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Booby Trapped Plastic Angel: Isis

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It seemed like a simple enough request. The patient wanted a letter stating that her fibromyalgia condition was diagnosed after she had her silicone breast implants. It was August 2004 and that spring the medical literature after years of careful scrutiny reached the conclusion that silicone breast implants did not cause fibromyalgia nor any previously suspected autoimmune disease. I explained this to her. It did not matter she said, her attorney told her the class action money was there for her and she was going to get her fair share. Somehow I was reminded of an interview with historian Forrest McDonald in Bill Moyers' book A World of Ideas. "...as a Scottish philosopher in the eighteenth century said 'Democracy cannot last long. It's not a durable form of government. It can last only until the people discover that they can reward themselves from the public treasury. And then they become dependents of the public treasury, and they're tyrannized over.' Did it not matter what the scientific evidence showed? Was this an attitude that was good for our country or was it threatening? I needed to know more.

In 1990 I presented a talk to the Bedford County medical society discussing the five greatest developments in rheumatology during the preceding decade. A new disorder called Eosinophilia Myalgia was discovered. Patients exposed to tryptophan which was commercially prepared by one company in Japan developed a disease that looked very much like scleroderma—one of the autoimmune connective tissue diseases. The company omitted one purification step in the preparation and patients with a particular inherited immunogenetics developed at times a fatal disease. This disease was similar to the Toxic Oil Syndrome described in Spain in 1981 found to be due to rapeseed oil treated with aniline and used for cooking. In the past we felt that rheumatology patients had an inherited predisposition to autoimmune diseases which was usually triggered by an infection. Rheumatic fever was the prototype. Suppose three of us are exposed to strep infection. Most likely, even without antibiotics, our immune systems would eradicate the infection. However, my immune system, once it is triggered by the infection begins to malfunction. As part of its surveillance function it begins to recognize antigenic materials in the skin, heart, and joints as strep-like and reacts against its own tissues—i.e. autoimmune. The subsequent rash, heart disease, and arthritis are features of rheumatic fever. Why did not the other two react this way? Inherited immunogenetics probably explain the different reactions. The importance of eosinophilia myalgia and toxic oil syndrome was the understanding that environmental triggers other than infection might trigger off autoimmune diseases in the immunogenetically susceptible patient. Was silicone one of these triggers? Was it not the inert substance we hoped it would be in silicone breast implants, joint prostheses, penile implants, and multiple medical tubing applications?

Marcia Angell, M.D.served as the executive editor of The New England Journal of Medicine and chronicles the silicone breast implant saga in her book Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case (1997). Before you dismiss Dr Angell as being biased or assuming a protective position of her profession or the medical industrial complex let me update you on her current work. She is the Senior Lecturer in the Department of Social Medicine at Harvard. In 1997 Time Magazine named her one of the 25 most influential Americans and her current book is The Truth about the Drug Companies and What to do about it. Perhaps a topic for a later presentation.

Silicone breast implants were started in 1962. By 1994 breast augmentation was the third most common cosmetic operation in the U.S. 20% of the patients had breast implants for reconstruction post breast cancer surgery. 90% of the women were well pleased with the results. As a foreign body, silicone might cause a mild inflammatory response probably important with leakage problems. However, the implants caused essentially no major problems compared with the direct injection of silicone into tissues like breasts, lips, chins, buttocks, etc as seen in the illicit silicone injection parties you read about and demonstrated years before in Japan. Four problems were apparent from the beginning: contractures from scarring, leakage, rupture, and problems performing mammography.

In 1990 President George Bush appointed David Kessler as commissioner of the FDA. By then breast implants had been on the market for nearly 30 years. Since 1976 the Medical Device Amendment to the Food, Drug, and Cosmetic Act extended the FDA's authority for devices such as implants. Having been on the market so long, the implants were "grandfathered" but in 1982 the FDA proposed requiring "premarketing approval" which meant the manufacturers would have to supply evidence of the safety of implants. About that time some anecdotal reports appeared of cases of connective tissue disease in women who had undergone breast augmentation. Earliest reports were from Japan relating directly injected parafin or silicone rather than implants (adjuvant disease). In 1982 an Australian physician reported CTDZ (connective tissue disease) in three women with silicone-gel-filled implants. The first successful lawsuit was the 1984 case of Maria Stern with a jury award of $2 million. In 1988 the FDA asked for evidence of safety and effectiveness but the manufacturers (by law given 30 months to gather data) were not forthcoming. Enter the media.

