

Testimony Submitted by:

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Biography:

Theresa Deisher, Ph.D. (President, Sound Choice Pharmaceutical Institute , CEO and Managing Member, AVM Biotechnology). Dr. Deisher, an expert in the field of adult stem cell therapies and regenerative medicine, brings 18 years of experience in scientific and corporate leadership positions involving research, discovery, production and commercialization of human therapeutics. Dr. Deisher's penchant for groundbreaking scientific discovery and her distinguished scientific research has resulted in 23 patents issued in her name. She has published numerous scientific manuscripts and is a frequent invited lecturer and guest speaker in the area of stem cell technology and regenerative medicine. Throughout her career, Dr. Deisher has been recruited by some of the country's top biotechnology companies, including Genentech, Repligen, ZymoGenetics, Immunex and Amgen. She has managed and mentored undergraduate honors students, post-doctoral fellows, scientific executives and over 20 research assistants/scientists at all levels of responsibility.

Dr. Deisher graduated with honors and distinction from Stanford University, and obtained her Ph.D. in Molecular and Cellular Physiology from the Department of Molecular and Cellular Physiology, Stanford University.

Subsequent to obtaining her Ph.D from Stanford, Dr. Deisher was recruited by Repligen Corporation (Cambridge, MA) and accepted a position as Research Scientist where she managed a staff of associates and scientists and directed the development of research and clinical assays in support of Phase I and Phase II clinical trials for various Repligen developmental efforts. Additionally, Dr. Deisher was selected by Sr. Management to participate in strategic alliance initiatives, including serving on the Repligen / Eily Lilly joint development committee.

Following Repligen, Dr. Deisher accepted a position at ZymoGenetics, Inc (Seattle, WA) as Sr. Scientist, Cardiovascular Biology. While at ZymoGenetics, Dr. Deisher's research and discovery in the area of cardiovascular biology led to the filing of dozens of patents. Dr. Deisher was the first person world-wide to identify and patent stem cells from the adult heart, including what are now called 'very small embryonic-like stem cells'. Her discovery remains one of the most significant discoveries in the area of stem cell research. Within the field of regenerative medicine, Dr. Deisher is also a patented inventor of the most potent mesenchymal growth factor ever identified (licensed to Serono for clinical development), and of the use of cytokines to mobilize adult embryoid-like cells.

Following ZymoGenetics, Dr. Deisher was named Sr. Staff Scientist, Vascular Biology at Immunex (Seattle, WA) where she was the project leader for both the Antithrombotic division and the Inflammation and Myocardial Repair division.

Dr. Deisher was named Principal Scientist at Amgen, inc. (Seattle, WA) following Amgen's acquisition of Immunex. She led multi-disciplinary teams working on the biology and commercial development of novel co-stimulatory pathways involved in the initiation and progression of cardiac failure. Her research interests encompassed stem cell therapies for myocardial regeneration. Additionally, Dr. Deisher's team introduced revolutionary non-invasive imaging technologies for pre-clinical research to the company, including ultrasound (echocardiography) and near-infrared imaging. As a result, the company was honored as an official 'Site of Excellence' by Philips Medical for her department's pioneering work.

Most recently, Dr. Deisher served as Vice President of Research and Development for Cellcyte Genetics Corporation, a post she held until October 2007 prior to founding AVM Biotechnology and Sound Choice Pharmaceutical Institute.

### Testimony on Conscience Rights related to biologic drug disclosure and alternative drugs.

I would like to discuss Fair Labeling and Informed Consent for our medicines, and to ask for your support for studies to examine the health consequences of having contaminating aborted fetal human DNA in our medicines and vaccines. It is a matter of conscience, whether for moral reasons or safety concerns, that a consumer should be informed of the source of contaminants in our medicines, and of alternative medicines that may be available that would not be morally or philosophically objectionable to them.

Some childhood vaccines that are mandated prior to entering kindergarten are only available in the US produced using aborted fetal cells, these include MMR (mumps measles rubella) and chickenpox. Other mandated childhood vaccines are available from both animal or human sources, and yet parents and grandparents are not informed of this so that they can choose a vaccine compatible with their consciences.

When pharmaceutical companies switched from using animal cell lines to using aborted human fetal cells lines to produce these vaccines, in the mid to late 1970s, they assumed, without any evidence, that using aborted fetal cells would result in a more efficient production system. Brief discussions about potential adverse health consequences of using aborted human cell lines for vaccine production were captured in minutes from FDA advisory meetings about this switch. However, no studies have been done to actually measure the extent of those potential adverse consequences.

Vaccines and biologics (engineered proteins as drugs) are too large to make in a test tube, so companies harness the normal machinery used to make these, cells. No final drug is ever completely 'pure' and you will find contaminating DNA and cellular debris from the production cell in your final product. When we switch from using animal cells to using human cells we now have human DNA in our vaccines and our drugs.

Shouldn't parents and grandparents know that when they immunize their children with a particular vaccine they are also injecting their children with DNA from an aborted fetus? Yet there are no laws that require drug manufacturers to inform the public of this. The package insert for the MMR II vaccine (mumps, measles, rubella) states : "MERUVAX\* II (Rubella Virus Vaccine Live), the Wistar RA 27/3 strain of live attenuated rubella virus propagated in WI-38 human diploid lung Fibroblasts", but doesn't tell you that contaminating DNA from the WI-38 propagation strain is found in the final product. The package insert for Varivax, a chickenpox vaccine, states that the vaccine contains "residual components of MRC-5 cells including DNA and protein", but how many parents or grandparents, let alone pediatricians and pharmacists, would know that MRC-5, or WI-38, is a cell line derived from an aborted fetus, and that the contaminating DNA and protein listed on the package insert is the DNA and protein of an aborted fetus? If we have the legal right to know what is in our Big Macs, don't we have the right to know what is in our vaccines and medicines? Contaminating human DNA in these vaccines has the potential to trigger auto-

immune responses and also the potential to become incorporated into our own genes, a process called homologous recombination.

