

Rocking the Boat

Information, personal musings, thoughts, gripes, and just plain old cage rattling from the mind-keyboard interfaced world of Dr. Anthony G. Payne

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ALS EDITION

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Welcome to the first edition of my personal mix of “sharing, caring and bearing”

BEATING BACK THE DEVIL

If you don't believe in a personal Devil AKA Satan, let me introduce you to his Earthly incarnation: ALS (Amyotrophic Lateral Sclerosis). I truly believe that if I could travel back in time to 1942 and challenge the attendees of the infamous [Wansee conference](#) in Berlin (where the Holocaust was mapped out) to come up with a single supremely insidious way to inflict unremitting mental torment on people— they wouldn't come up with anything as monstrous as ALS. Think about it: A disease that whittles away your motor functions until you wind up a puddle of unmoving flesh in a bed or wheelchair – fully conscious – kept alive by a respirator -- lying there day-after-day waiting for your lungs and heart to fail.

The first physician to describe the shriveled motor neurons that characterize ALS was an Englishman named Augustus Waller – in 1850. The first formal description of ALS to appear in the medical literature was made by a French doctor named Jean-Martin Charcot during 1869. Eventually scientists figured out that there are 2 forms of ALS: One appears to arise in people who churn out a defective version of an enzyme called copper/zinc superoxide dismutase (SOD1) whose job is to mop up cell damaging free radicals. This form of ALS afflicts 5-10% of those diagnosed with the disease. The other form of ALS is called “sporadic” which is believed to have many triggers and a multitude of molecular, physiologic and genetic players. One major contributor appears to be glutamate overload, in which this excitatory neurotransmitter builds up in motor neurons and induces die-off.

Despite intense research much remains a mystery about the origins and nature of ALS, and only a handful of drugs and other compounds have panned out in terms of impacting the disease. Mind you, the very best FDA approved drug available, glutamate release inhibiting Rilutek® extends the life of some ALS patients by 2-6 months.

Why so little progress? Is it the fault of ALS researchers? The FDA? The pharmaceutical industry?

The scientists doing ALS research are IMO adroitly using all the brains and technology at their disposal to identify ways to slow disease progression in both familial and sporadic forms. More than a few have ALS themselves or afflicted family members or friends and thus have no reason to drag their heels. The slow, gradual pace of progress has more to do with the insidious nature of ALS and the time-consuming nature of doing science itself than anything

else. I liken it to trying to contain a large blob of Jell-O with your hands. The harder you try to keep it from oozing between your fingers, the more it seems to do just that. You just can't get the (ahem) upper hand.

As for the FDA: This agency certainly does not have clean hands nor is always a model of efficiency or fairness when it comes to drug approval. Not so many years back officials there [refused to allow doctors who wanted to infuse ALS patients with cord blood from doing so without an IND](#) (New Investigational Drug permit). A few applied but were denied. As the risks were extraordinarily low and there was even some lab and human use indications of clinical benefit, the FDA's stance was puzzling to say the least. More recently there was some seeming foot dragging surrounding allowing ALS patients access to a drug called IPLEX, a combination of two substances: human insulin-like growth factor 1 (IGF-1) and human insulin-like growth factor-binding protein-3 (rhIGFBP-3); a drug which had shown some efficacy in a [handful of studies](#) conducted mostly in Europe. However, the FDA relented and [signaled a willingness to allow use by ALS patients under either a compassionate use IND or a clinical study conducted by the manufacturer, Insmed](#).

In light of the FDA's action with respect to IPLEX (and many other drugs), it can hardly be said the agency is heartless, unconcerned about the plight of terminally ill people or unable or unwilling to allow dying people access to unapproved drugs (So long as these will not do more harm than good or shorten their lives). But, yes, bureaucracy and more have likely worked to impede progress and even turned it on its head at times. Some critics, in fact, feel the agency is in need of a major overhaul that will better serve the interests of both safety and speedy progress (especially with respect to terminal illnesses).

This brings us to the pharmaceutical industry or "Big Pharma". While it is fashionable in some circles to portray the drug industry as engaged in some kind of carefully orchestrated conspiracy to place profits above human welfare, even to the point of using its resources to suppress or slow approval of viable non-pharmaceutical (especially biologic) treatments that might affect the sale of a particular drug or class of drugs, this overlooks abundant evidence to the contrary. Indeed, it reveals more about information filtering and the biases of "true believers" (in conspiracies) than virtually anything else.