My first impression of the power of the media in medicine came unexpectedly in May 1980. I was fishing for stripers on the Staunton River with Dr. J. Russell Rice one of my teaching clinical professors of rheumatology from Duke. As we floated down the river with no fishing success, Russ asked if I was going to use these two new meds coming out---Feldene and Oraflex for our arthritis patients. Probably not. Feldene's big advantage was once a day dosing but I worried with its long half life it might prove a high risk drug for GI bleeding (this has proven to be the case). Oraflex (benoxaprofen) was associated with some strange skin reactions including the desquamation of skin around the cuticles on sun exposure. As the afternoon wore on a thunderstorm started down the river toward us. We headed to shore for cover and as we approached the bank, Russ noted that he did not have a change of clothes and with no crowds on the river he undressed to leave his clothes in the boat protected from the rain. Have you ever been in an electrical storm when you were so close that the hair on your arms raised up when the lightning flashed? I was sure we would be struck by lightning and my 10 month practice in

Lynchburg would be highlighted in the paper when found dead on the banks of the Staunton River with a nude rheumatologist from Duke. Well, we survived but that night as I drove back to Lynchburg and Russ drove back to Durham, the godfather of anchormen Walter Cronkite announced to the nation that there were two major new medicines for arthritis that not only helped the pain but cured the disease. While this was not accurate, there was no question whether Russ and I would use the meds. You could not get samples quickly enough; the patients demanded the meds. Who could doubt Walter Cronkite—and that's the way it was. Rather impressive. Several months later Oraflex was pulled off the market due to excess liver toxicity felt at that time to be the type of adverse reaction that could not be appreciated till the drug was monitored on the open market although it had been in use in Europe for 2 years before the U.S. experience. Interestingly the Wall Street Journal December 31, 2004 has a front page article regarding monitoring adverse drug reactions implying that systems in France and Britain might be better than existing systems in the U.S. involving the FDA. While that was not the case with Oraflex, things may have changed in the last 20 years.

Certainly the biggest media event related to silicone breast implants occurred in 1990 on the TV show Face to Face with Connie Chung. Her spin was that implants were dangerous devices foisted on unsuspecting women. She interviewed women who claimed to have autoimmune disease caused by breast implants. There was no consideration of the lack of evidence in the presumed link of implants and disease. Chung implicitly blamed the FDA for permitting the sale of such risky products. She was joined by groups such as Nader's consumer group Public Citizen whose health director Dr. Sidney Wolfe (a classmate of Lynchburg's Dr. Terry Miller)who never practiced medicine, called for a ban on breast implants. Several years ago he wanted one of our helpful remittive agents for rheumatoid arthritis Arava (leflunomide) taken off the market. Cooler heads prevailed and evidence showed it was not necessary and a valuable medicine remains available. He most recently joined David Graham of the FDA in calling for the wholesale removal of Bextra, Celebrex, Crestor, Serevent and several other medicines. I suspect he is a Christian Scientist.

In spite of groups such as the AMA, American Cancer Society, and American Society of Plastic and Reconstructive Surgeons favoring implants being left on the market, Dr Kessler in 1992 decided to ban silicone-gel-filled breast implants. In an article that year defending his decision in NEJM the reason stated was the failure of the manufacturers to fulfill their responsibility in demonstrating the safety of the implants. Although a link with autoimmune disease was not proven, in 1991 there had been a $7.34 million dollar award to Mariann Hopkins who claimed the implants caused her to develop a rare autoimmune disease Mixed Connective Tissue Disease. In the next 2 years 16,000 lawsuits brought by over 1000 lawyers were filed in federal and state courts. One notable case outlined in Dr. Angell's book was Johnson v. Bristol-Myers Squibb Company in which an award of $25 million went to Pamela Johnson of Houston. This patient likewise had no autoimmune disease and her tearful complaints of recurrent sinus infections, sore throats, and upper respiratory infections were probably more related to her cigarette habit. Her attorney John O'Quinn was so successful in gliding over the issue of whether Johnson was sick and concentrating on the concern that she might get sick in the future and represented all the women with silicone implant "time bombs" that a teaching videotape was made by Video

