IN PURSUIT OF PRO-LIFE MEDICINES

SOUND CHOICE PHARMACEUTICAL INSTITUTE

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Christmas 2009 Newsletter

Editorial Contents:

1) **You can remain loyal to your faith and morals without ignoring the advances of modern science.**
2) **Human fetal DNA injected into a child's arm or leg could travel into that child's brain. Scientists call this retrograde axonal transport, and first studied this process using giant squid nerve axons. Is retrograde axonal transport from the nerve endings in a child's arm or leg the route used to deliver contaminating human DNA found in some of our childhood vaccines to the brains of children who subsequently develop autism?**

Introduction:

Do you feel foolish, ignorant, even regressive, when you are accused of rejecting modern science and the medical miracles it promises because you refuse to abandon your pro-life morals? Medical advances, true medical advances, should be safe, effective and affordable. Embryonic or fetal stem cells and vaccines do not meet these criteria. While lay people cannot possibly be expected to keep up with the latest data, the confusing vocabulary or the politics of these issues, they can stand by their pro-life morals with confidence and pride. The data – *the science* – demonstrates, particularly for the stem cell and the vaccine fields, that pro-life choices are the only choices leading to true medical advances. If you find yourself at a loss for 'data' in a stem cell or vaccine discussion, stand by your pro-life morals, and send the scientific questions to us. It is only the pro-life stem cells and vaccines that provide safe and effective healthcare to the world.

Dr. Theresa Deisher, President, Sound Choice Pharmaceutical Institute

Please remember Sound Choice Pharmaceutical Institute in your year end giving plans.

On 09 March 2009, President Obama signed an executive order related to stem cell research and promised to base 'public policies on the soundest science'. Let's take a look at the published science and see what the science really says. It does not support pursuit of embryonic stem cells.

Embryonic stem cells are not 'new' discoveries. Most people do not know this, but scientists have been working with embryonic stem cells since 1980, when mouse embryonic stem cells were first derived. Safety concerns that prevent human embryonic stem cells from advancing in to the clinic have been observed and 'researched' in mouse embryonic stem cells for close to three decades, without successful resolution of tumor formation or immune rejection issues. With the January 2009 FDA approval to start the first human clinical trial using an embryonic stem cell product, some were hopeful that these safety issues might have been resolved. However, in August 2009, a mere nine months after first giving approval, the FDA indefinitely delayed this embryonic stem cell trial because of safety issues that belatedly became apparent from previous animal tests. Thankfully, no one had yet been given the embryonic stem cell therapy.

While the tumor forming properties of embryonic stem cells are presented to the public as 'benign' tumors which might be avoided by some laboratory cell culture techniques, *science* has demonstrated that embryonic stem cells are by nature 'neoplastic' (Nature Biotechnology 2009 vol 27 page 91), which means cancer forming, once they have been removed from their normal environment. This should not be surprising, really, since we have accumulated significant clinical evidence that cancer stem cells, particularly for aggressive cancers, express the unique and special genes that embryonic stem cells express (Nature Genetics 2008 vol 40 page 499).

The allure of embryonic stem cells lies in their ability to differentiate into any and all of the potential cells of the human body. People, educated scientists and physicians among them, have rushed forward with claims of imminent cures for almost every human disease imaginable, a promise almost too good to believe, and like everything else in life, if it looks too good to be true it probably isn't. The NIH released draft guidelines for embryonic stem cell research in May 2009, in which they stated that embryonic stem cells might treat Parkinson's Disease, ALS, (Lou Gehrig's disease), diabetes and arthritis. How often do we also hear promises of a cure for Alzheimer's as well? I took the opportunity to point out to the NIH that the diseases they had highlighted are complex, polygenic diseases that are driven by an auto-immune attack. One cannot treat these diseases with an embryonic stem cell and promise a cure – the auto-immune attack will destroy the stem cells as well. In response to my comments and probably to similar comments from other objective people, the NIH toned down their promises in the final guidelines and state only that embryonic stem cell research has the potential to improve our understanding of human health and illness (http://stemcells.nih.gov/policy/2009guidelines.htm).

