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Introduction:

One day after I wrote the first draft of this article, I received a link to The Daily Galaxy (http://www.dailygalaxy.com/my_weblog/2009/03/the-worlds-fi-1.html) and an article lauding the first genetically modified human embryo. Scientists at Cornell University had recently announced that they had genetically modified a human embryo to express what is called 'green fluorescent protein' (GFP) (<http://www.timesonline.co.uk/tol/news/uk/science/article3908516.ece>). There is nothing significant in having human embryos express GFP, it is only a marker so that the scientists can easily see that their genetic modification has worked. When expressed, this protein fluoresces bright green and can be readily observed by microscope, or even the human eye. The expression of GFP is a test of the technique. As quoted in the article, the lead scientist, Nikica Zaninovic, pointed out that in order for them to know that the genetic modification had stably inserted into the genome, they would need to 'grow' the embryo. That's not quite correct. In order to know that a genetic modification has stably inserted, one needs to 'breed' the resulting embryo. This is how we determine whether a gene has stably inserted into an animal, such as a mouse. Only by breeding can one determine whether the genetic modification is stable.

Human cloning and genetically modified and selected humans are no longer science fiction. How does embryonic stem cell research lead to this? Read on.....

Dr. Theresa Deisher, President, Sound Choice Pharmaceutical Institute

What Can Embryonic Stem Cells Provide that Reprogrammed Adult Cells Cannot? A Need for Embryos : A Means for Reproductive Cloning.

With the advent of pluripotent stem cells derived from adult skin cells or isolated from testicular biopsies, one would think that the hue and cry for embryonic stem cells would diminish. However, that isn't happening. Scientists, physicians and celebrities originally celebrated the isolation of human embryonic stem cells because of the pluripotent properties of these cells. A pluripotent stem cell is a cell that can develop into the cells and tissue of all three of the primary germ layers. In layman's terms this is a cell that can develop into any cell of the body under the appropriate conditions. Embryonic stem cell proponents argued that these pluripotent cells held the key to curing a plethora of grievous human diseases that they wrongly claimed adult stem cells could not. They argued that we had a moral imperative to use these cells to cure people. Without discussing the utility, or lack thereof, of pluripotent stem cells for treating humans, I ask you to consider this simple question : why the continued insistence on obtaining new embryonic stem cells when we now have pluripotent stem cells called reprogrammed cells (iPS) and pluripotent stem cells isolated from testicular biopsies (SSC)?

If it were merely the pluripotent properties of the embryonic stem cells that were desired, as was once claimed, then iPS and SSC are morally acceptable pluripotent equivalents. If we want pluripotent stem cells to cure grievous human disease, then don't we have a moral imperative to devote all of

our efforts and funding to moving iPS and SSC cells into clinical trials? Why the tentative embrace of these morally acceptable pluripotent stem cells? Why do we still claim that we need embryonic stem cells, and, furthermore, that we need fresh embryonic stem cells?

Scientists claim that they need embryonic stem cells as a reference for the properties of these other pluripotent stem cells. However, the test for pluripotency does not require embryonic stem cells at any step. The test for pluripotency, which is the quality control test used by companies that sell embryonic stem cells, requires a mouse, a needle, and a waiting period to see if cells injected into the mouse form teratomas (tumors containing cells from all three germ layers; see [http://www.millipore.com/publications.nsf/a73664f9f981a8c852569b9005b4ee2/217a48a54d06ca18525730600751611/\\$FILE/SCC021.PDF](http://www.millipore.com/publications.nsf/a73664f9f981a8c852569b9005b4ee2/217a48a54d06ca18525730600751611/$FILE/SCC021.PDF) page 2 and 3 product specification pdf for MEL-1 and MEL-2 human embryonic stem cell lines).

Embryonic stem cells are not required for this test.

Scientists then argue; well, we need embryonic stem cells as a comparator for these other cells as to how they behave in a petri dish. That's absurd. Embryonic stem cells become fetal type cells in the petri dish, not adult type cells. Ultimately we need adult cells to treat human disease. Scientists have already taught us that fetal cells don't work to treat human diseases, because they have used aborted fetal tissue to treat patients with Parkinson's and other neurological degenerative diseases with disastrous results. Many people read recently about the young Israeli boy who developed tumors after aborted fetal tissue treatment. We need to compare pluripotent

stem cells such as iPS or SSC cells to adult nerve cells, or adult heart cells, or adult insulin-producing cells, not to embryonic or aborted fetal stem cells.