Trial Report, a joint venture of American Lawyer magazine and Courtroom Television Network. It was titled "Look Over Here: Johnson vs Bristol-Myers Squibb Company: How Houston Plaintiff's Lawyer John O'Quinn Won the Largest Breast Implant Verdict to Date by Keeping a Jury on the Strongest Elements of His Case." The narrator makes it clear that O'Quinn had to avoid the issue of whether Johnson was sick and instead concentrate on the possibility that she might in the future become ill because of the silicone in her body. O'Quinn's fee was 40% of the award plus expenses. He previously had won more than a billion dollars in his three largest verdicts—a 1986 case against Monsanto, a 1988 case against Tenneco, and after the Johnson case a 1993 case against Amoco. After this first breast implant case by the end of 1992 he had some 700 cases pending.

Perhaps related to the Monsanto case was an editorial by the CEO of Monsanto in Forbes magazine discussing a number of potentially helpful products he and some fellow large company executives were not bringing onto the market due to liability concerns. Do you remember this famous movie line? "There's a great future in plastics. Think about it." This was advice given by Mr. McGuire when counselling Ben (Dustin Hoffman) in "The Graduate." Today this would be given with special caveats. Most specifically to medicine there is an indirect threat to all medical devices. A peculiar feature of our product liability laws is that plaintiffs can make claims against any party involved in the manufacture of an allegedly harmful product even with remote involvement(discussed in an article by R.F.Service "Liability Concerns Threaten Verdict in Implant Research" Science 266 (1994) 726-7). That is, suppliers of raw materials can be sued, even if they have nothing to do with the design and manufacture of the product. DuPont supplied Teflon to a company called Vitek that used it to manufacture jaw implants. When problems with the implants were discovered, Vitek declared bankruptcy and aggrieved patients sued DuPont. Although the courts ruled fairly consistently in favor of DuPont the company over five years spent $8 million defending itself. This amounted to far more than the return on five cents worth of Teflon in each implant ("Implant Market a Minefield for Raw Material Suppliers" Chemical Marketing Reporter, 245, May 1994; 20). The results? Dow Corning has scaled back sales of silicone to other manufacturers of medical devices including pacemaker wires, artificial joints, mechanical heart valves, intraocular lenses, implantable arteriovenous shunts for people on chronic dialysis, and shunts for people with hydrocephalus. DuPont in 1993 decided it would no longer supply medical manufacturers with Dacron polyester for vascular grafts, Teflon, or other biomaterials with the fear of liability for any constituents of medical devices.

But what about scientific evidence? Observational epidemiologic studies offer a way to study connections between disease and potential risk factors. A cohort (group) study would start with a group of women who have implants and a group who do not, none of whom has CTDZ and keep track of the two groups to see how many in each group develop CTDZ. A case-control study would start with a group of women who already had CTDZ (cases) and a group who did not (controls). The researchers then would find out how many women in each group had implants. If more cases than controls had breast implants, it would support breast implants as a risk factor. If you had a rare disorder or were ill and unable to be diagnosed or wanted a second opinion, where might you go for help? The Mayo Clinic, Johns Hopkins, and Harvard (Mass General) come to mind.

The first reliable study was published June 16,1994 out of the Mayo Clinic (Gabriel "another angel?", et al "Risk of CTDZs and Other Disorders after Breast Implantation" NEJM 330 (1994):1697-1702).This retrospective cohort study of 749 women who received breast implants between 1964 and 1991 and 1498 women without implants found that the implant group was no more likely to develop CTDZ (or related symptoms or abnormal blood tests) than the group without implants. At the time of this publication implants were off the market for 2 years and it was 2 months after a class-action settlement was negotiated. A Harvard study (Sanchez-Guerrero, et al "Silicone breast implants and the risk of CTDZs and symptoms" NEJM 332 (1995):1666-70.) was the Nurses' Health Study. This was a similar retrospective cohort study involving 87,501 women with again no findings of an association between silicone breast implants and CTDZs. Hopkins looked at the specific disease scleroderma again finding no association (Hochberg,et al"Frequency of augmentation mammoplasty in patients with systemic sclerosis" J Clin Epidemiol 48 (1995): 565-9). In March of 2000 UNC published a study looking at all the prior investigations (Janowsky et al "Meta-analyses of the relation between silicone breast implants and the risk of CTDZs" NEJM 342(2000):781-90). They conclude "...there was no evidence of an association between breast implants in general, or silicone-gel-filled breast implants specifically, and any of the individual CTDZs, or other autoimmune or rheumatic conditions. From a public health perspective, breast implants appear to have a minimal effect on the number of women in whom CTDZs develop, and the elimination of implants would not be likely to reduce the incidence of CTDZs."