What will this cost? Here we have cells with intrinsic neoplastic properties (cancer formation), that cannot treat the diseases that are so outrageously hyped

to the public, being funded by federal tax dollars and yet no one seems willing to talk about the price tag.

When they don't tell you how much something will cost, that is usually because you cannot afford it. In their excitement over finally receiving FDA approval for their clinical trial, which as I mentioned earlier has been put on clinical hold due to safety concerns that became evident after the approval, Geron told the general public how expensive their embryonic treatment would be, "not … $500,000.00" (http://neurologist.wordpress.com/2009/01/25/fda-allows-first-stem-cell-test-for-spinal-injury/). If this embryonic stem cell therapy won't be $500,000.00 then what will it be, $490,000.00? That seems like a lot to pay for a neoplastic stem cell. Morally derived embryonic-like stem cells, such as the reprogrammed adult cells we have been hearing about, likewise have neoplastic properties and we don't need Bob Barker to tell us that the price won't be right.

I don't want to write a Christmas newsletter without knowing that I have spread some joy amidst all the embryonic stem cell gloom, so let's talk briefly about 'self' adult bone marrow stem cells. Each one of you has stem cells within your body, as a matter-of-fact, within every organ of your body. Stem cells taken from a patient's own bone marrow have been used to treat heart attack, stroke, paralysis, diabetes, lupus and multiple sclerosis. The price tag, you might ask? On average $25,000.00.

For those of you who follow the stem cell debates closely, you may think I have made a mistake in listing diabetes, lupus and multiple sclerosis as diseases that have been treated with 'self' adult stem cells. Those are auto-immune diseases, and as I pointed out when discussing the false promises made for embryonic stem cell research, auto-immune diseases are not amenable to stem cell therapy per se. So, how can adult stem cells possibly treat or cure these diseases? What has been done recently has been to use non-myeloablative 'mini' chemotherapy to kill off the auto-immune attacking cells. Before the patient is given 'mini' chemotherapy , stem cells from their blood or bone marrow are taken and then used to help the patient recover rapidly from the chemotherapy. For auto-immune diseases, the chemotherapy treats the disease and the adult stem cells treat the damage from the chemotherapy. Embryonic stem cells cannot be used in this same way.

I know where I would like to see my tax dollars invested : public money should be dedicated to advancing affordable, effective and safe stem cell therapies, particularly those using 'self' adult bone marrow. In fact, these therapies *require* public money because they are not the types of treatments that commercial companies will pursue. Ask your elected representatives for a Christmas present. Ask them to demand that public monies be used to advance stem cell therapies we can all afford.

Autism is a polygenic disease requiring an additional environmental trigger. In our June 2009 newsletter we asked whether the presence of aborted human fetal DNA, introduced into our childhood vaccines in 1979, could be an environmental trigger for autism.

A polygenic disease requiring an environmental trigger is a disease for which multiple underlying gene mutations have been implicated, yet none of the mutated genes or gene combinations are sufficient to predict who will actually get the disease. These types of studies are done by looking at disease prevalence in monozygotic twins, who share the same genes and gene mutations. For autism and autism spectrum disorder, over 230 genes have been implicated as predisposing to the disease. Most polygenic diseases, such as type I diabetes and multiple sclerosis, have only a handful of gene mutations associated with predisposition to develop the disease. In comparison to those polygenic diseases, it actually becomes a stretch to hypothesize that autism disorder, with over 230 associated gene mutations, is a polygenic disease in the classical sense.

How might such diverse genetic predispositions all lead to the same general disease phenotype of autism spectrum disorder? Prior to 1979, autism prevalence was between 1 in 10,000 and 1 in 2,500 and was most likely caused by single gene mutations in X chromosome genes such as AFF (Fragile X Syndrome), MecP2 (Rett Syndrome), and an Xq28 translocation/exchange with chromosome 15 (Angelman's Syndrome). In 2009, as many as 1 in every 150 children has been diagnosed with an autism spectrum disorder, and as I mentioned in the last paragraph, over 230 genes have been associated with the disease.