Yet scientists insist that they need fresh embryonic stem cells. What can fresh embryonic stem cells provide that existing embryonic stem cells or reprogrammed cells (iPS) or spermatogonial stem cells (SSC) cannot? Access to human embryos, if nothing else. If we convince ourselves that we need fresh embryonic stem cells then we provide ourselves with access to fresh embryos.

Why might we want fresh embryos? We might, and I grant you subconsciously, want to reproductively clone after all. A very neat trick, to quote a writer for the journal *Science*, has been learned. Scientists take two embryos and fuse them together and get what is called a tetraploid embryo. This embryo can make the placenta but not the fetus. This has been done and published for embryonic stem cells and for reprogrammed adult stem cells from mice (*Cell* 2008 v133 page 250, *Molecular Reproduction and Development* 2005 v71 page 154). Unlike animals such as Dolly the sheep, produced using somatic cell nuclear transfer (SCNT), these tetraploid-produced mice have been 'normal' and are exact genetic copies of the pluripotent stem cell used to make them. I don't know that scientists will really want to take the skin cell from John Doe, reprogram it, inject it into a tetraploid embryo, and make a clone of John Doe, but the point is they could. All we need is access to embryos.

In summary, what can the need for fresh embryonic stem cells provide us that other pluripotent stem cells cannot? We don't really need fresh embryonic stem cells as comparators for the adult pluripotent stem cells. The quality assurance tests don't require or call for these. We don't really want adult pluripotent stem cells to behave like embryonic stem cells in the petri dish. We want pluripotent cells to turn into adult cells in the petri dish. Why then do we insist on fresh embryonic stem cells? A need for fresh embryonic stem cells assures a source of embryos. What neat tricks could we do with embryos? Well, we could, if we wanted to, clone John Doe from a reprogrammed skin cell. Now isn't that frightening?

Vaccines and Autism Make the News. Forced Vaccination Again?

While the press and the vaccine manufacturers debate who is winning the court battles and public opinion polls on the vaccine-autism controversy, concerned parents seem to be forgotten or ignored. On February 12 of this year the U.S. Court of Claims appeared to deal what many considered a death blow to the vaccine-autism controversy. At least, that's how the press misleadingly reported the ruling with headlines that read "Vaccines didn't cause autism, court rules" (<http://www.cnn.com/2009/HEALTH/02/11/autism.vaccines/index.htm>).

In contrast, less than 2 weeks later, on February 25, the parents of an autistic child were awarded damages from this same court, after the court concluded "Petitioner has carried his burden of proving to a preponderance that the MMR vaccine at issue actually caused the condition(s)..." (<http://www.vacinfo.org/Zeller.pdf>). The press chose not to carry this story. Neither of these rulings is comforting to parents concerned about the current U.S. vaccination policies or the lack of 'choice' when vaccinating their children. No damage award can take away the pain of families living with autism.

Parents concerned with the rapidly growing trend for multi-valent (combination) vaccines were devastated by the January 2009 announcement that Merck will no longer manufacture monovalent (single) mumps, measles or rubella vaccines. Parents concerned about the ethical production of vaccines have been dealt a devastating blow by this news, as the monovalent mumps and the monovalent measles vaccines were produced using animal cells. Now, the only available vaccines in the U.S. for mumps and measles are produced using cell lines from an aborted fetus. As vaccine manufacturers continue to move towards making combination vaccines, we will most likely lose even more of the current morally acceptable vaccine alternatives.