The reaction of plaintiffs' attorneys to the initial studies was of interest. Dr. Angell was subpoenaed twice to produce a large number of documents in addition to all records of peer review of Gabriel's study and any documents that showed that breast implant manufacturers paid her to publish the Mayo Clinic study. Likewise, Gabriel and other epidemiologists were subpoenaed to produce volumes of material. In a May 16, 1995 New York Times article she described the harassment. Plaintiffs' attorneys in Houston demanded that she produce over 800 manuscripts from researchers, hundreds of data bases, dozens of file cabinets and the entire medical records of all Olmsted County women whether they were in the study or not (this is the massive data base the Mayo Clinic uses for its many epidemiologic studies). Dealing with these demands consumed all her time and compromised her ability to do her work. In her view, her experience and that of others would have a chilling effect on implant research. Dr Gabriel felt that no one would want to do it given the likely consequences.

I did not have the benefit of some of these studies when I was invited to give a talk on Fibromyalgia to the Medical staff and nurses at Cabarrus County Hospital in N.C. in 1992.However, it previewed problems and reactions to scientific evidence. At the end of my talk during question and answer time, a doctor who was a fellow intern in medicine with me in 1972 and was subsequently chief resident in medicine at Duke asked about the association of silicone implants and fibromyalgia or other CTDZs. I felt then, as now, that based on scientific evidence, there was no association. Well, according to my old fellow house officer, I was wrong. The reason we couldn't find an association was because this was a "new disease" and like fibromyalgia would have no identifiable abnormal tests. He knew this because he was reviewing cases for some lawyers at $700 per new patient evaluation. This attitude was not unique to this doctor. Dr. Robert Levy was a

hematologist in Houston who set up a foundation called Breast Implant Research, Inc. working with women with implants who were considering litigation. According to him the disorder would not be identified by the usual diagnostic tests because it was a combination of components of CTDZ and MS. According to a New York Times article (Sept 18,1995:"Implant Lawsuits create a medical rush to cash in") 93% of the implant recipients he saw were diagnosed as ill. Over 90% were referred to him by lawyers. Levy's income in 1994 was $2million. Were these doctors true believers or true opportunists?

A more recent example of a flawed mix of science, law , and media is the Jessica Santillan case. Do you remember who she was? This 17 year old girl was awaiting a heart-lung transplant. Her mother brought her to this country from Mexico and Duke was enjoying great publicity for taking her expensive care as a charity case. Local groups championed fund raising. She was desperately ill and there was great excitement when the New England Organ Bank in Massachusetts offered the available organs in February 2003. However, the most basic matching of ABO group compatibility was not confirmed and she received organs that were incompatible with her system and severe rejection occurred. This rejection involved the development of diffuse deposits of fibrin coagulation products of antigen-antibody reaction throughout the body. Not only were the transplanted organs rejected but severe damage to the brain and kidneys of an irreversible nature most likely occurred. The media nationwide and worldwide covered the story. The man who championed much of the public support was outraged and pursuing legal recourse. Because of this, somehow, another set of organs became available and I believe science was ignored in the face of litigation and hype of media coverage. In truth there is no way the patient could survive after the first rejection event involving ABO incompatability and the organs used could have gone to one or two recipients in need with a better chance of success. Three patients possibly died instead of one.