This is not to say the drug industry hasn't had its share of impropriety, illegal activities, scandals and such. Where there is a great deal of money and influence at stake, human foibles and moral weakness will find a way to express itself unless restrained and constrained. So, yes, drug companies are occasionally caught putting their own interests above that of the public their products are supposed to help. But – and this is the big but – there is no credible evidence this is part of some kind of grand conspiracy to ace out all would-be competition by suppressing cures or treatments they do not control or otherwise profit from.

This brings me full circle: So what is the bottom line? Why such a seeming slow rate of progress when it comes to ALS? The scientists are working hard but are undermined by the incredibly insidious nature of ALS itself. Their progress comes by hard won inches not miles. As for the FDA, it has enacted and adheres to a body of regulations, procedures and enforcement policies that place an emphasis on safety and efficacy, but which at times has been anti-progressive insofar as it has moved too slowly when it came to giving dying ALS patients access to experimental drugs and therapies (Some would argue this applies to many, many other health conditions and issues as well, but as ALS is my focus in this article I will forego delving into this). Reform has taken place, but likely more is needed. Some medical advocates argue urgently so. And finally, there is the pharmaceutical industry: No conspiracy, no suppression of a cure for ALS or such (More than a few pharmaceutical company CEOs,

directors, staff and scientists have their lives touched by ALS in some way, shape or form, after all) or articulated policy to place profits above the interests of the public they serve. But yes, they are engaged in a highly competitive business enterprise that sometimes tempts them to cut corners or engage in activities that actually do prove an impediment to genuine progress.

In the final analysis, what many are tempted to label some kind of vast conspiracy or premeditated unholy marriage (especially twixt the FDA and the pharmaceutical industry), is merely an emergent system; a confluence of interacting influences, players, regulations and so much that has almost taken on a self-perpetuating and self-sustaining life of its own.

Of course, for those visited by ALS, that wily devil, knowing why progress is sometimes so hobbled is of little consolation. Yes, the system is faulty and beset with bottlenecks and counter-progressive mechanisms, but waiting for needed reform and repair to not only come to pass but result in speedier access to such highly experimental therapies as genetically engineered stem cells, e.g., cells that churn out growth factors that preserve motor neurons, is simply not an option for the vast majority of ALS patients alive today (And for many other folks with terminal or intractable conditions as well). Most will likely be cold in their graves before substantial “course correction” and “systems redesign” makes its way from debate to action to new treatment options.

Rather than wait for a clinical trial that may never come, many are opting to head to research and treatment centers outside the US for experimental therapies of various kinds. The vast majority involve some form of stem or progenitor cell intervention – some autologous (cells from self) – some allogenic (Donor cells such as cord blood stem cells, fetal cells) – some both. There are risks involved, yes; though these appear “few and far between” (Tens of thousands of cord stem cell, fetal cell and other adult stem cell treatments are done annually across the world with reports of adverse side effects or worse being exceedingly rare).

And sick people on a quest for a “medical reprieve” aren’t all that’s leaving America. Many American scientists now live and work in places like Singapore, where scientific advances move much faster from the lab to the hospital or clinic. In addition, some highly innovative stem cell technologies and lab methods which can only be used to create cells for use in lab animals stateside are being licensed or otherwise transferred to facilities abroad for use in producing cells for use in human patients.

There is no doubt but that many folks find fault with foreign stem cell treatment offerings in particular and spend their time railing against it, while others exploit human desperation or exasperation by setting up shop on far flung shores and “sell hope” in the form of worthless cell-based treatments and others of dubious merit. The problem is, there are clinics and hospitals that offer experimental adult stem cell therapies that are predicated on findings gleaned from lab and even human studies which are dismissed out-of-hand by critics and skeptics or, worse yet just willy-nilly lumped in with facilities that base their treatments on what appears to be sheer guesswork or nonsensical, even pseudoscientific notions. Rather than toss the baby out with the dirty diaper as many critics do, I would prefer instead to see people armed with the intellectual tools to critically examine clinics, their staffs and claims, and then leave them to reason things out for themselves. And no, it doesn’t take training in the sciences to pull this off. This article of mine is but one example of helping people critically think about the issues surrounding having an adult stem cell treatment outside the US: [For Those Who Are Considering Having Stem Cell Therapy Abroad](#)* The article includes links to all kinds of websites devoted to equipping people to think critically.