Time magazine's June 8 2008 cover story highlighted the increasing numbers of US parents opting out of the recommended vaccine schedule due to, among other reasons, their perceived concern about a link between vaccines and autism. According to the Time article and CDC statistics, on average, 10% of US children are not fully vaccinated, and in some states the rate is much higher. For instance, Washington State has a reported vaccination compliance of only 70%. Vaccine compliance rates this low raise the specter of epidemic outbreaks of diseases such as measles that could cripple local and state economies. Parents, lead by celebrities such as Jenny McCarthy, are demanding 'green' vaccines. These parents, however, don't know what it is that will produce 'green' vaccines. They don't know what to demand. How could they? They don't actually know what is in the vaccines.

The perceived link between childhood vaccines and autism has generated significant press and controversy since 1992. The suggested link has been, and is today, the MMR vaccine. Since 1983, the MMR vaccine in the US has only been produced using aborted fetal cells. Coincidentally, severe autism began to rise in the US in 1983, increasing from less than 1 child per 10,000 to 16-17 children per 10,000 (or about 1 in 500) by 1990. The aborted fetal produced MMR was introduced to the UK almost a decade later, and an immediate rise in autism levels was noted, which lead to the suspected link between the vaccine and autism.

International studies have been performed to refute this link, focusing on Thimerosal (mercury) found in the vaccine's buffer, and on the measles component of this vaccine. Studies that have been conducted have not found an association between mercury or the measles component and autism. The published conclusions, including a recent Washington Post story, have been that the MMR vaccine is therefore not linked to autism. And yet, parents remain fearful and unconvinced, and justifiably so. The only conclusions that can be drawn from the studies that have been done is that neither mercury nor the measles virus in the vaccine can be associated with autism. One cannot conclude from the studies that there is no link between this vaccine and autism. I find it fascinating, perplexing really, that such a broad conclusion "**MMR vaccine is not linked to autism**" has nevertheless been spread to the public, to the scientific community and to public officials. No well designed studies, either

retrospective or prospective, have been done to truly examine this potential link. No studies have been done to examine the link between vaccines containing human aborted fetal DNA and epidemic levels of diseases such as autism.

How might the human DNA contaminated vaccines contribute to human disease? First, there is the potential for the contaminating DNA to be mixed with our own genes by a process called homologous recombination. Homologous recombination is an established biologic phenomenon in which a segment of a cell's DNA is substituted by another segment of DNA that is similar. This can occur during cell division or DNA repair. Homologous recombination occurs naturally to create genetic diversity in our offspring, and is also conveniently harnessed by scientists to introduce experimental DNA into cells or animals. We do not yet know if this occurs with the contaminating human DNA found in some of our vaccines, and if so, to what extent. Imagine the potential consequences of human DNA from a vaccine, a vaccine that is given to children at an average age of 15 months, being incorporated into a child's developing brain. One does not need to be a rocket scientist to know that this potential has to be studied.

In addition to the potential for homologous recombination, DNA is known to be a powerful immune stimulant. Diseases like graft versus host, juvenile (type I) diabetes, multiple sclerosis, lupus and some forms of arthritis are what are called auto-immune diseases. What these are are diseases driven by immune attack from our own immune system on our own organs, a system normally responsible to attack invading bacteria and pathogens. Targeted self-destruction, if you will. Science does not yet know, except for graft versus host disease, what triggers the auto-immune attack. We certainly lack studies that have examined the relationship between immune responses to human DNA containing vaccines and auto-immune diseases.

I would ask all of you to support FLICA legislation, Fair Labeling and Informed Consent, to insure that consumers, whether for moral, philosophical or safety reasons, KNOW what they are giving their children in vaccines. The FLICA legislation would require not only informed consent, but education of each parent about alternative vaccines. With the approval of the creation of HUMAN-ANIMAL hybrids by the UK this past spring, this legislation is now gaining bipartisan and pro-choice support. Wouldn't you want to know if your medicine contained DNA from a human-animal hybrid?

Aborted human DNA in our vaccines is not the end, it is only the beginning, as the creation of human-animal hybrids demonstrates. A new aborted fetal cell line has been developed, called PerC6, and licenses have been taken by over 50 partners, including the NIH and the Walter Reed Army Institute, to use this cell line for new vaccine and biologics production. The goal of the company that created the PerC6 is to become the production cell line for ALL vaccines, therapeutics antibodies, biologic drugs and gene therapy. We must know the consequences of contaminating human DNA before we wake up and discover that all newly approved recombinant drugs are produced by aborted fetal cells.

Aborted fetal cells are also now used to discover new food additives and flavor enhancers. Imagine that; the cells from an aborted fetus used to make your candy sweeter. Isn't that disgusting? And furthermore, as the company that performs this research states, one may never know these additives will someday be in our food products due to the current labeling guidelines which would allow these new additives to be captured under the generic label of 'artificial flavors'.

The conscience rights of almost half of the US population are being denied by our current labeling guidelines for biologics and food additives. A lack of information forces people to be complicit in a practice that many would find reprehensible if they only knew that aborted fetal cell lines are being used for drug discovery and production.

Thank you for your attention.