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March 2011 Newsletter

Editorial Contents:

1) What do embryonic stem cell proponents have against patients?

For the past fifteen years embryonic stem cell proponents have dismissed, minimized, and hostilely attacked adult stem cell advances. They did this so that the American public would accept the lie that there was no alternative to embryo destruction. The result of these attacks? Americans have been robbed of life saving adult stem cell treatments.

2) How can we keep the CDC 'honest' as they finally do some studies about vaccine-autism connections?

The CDC recently announced that they would finally do studies to investigate the suspected link between vaccines and autism. Will the CDC conduct appropriate, rigorous scientific studies or will they 'white-wash' the studies to support the pharmaceutical companies? How objective can the CDC be when the former head of the CDC now runs Merck's vaccine division?

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Dr. Theresa Deisher, President, Sound Choice Pharmaceutical Institute

Let's debunk some commonly repeated false criticisms of adult stem cell advances.

During the September 16, 2010 Senate hearings on embryonic stem cell research, skewed to selectively advance the embryonic stem cell agenda, the Director of the NIH stated that the NIH does not support adult stem cell research to the extent that they should because the treatments are not yet 'standard of care'. That has to be one of the most ridiculous statements I have heard in a long time! The laws of the United States require drugs and therapies to be tested in a series of clinical trials before they can be approved to treat patients. Adult stem cell therapies cannot become standard of care in the United States until the National Institute of Health (NIH) steps up to do their job and fund, promote and encourage adult stem cell clinical trials. Justifying the absence of NIH promotion of adult stem cell therapies because they are not yet standard of care should have every American shaking their head and asking why their tax dollars are not being used appropriately. Horses, dogs and donkeys can get safe, effective and affordable adult stem cell treatments in the US, but people cannot. This is outrageous!

What is the NIH funding and promoting? They are funding and promoting embryonic and other pluripotent stem cell research that leads only to cloning and to advances like creating ways for two males to have children (Deng *et. al.*, **Generation of viable male and female mice from two fathers.** Biol Reprod. 2011 Mar;84(3):613-8; work was funded by the NIH)

Just a few weeks ago I heard another embryonic stem cell proponent, on a live webinar, justify his dismissal of adult stem cell therapies by saying that the clinical trials were 'unethical' and even in violation of Nuremberg Codes. His implication is that adult stem cell scientists are on a par with the Nazis. What an outrageous and absurd statement!

Drugs and therapies must go through a series of clinical trials before they can be approved to treat patients. This series of clinical trials is divided into several phases; Ph I, Ph II, Ph III and Ph IV. The Ph I trials are generally the first time the drug or therapy has been given to humans, and are safety studies often done on normal volunteers. Embryonic stem cell proponents criticize the adult stem cell clinical trials that have been done in Europe because the Ph I studies were not 'double-blinded'. Double-blinded means that neither the volunteer nor the doctor knows what each volunteer is getting. Imagine what might happen if the doctor or nurse administering the drug in a Ph I study did not know what each volunteer was receiving? Ph I trials are safety studies of drugs that have never been given to humans before. If something went wrong they would not know what to do. If they did not know what each volunteer was getting in the Ph I study and something was not going right, they would have to call or email or otherwise contact the person who controlled the code. That might take awhile to get that information since codes for double-blinded studies are very tightly controlled. While they were waiting to find out if volunteer Joe had received placebo or study drug, volunteer Joe could be getting very sick or even dying. There have been Ph I trials where things went very wrong and thank God they were not double-blinded. So, if you ever hear anyone saying that adult stem cells have not been tested rigorously in Europe because the studies were not double-blinded, speak up and tell whoever said that what a ridiculous statement they have just made. Conducting double-blind Ph I clinical trials is completely unethical and not permitted!

Another criticism I have heard of the adult stem cell clinical trials done in Europe is that the Ph II studies were not placebo controlled.

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Ph II studies are done on small numbers of patients, once the drug or therapy has been shown to be safe in the Ph I volunteers, to determine how to administer the drug or therapy effectively. Ph II studies are generally double-blinded and placebo controlled. Embryonic stem cell proponents smear the adult stem cell Ph II clinical trials that have been done in Europe by claiming that they are not fully placebo controlled. Placebo controlled means that some patients in the trial go through everything that the patients who are going to get the treatment go through, except they do not get an 'active' drug or treatment. In the case of adult stem cell therapy for heart attack, what this would mean is that patients in the placebo control group would have bone marrow taken (a painful procedure) and then a catheter wound up through blood vessels in their groin into their heart (a procedure not without dangers) and then 'dead' stem cells would be injected into their heart instead of live adult stem cells. No ethics committee would approve such a clinical trial. It would be absolutely unethical for adult stem cell trials to be conducted in a fully placebo-controlled manner. The next time you hear someone smearing the reputations of European adult stem cell clinicians, tell them how ridiculous they are and that the adult stem cell Ph II trials were conducted in the most scientifically rigorous and ethical manner possible.

Adult stem cell therapies are now almost through Ph III clinical trials in Europe, which means that Europeans may get adult stem cell therapies as standard care soon. We Americans won't! Our Director of the NIH doesn't want to support these trials here because adult stem cells are not yet standard of care, he says. Embryonic stem cell proponents go to horrific lengths to keep Americans from hearing the truth about adult stem cells. Do these embryonic stem cell proponents not know or understand how drugs and therapies become standard of care? Do they not know or understand the regulations and phases of conducting clinical trials? One would think that the director of an institution like the NIH, which conducts thousands of clinical trials, would know these facts and not make such absurd statements. Why would our Director of the NIH make such ridiculous statements about adult stem cell clinical trials done in Europe? I have no idea. Either he doesn't know how clinical trials must be conducted in which case one wonders why he is the Director of the NIH, or he is so blinded and wedded to the cloning and other reprehensible goals of the embryonic stem cell camp that he will say anything to keep Americans from the truth about adult stem cells.