Ideally, people with ALS and other terminal or intractable diseases or conditions could count on having access to the means to beat back the devil right here at home, even those deemed

highly experimental. This isn't always the case, of course. So until it is, many will have no recourse but to opt to circle their wagons in foreign lands and do battle using weaponry only available there.

*I would be remiss if I did not point out that I am (1) no expert on biology, stem cell biology or such and (2) am involved (as a theorist & senior science writer) with the firm (Weller) that manages the US-based lab that developed the truly groundbreaking (USPTO patent pending) technology and lab methods licensed to the Nepsis Institute-Ramirez program in Mexico; and (3) also serve Nepsis as one of two staff patient educator & liaison persons.

CIRCLING THE WAGONS: FRED JENKINS



Fred Jenkins had it all: He married his high school sweetheart, served a stint in the US Army and went on to use his skills and expertise in the plumbing trade to create a thriving plumbing business. A son followed in his footsteps and entered the plumbing biz and he and his wife, Dawn found themselves looking forward to growing old in the company of their children and grandchildren. Then, almost as though some malevolent force had become incensed by his blessings, one of the most insidious, unmerciful physical curses imaginable was visited upon Mr. Jenkins: He was diagnosed with sporadic Amyotrophic Lateral Sclerosis (ALS) and told by the doctors to get his affairs in order.

Plumbers, of course, are used to tackling tough technical problems and finding or jury-rigging solutions. And though medicine and its tools are far removed from the world Jenkins was accustomed to, he rolled up his sleeves and began learning everything he could about his condition and the treatment options available (including clinical trials he might qualify for). Thankfully, he received liberal guidance from his neurologist, [Thomas C. Merell, MD](#), who made time to peruse whatever literature Jenkins brought him concerning nonstandard treatments and offer an informed opinion.

One of the things Mr. Jenkins brought to Dr. Merell was a body of material on the Nepsis Institute-Ramirez Clinic Stem Cell Program. He also discussed the positive responses reported by ALS patient [Jerry Porter](#) who had undergone treatment with enhanced autologous bone marrow derived stem & precursor cells produced and administered at the Nepsis-Ramirez clinic (February 2009). After reviewing everything, Dr. Merell told Jenkins that the information and science outlined looked credible and sound.

Following his meeting with Dr. Merell, Jenkins had several detailed phone discussions with "yours truly" and then booked an appointment to be treated in Mexico on April 29th.

Mr. Jenkins scheduled treatment went off without a hitch. He was, in fact, feeling so full of vim and vigor by the next morning that he and his family decided to take off and visit various scenic sites throughout southern California. A few days later he and his companions flew back to his home on the southern tip of Florida and settled in to see what, if anything might follow in the wake of his treatment.

On May 8th Jenkins called me up to share the results of an office visit to his neurologist. In-a-word, Dr. Merell was literally flabbergasted by the progress Mr. Jenkins had made in just a few week's time. Indeed, he fell back in his chair and exclaimed that he hadn't seen him "look this well in over a year" and was stunned by the fact Jenkins was showing "muscle movements I haven't seen in over nine months".

Mr. Jenkins added that he was now able to adjust himself in his wheelchair, something he

hasn't been able to do for quite some time.

In addition, Jenkins mentioned having been visited by a female VA nurse who measured his oxygen saturation level. Prior to his treatment in Mexico his O2 sat level averaged 92%. According to her test, his oxygen saturation level was holding steady at 98%.

On May 13th, Mr. Jenkins spoke to me by phone in a voice brimming over with excitement. "Why are so excited?" I asked. He blurted out that he was now able to hold himself up in a whirlpool bath for up to one minute at a time (Something impossible before his stem cell procedure). In addition, Jenkins noted that prior to his treatment he was racked by pain so intense that he had to take between 90-180 mg of time release morphine on a daily basis. He was now free of pain and as a result no longer needed to use morphine or any painkiller.

Click [here](#) to read a letter from Dr. Morell concerning his assessment of Mr. Jenkins progress (May 8th).

WILL THE EFFECTS LAST?

