medicines:** A number of alternative therapies claim to ease the symptoms of psoriasis, including special diets, creams, supplements and herbs. None have been proven effective. They include: **Aloe Vera, fish oil (Omega-3) Oregon grape,** also known as barberry, Oregon grape



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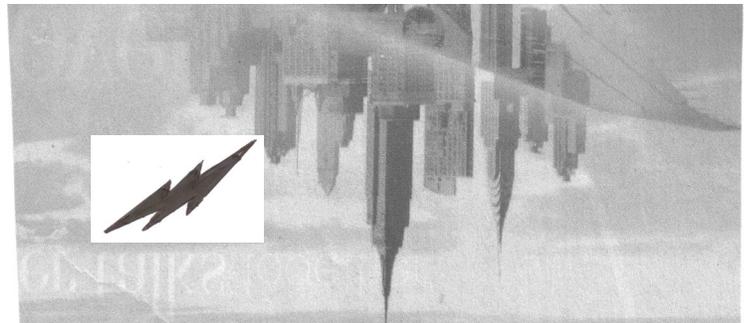
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