When Americans finally learn the truth that diseases can be treated and cured with adult stem cells that don't kill or exploit anyone the embryonic stem cell proponents will be put out of business. Of course they don't want us to know the truth.

Can the CDC conduct objective studies of the suspected link between vaccines and autism?

The CDC just announced, in 2011, that they will accept the June 2009 recommendations of the National Vaccine Advisory Committee (*www.hhs.gov/.../nvac/NVACRecommendationsISOScientificAgendaFinal.pdf*) and study the suspected link between vaccines and autism (*www.huffingtonpost.com/.../cdc-to-study-vaccines-and_b_837360.html*). It seems quite odd that we read about this in the Huffington Post while the major newspapers and media outlets are quiet on the topic. The CDC statement says that they will include biological agents in their study questions. Biological agents must include studies into the potential dangers of contaminating aborted fetal cell DNA injected into our children with several of the childhood vaccines, including MMR, chickenpox, hepatitis A and some polio vaccines. You can help us make sure that the aborted fetal cell DNA is studied by contacting the CDC (1-800-CDC-INFO; 1-800-232-4636; TTY 1-888-232-6348; cdcinfo@cdc.gov) or your elected officials and asking them to include this in the studies.

The amount of aborted fetal cell DNA is so high in the chickenpox vaccine, that Merck even did some additional studies (*www.fda.gov/downloads/BiologicsBloodVaccines/.../UCM142826.pdf*). Unfortunately, Merck did not do the scientifically appropriate safety studies. They studied the impact of the human aborted fetal cell DNA in mice. The human aborted fetal cell DNA poses a danger to humans, not mice, so, not surprisingly, Merck concluded the extremely high levels were not a danger. SCPI is the only organization currently doing the scientifically appropriate studies using human cells. We are certainly encouraged that the CDC has decided to conduct and support studies in this area, and hope that they will fund our work as part of the investigation to ensure that the studies are rigorously and objectively conducted and that the results and conclusions are valid.

In 2010, Victoria et. al., reported the presence of viral contaminants in several live attenuated vaccines (Viral nucleic acids in live-attenuated vaccines: detection of minority variants and an adventitious virus. J Virol. 2010 Jun;84(12):6033-40). They reported that Rotarix, a vaccine against rotavirus made by Glaxo-Smith-Kline, was contaminated with porcine circovirus-1 (PCV-1), a non-pathogenic pig virus that has not been shown to infect humans. The FDA recommended that physicians and public health officials in the US suspend the use of Rotarix (*http://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm205540.htm*). Merck makes a competing rotavirus vaccine called RotaTeq, which the FDA recommended instead of GSK's vaccine.

When not only PCV-1 but also PCV-2 was found in Merck's RotaTeq vaccine just a few months later, however, the FDA's response was quite different that their guidance in regards to GSK's Rotarix (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm211101.htm). Instead of recommending the suspension of RotaTeq, now that PCV-1 and PCV-2 had been found in Merck's vaccine, the FDA reassured the public about the safety of RotaTeq. Isn't that odd? When PCV-1, a virus without any known danger to humans or pigs, was found in GSK's vaccine, the FDA recommended we not use the vaccine. However, when PCV-2, a virus which is very dangerous to pigs, causing wasting disease, immune suppression and even death, is found in Merck's vaccine the FDA does not recommend suspension of RotaTeq. In fact, the FDA assures us of the safety of RotaTeq, without doing any safety studies on the dangers of this PCV-2 virus. A reasonable person might ask : what does Merck have that GSK does not?

Merck has the former head of the CDC, Julie Gerberding, now heading their international $5 billion annual global vaccine business. One would hope that public officials like Julie Gerberding could transition to the private commercial sector without inappropriately or illegally using their previous government positions to influence decisions about their new employer's products. There is no evidence that Julie Gerberding exerted inappropriate influence on the FDA's decision to suspend Rotarix, which gave her current employer Merck a dramatic commercial advantage, or on their decision not to suspend Merck's RotaTeq when both PVC-1 and PCV-2 were found to contaminate that vaccine. HOWEVER, the appearance of impropriety in this case is so disturbing, that regardless of whether any actions were taken or not, we are forced to question the impartiality and objectivity of the FDA and CDC.

Given this recent history, will we be confident in the results and conclusions if the CDC alone conducts studies into the link between vaccines and autism? The former head of the CDC now runs Merck's vaccine division, and a documented link between vaccines and autism will significantly impact Merck's bottom line. If the FDA and CDC cannot be impartial and objective about PCV viruses in Merck's vaccines, how can they possibly be impartial and objective about a link between multiple vaccines and autism. We want the CDC and FDA support for vaccine-autism studies, but most importantly, we want impartiality and results that the public can trust. You can help – contact the CDC and your elected officials and ask them to make sure that outside, unbiased organizations participate in all aspects of the vaccine-autism studies. Tell them to fund work that will be conducted independent of the CDC and FDA as well. This is too important to all of us to let a study potentially be a white-wash job in favor of the vaccine industry.

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