One of the cyber-forums I participate on is Stem Cell Pioneers – www.stemcellpioneers.com Recently a member posted this concerning what he'd read about the powerful responses of ALS patients treated at the Nepsis-Ramirez clinic (Mexico):

"Anyone got any more information on the Nepsis service efficacy?? These articles sound promising, but other SC treatments have shown benefit for ALS over the first month or so and then revert back to old symptoms"

My response follows below:

While it is true that stem cell benefits fade in many instances, one must qualify this:

In the case of cord stem cells, there is evidence the cells are cleared by the immune system over time and with this there is a corresponding loss of clinical benefit patients with certain diseases or conditions -- especially progressive ones (IMO a great deal of the clinical benefits seen in patients who have had umbilical cord stem are due to growth factor expression). The Nepsis-Ramirez is not using cord blood stem cells in ALS patients, BTW, but I nonetheless wanted to pass this bit of information/insight along to illustrate why "fade out" occurs in (ALS) patients so treated by other stem cell facilities.

With bone marrow derived stem cells, there is no rejection/subsequent immune clearance so the cells tend to stick around and exert a more lasting physiological influence. However, the paracrine signaling and other biochemical influences that appear to remediate certain diseases like ALS can only go so far -- especially in the face of a disease or condition that is progressive and by that very token is hard at work undoing the restorative activities of the engrafted bone marrow cells. I am, however, inclined to believe that Nepsis-Ramirez patients will see clinical benefits that outlast other autologous BM-derived stem cell approaches for these reasons:

(1) Massive numbers of bone marrow derived stem and precursor cells are employed (Far beyond what I have seen utilized by other clinics or hospitals). There are more Cavalrymen on the ramparts of the fort to battle the enemy, in short.

(2) A substantial %age of the cells infused are pluripotent and thus have greater biologic plasticity and clinical benefits potential than treatments involving use of just multipotent stem and/or precursor cells (Multipotent cells have lesser plasticity *in vitro* and *in vivo* than pluripotent cells).

(3) The bone marrow derived stem and precursor cells used by Nepsis-Ramirez physicians in Mexico are biologically primed to seek out the target organ or tissue (Without this the cells wander about and can land in tissues and organs other than the desired one). Think of the stem or precursor cell as a letter -- Nepsis scientists add a "zip code" that matches the intended "recipient" (Target tissue or organ).

And

(4) The bone marrow derived stem and precursor cells utilized are prepped (to put it simply) to become the type or types of cells that will support and have a restorative influence on the target tissue or organ.

Again, I tend to believe that the autologous primed/targeted bone marrow derived stem and precursor cell mix being employed by Nepsis-Ramirez in patients with ALS and other progressive disease and conditions will resist the onslaught of the disease process far longer than what is being used by other stem cell medicine facilities throughout the world. This is not certain -- this being highly experimental science -- but is suggested by the results seen in animal models.

HIGH STANDARDS

The American Stem Cell Therapy Association “is a physician run organization dedicated to establishing best practice lab and clinical guidelines for adult stem cell use.” After carefully reviewing the [articulated standards](#) set forth by ASCTA for clinical practices, Nepsis-Ramirez Clinic Medical Director Fernando Ramirez, MD and his board of directors issued this statement:

INBICTO-ORTHOLAB (Tijuana, Mexico) AKA 'The Fernando Ramirez, MD Clinic' is in full compliance with the practice standards set forth by the American Stem Cell Therapy Association.

Attested and sworn to by:

Fernando Ramirez del Rio, MD, Medical Director, INBICTO-ORTHOLAB

Juan Jose Ramirez del Rio, Attorney at Law, Secretary for INBICTO-ORTHOLAB

Francisco Javier Ramirez del Rio, Attorney at Law, Treasurer for INBICTO-ORTHOLAB

Susana M Ramirez de Berdeja, Business Administrator for INBICTO-ORTHOLAB

ALS WEB-SOURCES

[Stem Cell Pioneers website "Ask The PhD" - May 2009](#) – Check out Question 10 (Diet for ALS)

[Experimental regimen targeting the ependyma slows disease progression in four patients with amyotrophic lateral sclerosis.](#)

[ALS - Chief Eng. Jerry Porter's Website](#)

WANT MORE INFORMATION ON THE NEPSIS PROGRAM?

Nepsis Institute-Mexico USA Phone #: 1-949-498-8074 (9 AM – 6 PM Pacific Time, M-F)

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