In our June newsletter I introduced you briefly to the concept of 'hotspots', which are regions of the genome particularly susceptible to DNA insertion. Of the 230 published autism associated genes, 15 are located on the X chromosome, and 5 of those contain large numbers of hotspots in the transcribed region of the gene. What this means is that insertion of contaminating human DNA at one of these hotspots is likely to lead to gene disruption and abnormal protein product formation. The 5 X chromosome located autism associated genes that contain 'hotspots' are genes that are 1) critical for neural synapse formation, 2) involved in mental retardation or 3) related to gut metabolism.

The amount of contaminating aborted human fetal DNA in vaccines is actually quite high, and in some childhood vaccines greatly exceeds the limits recommended by the FDA. How could this contaminating DNA reach the neurons in the brain of a young child? DNA injected into a muscle can be picked up by receptors on the nerve ending. Once DNA has been taken up in to the nerve endings, it can be transported back up the nerve's axon to the brain.

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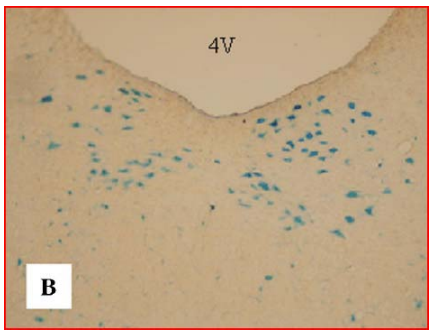
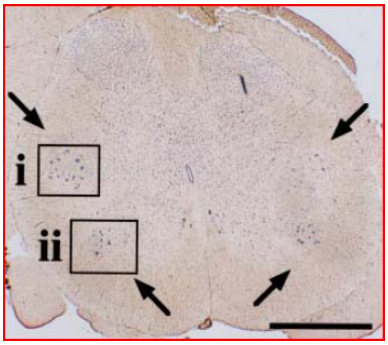
We know from studies in the giant squid axon that retrograde transport can occur at speeds between 2 millimeters and 1.0 meters per day. Let's translate that to measures we are all familiar with. An average 18 month old boy is .82 meters in length (about 2 feet 8 inches) (from CDC growth charts). Let's take1/3 of that length to be the distance from a nerve terminal in the child's arm muscle to the nerve body located in the brain and 2/3 of that length for the distance from the leg. This means that contaminating fetal DNA in a vaccine jab to the arm could take anywhere from 1 to 30 days to get to the critical thalamic relay station in the brain and anywhere from 3 to 60 days from a vaccine jab to the leg.

Indeed, retrograde axonal transport is being leveraged by scientists to deliver therapies for diseases such as ALS and Alzheimer's into the brain. The picture below is reprinted with permission from Nature Publishing Group and Macmillan Publishers Ltd., Molecular Therapy, 2001, vol 3 (http://www.nature.com/mt/index.html). The picture shows hypoglossal nerve bodies in the brain stem that are blue 2 days after injecting the DNA responsible for this blue color into the tongue muscle. DNA that codes for a protein called lacZ was injected into a rat's tongue near the hypoglossal nerve terminals, or endings, are known to be. The DNA was picked up by the nerves, transported back up the axon into the nerve cell bodies and then into the nucleus located in the brain stem, where it made the protein that turns blue when β-galactosidase is added.



Here is a picture of another study where they injected the lacZ DNA into the calf muscle of a rat and 15 days later they saw that the gene had been transported into nerve bodies in the spinal cord. The arrows in the picture point to the blue staining from β-galactosidase. The lacZ DNA was evident in the spinal cord for up to 132 days, which is the latest time point they examined.



Reprinted with permission from Nature Publishing Group and Macmillan Publishers Ltd., Gene Therapy, 2000, vol 7 (http://www.nature.com/gt/journal/v7/n11/pdf/3301185a.pdf).

You might ask why no one has looked to see where the contaminating human DNA found in several of our childhood vaccines ends up? Sound Choice Pharmaceutical Institute is doing these types of studies now. Scientific research takes time, particularly as we perform our work with all necessary controls and diligence. We'll update you as we generate more answers to some of these important questions: how much aborted human DNA is in the vaccines? is the DNA the right size for genomic insertion? how readily does the contaminating DNA actually insert into the human genome? and other critical safety questions.

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