More recently we have seen estrogen therapy and arthritis medicines come under attack. The Women's Health Initiative showed that although estrogen therapy combined with progesterone did help prevent osteoporosis, menopausal symptoms of hot flashes, and decreased the incidence of colon cancer there was an increased relative risk for heart attack and stroke in women on the medicine combination. Absolute risk figures revealed 3 out of 10,000 women who were not on the med had stroke or heart attack while 8 out of 10,000 estrogen-progesterone users had stroke or heart attack. Relative risk is 8 divided by 3 or 2.67. This is statistically significant and relative risk is considered one of the strongest bits of statistical evidence. But a strange thing happened over the next 4 to 6 months. Universally, women stopped their estrogen therapy and four to six months later a tremendous number chose to accept the risk and go back on estrogen-progesterone combinations. Rheumatologists saw a flare of polyarthritis along with hot flashes. Basically, many patients said "I will minimize my risk factors by taking a baby ASA a day, better diet, and medical attention to any other risk factors such as hypertension or hypercholesterolemia and take the chance that I will not be among that additional 5 out of 10,000 to have a stroke or heart attack", because 7000 out of 10,000 felt much worse. They felt the chance of benefit (probably greater than 9500 out of 10,000) outweighed the risk of heart attack or stroke (5 out of 10,000). Unlike the situation with Vioxx, estrogens were not taken off the market and our female patients could make a choice.

Is there anyone here who has not taken an NSAID? A NonSteroidal AntiInflammatory Drug. The oldest is aspirin. They are ubiquitous in their use. A problem for over 50 years has been gastrointestinal side effects from the meds. Heartburn and dyspepsia were common but of greater concern was over 16,000 deaths each year from gastrointestinal hemorrhage complications. This was a great and well realized benefit of the class of Cox 2 selective inhibitor drugs like Vioxx, Celebrex, and Bextra. Their strongest benefit of less gastric irritation was combined with a lack of inhibition of platelet function making them medicines which could provide pain relief and antiinflammatory effects up to and through surgery with less bleeding tendency. If you had a patient with risk factors for cardiovascular or cerebrovascular disease, this could be handled with a baby ASA a day and still have less GI irritation. Why are there so many NSAIDs? Because one does not work for everyone. We need choices. One man's wine is another man's poison. Within two to three days many patients called wanting to stay on Vioxx and accept the increased risk for heart attack or stroke. Many had previously failed on Celebrex, Bextra, or the older traditional NSAIDs. However, unlike the estrogen story they do not have this choice. Soon after Vioxx was pulled from the market I had a mini med school reunion with two classmates who are superb cardiologists. I asked them if there was something in their literature that we were missing in rheumatology. I thought that a baby ASA per day took care of any increased risk from Vioxx. They concurred. These medicines were being investigated for potential roles in the prevention of GI cancer, skin cancer, and Alzheimer's . We have a tendency to measure medication safety in terms of heart attack and stroke risk. Any increased risk supersedes potential benefit. Will we be as well off 10 or 15 years down the road when drug companies cannot take the risk of developing potentially helpful meds? In an interview with Dianne Sawyer the director of the FDA Lester Crawford tried to explain the concept of risk and benefit—implicit in any disease intervention whether with medications or surgery. When he mentioned that patients might take Celebrex or Bextra in place of Vioxx she jumped all over him about these being the same class of drug. Indeed such fear has been promulgated in the general public that none of us in rheumatology would be surprised to see Celebrex pulled from the market. In an article Wednesday Janurary 5, 2005 in the News and Advance a study at the National Cancer Institute was halted with respect to increased risk for heart attack or stroke. This study found dramatic shrinkage of tumors in patients taking the drug at high doses often in conjunction with chemotherapy. For over 15 years doctors had noticed that arthritis patients taking cox-2 inhibitors had lower rates of certain cancers. Some patients might find the risk of heart attack or stroke acceptable for the potential benefit of cancer prevention or treatment improvement.

There was an editorial of reason by Mr. Thomas Sowell in The News and Advance Jan 2, 2005 entitled "Neither ideology nor lawsuits cure disease."He is a senior fellow at the Hoover Institution Stanford University. He writes: "Where do people not recognize trade-off? Where they are making decisions for other people. That's where they make unrealistic demands, including demands for safety. Maybe Vioxx or Celebrex is too dangerous, all things considered. Maybe not. The problem is that all things are not considered....The great majority of people taking even heavy doses of these drugs over an extended period of time did not have either a stroke or heart attack. However, the small number of people who did was greater than those who did not take these drugs. Obviously

people would not be taking these or other medications unless they had a problem that these drugs were intended to help. The question then is whether the benefits exceed the costs or vice-versa. This is a medical decision which can vary from patient to patient. As an aside 2 weeks after Vioxx was withdrawn and the TV physician pundits advised going back to the old traditional NSAIDs I had a patient referred by his good primary care country doctor on Indocin with exactly one half of his blood volume gone with a massive GI bleed. As we know the pundits quickly had to reverse their advice when one of their favorite traditional NSAIDs Aleve came under suspicion of increased heart and stroke incidence. Would you like me to scare you more? The popular press apparently has not picked up on a much more important study published in NEJM 2 years ago in which the investigators found that ibuprofen might block the cardiovascular and cerebrovascular protective effect of aspirin. That's a much more significant problem than eliminating Vioxx risk by taking a baby ASA.