What are parents to do? More and more are opting not to fully comply with the U.S. recommended and state mandated vaccination schedules. The numbers of children who are not fully vaccinated has reached the point where we as a community have lost or may be close to losing what is known as 'herd' immunity. The official definition of herd immunity is "immunity of a sufficient number of individuals in a population such that infection of one individual will not result in an epidemic." In general, one aims to have 95% of a susceptible population immunized against a particular virus in order to protect the population as a whole. We are seeing outbreaks of mumps and measles in some areas. Parents, however, concerned about the number of immunizations required, about the timing of those immunizations, and about the source of many of these vaccines must weigh the perceived risk of autism (1 in every 150 children) with the risks of mumps or measles. Parents who morally object to the source of many of these vaccines are terribly torn.

What will the response of our elected officials be to this issue, which does create the potential for national security, public health and economic disasters? The CDC recently held a Town Hall Meeting in Ashland, Oregon, the 'least vaccinated city in the U.S.', where 28.1% of kindergartners were at least partially 'exempted' from vaccinations in 2007. Concerns expressed by parents at this Town Hall Meeting were whether all of the recommended vaccinations are really necessary, as well as questions about rare vaccine-induced adverse events that have not been well studied. Understanding and

acknowledging parents' concerns about vaccines is a positive step. Will action or future studies result from these types of Town Hall Meetings? That remains to be seen.

Other public initiatives related to the diminished vaccine compliance are less encouraging. Washington State is another region with a particularly low vaccine compliance rate. Arguing that federal statistics may not be entirely accurate, Washington State Senator Cheryl Pflug has introduced a bill, SB 6041 to enact an immunization registry program for all children ages 0 to 18 residing in the state of Washington. The immunization registry would be a shared, secured database accessible by school districts; however, patient identification would not be protected. The bill as originally proposed requires health care providers to participate but does allow parents to exempt their children from being included in the registry. Washington State currently has a voluntary immunization registry (CHILD), that approximately 80% of health care providers participate in. Why is the switch to mandatory participation disturbing? It is disturbing because it is a move towards compulsion, rather than a move towards understanding and responding to parents' vaccination concerns.

During this same legislative session a separate immunization bill was passed by the Washington State House of Representatives that would limit exemptions from the state mandated vaccination schedule. A summary analysis of the House Bill states, without citing evidence, that most parents exempt their children from immunizations out of convenience, and claims that parents are not being 'thoughtful' or informed (<http://apps.leg.wa.gov/documents/billdocs/2009-10/Pdf/Bill%20Reports/House/1703%20HBR%20HCW%2009.pdf>). To state that parents are not thoughtful or informed is an affront to those parents who ask only for morally produced vaccines, for safer immunization schedules, or for further studies into the U.S. burgeoning vaccine program.

Many states require a parent who chooses to exempt their child from a vaccine to sign a 'Vaccine Refusal Form'. Templates are provided by the American Academy of Pediatrics, in which an exempting parent must acknowledge that "failure to follow the recommendations about vaccination may endanger the health or life of my child and others with which my child might come into contact" (http://www.cisimmunize.org/pro/pdf/Refusaltovaccinate_revised%204-11-06.pdf). This form has some parents concerned about Child Protective Service intervention in the vaccine issue. Contrary to the derogatory statements in the Washington State House Bill 1703 report, it seems that obtaining exemptions and signing 'Vaccine Refusal Forms' would be the least convenient choice for a parent.

These are just two examples of what appears to be a national trend towards compulsory vaccination. Compulsory vaccination would not be completely new to the U.S., although most of us do not recall the forced vaccination campaigns of the 1920's. In 1970 children received just 10 immunizations, while today they receive up to 36 state mandated shots containing a total of 126 viral antigens, before the age of 6. More and more vaccines are being combined into one shot for the economic benefit of the manufacturers. Fewer morally acceptable vaccines are available. Autism and other neurological disorders of children, particularly boys, have risen to epidemic rates and parents are frightened. At the same time, the U.S. faces the specter of epidemic outbreaks of diseases as more and more parents exempt their children from full vaccination.

Will we respond to parents' concerns? Will we make sure that monovalent vaccines are available? Will we allow freedom of conscience and insure that morally acceptable vaccine choices are available? Sound Choice Pharmaceutical Institute is dedicated to answering parents' concerns, to supplying safe and morally produced vaccines, and to unbiased scientific research about the potential health consequences of the residual aborted fetal DNA that contaminates some vaccines and drugs. We ask for your prayers and support for our work.

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