Sowell concludes:"If a drug is not safe, neither is the illness for which the drug is prescribed. Nor are alternative drugs likely to be perfectly safe, since nothing else is. Life involves weighing alternative risks…Politically, it is always easy to be on the side of the angels (more angels!) with ringing pronouncements about making sure our medicines are safe. Ideologues are in their glory denouncing "corporate greed" among drug companies. But ideology never cured any disease. Neither do lawsuits. Maybe we need to cure ourselves of listening to rhetoric and ignoring realities." This reminds me years ago of attending a medical conference as we discussed evidence based medicine. We were warned to not be swayed by effusive presentations in which ideas were vehemence based rather than evidence based.

Perhaps this is the problem in our society today. As the only physician in our immediate family and relatives I have been impressed how true science can be much less convincing than a good anecdote. My late Aunt Ruth was a master story teller. When she decided to straighten me out on a medical matter the story usually started off with "I know what you doctors say, but my friend Myrtle.." By the time Ruthie finished the story you were inclined to think that maybe she was right and Jogging in a Jug was better for rheumatoid arthritis than Methotrexate! Anecdotal evidence is much more appealing and easier to understand than boring study numbers, statistics and P values. This is part of the appeal of alternative and complementary therapies. It satisfies our skepticism of pure science—"they don't know everything" and our attraction to magic, the natural, and at times the supernatural. Former Sphex member Dick Harbison when presiding over the ordination of Blane Hill mentioned that in our country there are greater numbers of people who claim to have been abducted by aliens than are members of the Presbyterian Church.

In a chapter in her book entitled "Americans and Health News: the Alarm of the Day" Dr. Angell points out that for the media in terms of health news, danger is a story; safety is not. The recent flu vaccine shortage demonstrates the media hysteria. Dianne Sawyer was interviewing the director of the CDC (Communicable Disease Center in Atlanta). This position is held by an absolutely top notch physician-scientist. Dianne tried to hype the situation as "a crisis." The Director Dr. Julie L. Gerberding tried to reassure the viewers and Dianne that they really did not define crisis in that way—i.e. a shortage of vaccine before any outbreak occurred. In her last word Dianne again stated that it was a

crisis—and the vaccine shortage was Bush's fault. Responsible reporting might have pointed out that 2 years ago the strains of flu that were guessed to prevail and serve as the basis for that year's vaccine were an incorrect guess and we probably had an ineffective vaccine; we survived. A crisis was the pandemic of 1918 when there was not only no vaccine but more importantly there were no antibiotics. The mortality then as now was from secondary bacterial infections in the form of pneumonia on top of the viral flu illness. Respirators and support for the critically ill was non existent. Now that was a crisis. I don't believe the media wants to see any of us die of natural causes—we are all to be scared to death and die of fear and anxiety.

My original presentation tonight was to be a look at the power of placebo. There is fascinating evidence that the mind can have incredible beneficial effects in response to illnesses and effectiveness of meds. I am afraid that it may also work in the reverse. As we produce a society scared to death by media hype I already see a shift in attitude of patients. Not uncommonly, after reviewing information on a medicine or obtaining information on the internet or the media, a patient will say they don't want to take, for example, the Methotrexate because they don't want any side effects. One patient asked me "Have you read all those side effects?" I usually respond by saying that I'm not giving them the medicine for the side effects. You can bet that there will be no beneficial placebo effect from the medicine and many patients miss the opportunity for benefit because of fear of unlikely side effects.

Well, it looks like Vioxx is heading down a common road. An add on TV by a lawyer soliciting clients stated to contact him if "You or anyone you know who used Vioxx had a heart attack, stroke, or died." Looking for an intersection of 3 common events—ingestion of Vioxx, heart attack, or stroke and one inevitable event—death.

One other more recent situation where process supersedes reality involves the drug Neurontin (gabapentin). This medicine was developed as an anticonvulsant medicine. As an anticonvulsant the medication is weak. However, over the past 4 or 5 years it has been found to be one of the most useful medications for the increasingly common problem of painful peripheral neuropathies. It is a major player in Pain Clinic therapies. It is reminiscent over 25 years ago when inderal was brought on the market as an antiarrythmic agent but was used for 8 to 10 years as a major antihypertensive medication before it was approved for that use. Therein is the rub. The reality is that Neurontin is a minimally useful anticonvulsant but a tremendously helpful treatment of painful peripheral neuropathy; but it is not approved for that use by the FDA or in the PDR. Last year Pfizer was fined over $400 million because their drug detailers were discussing the valuable, real pain relief use of Neurontin with physicians when it had not been officially approved for that use. The whistle blower in the company got $21 million. Last week Pfizer sent $35 million in drugs and funds for Tsunami relief efforts. The Charleston (WVa) Daily Mail reported Dow Chemical providing $5million dollars of relief for the tsunami victims. Greedy pharmaceutical and chemical companies indeed.

So where does Isis fit into this? Who is schooled in the classics with knowledge of mythology? Isis was one of the chief deities of ancient Egyptian religion who was a goddess of fertility. She is often represented with cow's horns and a sun disk as a crown. In this case, she is a typo. It is supposed to read "Is is". I believe a group like the Sphex

Club is an ideal collection of diverse backgrounds to consider the problems of scientific knowledge being superseded by process of law or media hysteria. Are we approaching the time when our general society ignores science and truth? Is perception more important than reality? Remember the statement from one of the O.J. Simpson jurors "Don't tell me about no DNA." ? The first president from my generation was the first during testimony regarding Monica to pose the unforgettable response to a question "It depends on what your definition of is is." More recently he impressed me on an interview with Katie Couric while promoting his autobiography when questioned about his famous statement "I did not have sex with that woman." His response was "What I should have said is I did nothing illegal". Well, that clarifies things. It reminds me of the Kobe Bryant case where probably consensual sex was nothing illegal; it was only adultery. I believe it was columnist George Will either commenting on Bill Clinton's impeachment hearings or Hillary Clinton's Travelgate involvement who stated to the effect that if you did not have the facts or truth, rely on the process or law. If facts and process fail you, attack your accuser—in their case the Right Wing Conspiracy.

Is this a new problem? An MIT professor William Sedgewick writes:

"The century just closed has witnessed a remarkable liberation of natural science and education from dogma. Geology was first set free by Lyell and his school, and then biology, by the discoveries of fossil man, and the splendid inductions of Darwin. Slowly but surely the teaching of natural science, which, like all teaching, follows closely in the footsteps of discovery, has also cast off its chains and freed itself from the subjection of theology. But as the church has declined in temporal power the state has become supreme, and with the recognition of its power has come the belief in its sufficiency—even its sufficiency to remedy all ills, real or imaginary—and scarcely had science and education freed themselves from the bonds of the church before they began to be threatened with subjection by the state...

With propagandists besieging more or less successfully our halls of legislation, the time has come when bodies like the American Society of Naturalists and the American Association for the Advancement of Science should have standing committees on legislation to take care, as far as possible, that unwise, extravagant or fanatical ideas regarding science and education shall not be given the force of law by the several States or by the Federal Congress.

If today we have little to fear from dogma or theology we may still have much to dread from foolish or needless legislation; and I desire to urge upon all those to whom these words may come, the duty, alike of individual watchfulness and of united effort, to resist everywhere and always the statutory subjection of science and education to propaganda."

This is an abstract from the President's Address delivered before the American Society of Naturalists—Jan 1, 1902.

Today I see us overwhelmed by the Information Age. Patients come in daily with internet printouts. Sometimes the exponential increase in information reminds me of a nightclub on fire with one exit—eventually there is so much pressure on the exit that nothing gets out to make the transition from information to knowledge and then to wisdom. An example: We obtain all the information in the form of basic science regarding the atom. We now have the knowledge to make more efficient forms of nuclear energy or world threatening nuclear armaments. Will we arrive at the Wisdom to make the correct

use of this knowledge? What can we do to increase the likelihood that we will achieve wisdom for the future of our world? I suggest that we will need a balance of process, perception, and fact but we cannot afford to disregard or distort or booby trap our basic scientific information and knowledge. Dare I say we need to be fair and balanced?