Testimony to Minnesota Legislature
April 28, 2011
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1. Good afternoon. My name is Theresa Deisher. I am here to share with you some information and data that my organization, Sound Choice Pharmaceutical Institute, has been working on for the past several years. Sound Choice is a non-profit research and education organization dedicated to increasing awareness about the widespread and pervasive use of aborted fetal material in biomedical research and drug production, in cosmetics and in the food and beverage industry. I obtained my doctorate from Stanford University in Molecular and Cellular Physiology in 1990, and completed my post-doctoral work at the University of Washington. My career has been spent in the commercial biotechnology industry at companies that include Genentech, Repligen, ZymoGenetics, Immunex and Amgen. During my career I have done work from basic biological and drug discovery through clinical development. I am an inventor on 22 issued US patents. Several clinical trials have resulted from these patents. FGF18 (zFGF5) is currently in Ph I trials for osteoarthritis and Ph II trials for cartilage repair (Merck licensee), while Factor XIII completed Ph II surgical bleeding clinical trials in February 2011 (Novo Nordisk licensee).

2. In January 2011 the US Department of Health and Human Services Interagency Autism Coordinating Committee (IACC) released a Strategic Plan for Autism Disorder Research (Appendix A). In this plan they accept the June 2009 recommendations of the National Vaccine Advisory Committee (Appendix B) to support additional studies into the link between vaccines and autism disorders. Autism disorder is a polygenic disease requiring an additional environmental trigger or triggers. A polygenic disease is a disease for which multiple diverse genes may be involved, however, no single gene is either necessary nor sufficient to induce the disease. In the case of autism disorders, over 300 genes have been associated with the disease. Additional environmental or health insults are required to trigger this disease in genetically susceptible individuals. What this means, 'polygenic', is that having a mutation in one of the genes associated with a polygenic disease does not mean the person will develop the disease – some additional insult is what triggers the disease. For instance, in animals, we know that Crohn's like disease requires a genetic mutation, an intestinal bacterial anomaly and a viral infection in order to be triggered (Appendix C).

3. In the IACC 2011 Strategic Plan the fact that spontaneous, de novo, genetic mutations are associated with autism disorders in **at least** 10% of the cases is discussed (Appendix A page 33). What this means is that some mutations that have been associated with autism are not present in the parents and therefore have occurred only recently in the children. Some of these de novo mutations are present in genes that code for proteins that are critical for nerve cell communication, which is also called synaptic connectivity. The IACC Strategic Plan states (page 34) that "Progress in identifying environmental factors that increase autism risk has been made recently, although this area of research has received less scientific attention and far fewer research dollars than genetic risk factors. Environmental factors may be pertinent not only to brain development, but also to chronic systemic features of at least some subgroups of ASD (autism spectrum disorders). The Strategic Plan goes on to state on page 35 that "Recent studies suggest that factors such as parental age and exposure to infections, toxins, **and other biological agents** may confer environmental risk. These findings require further investigation and testing."

4. How would such investigation and testing be done? Analysis of autism disorder rates, using what is called 'hockey-stick analysis', published in March 2010 by the Environmental Protection Agency (Appendix D) has identified what is called a 'changepoint' in US and worldwide autism rates. Their changepoint analysis, as well as Sound Choice's independent changepoint analysis, consider autism prevalence for birth years. What this means is that a changepoint, in say 1988, is not a year when diagnosis of autism suddenly increased, it is the year that children subsequently diagnosed with autism disorder were born. This is important to remember because other statistics relevant to the topic we are discussing today are not given for birth year cohorts but for actual year of measure. Another important point to keep in mind is that the EPA and Sound Choice's changepoint analyses considered ONLY autism disorder, and not autism spectrum. Autism disorder is the more severe form of autism, and is diagnosed prior to the age of 3.

5. From the datasets that the EPA analyzed, a changepoint occurs in birthyear 1988. What this means is that autism was rising at a lower rate in children born prior to 1988 than in children born after 1988. Analyses such as this have been used to detect ecosystem response to environmental toxins, and resulting estimated thresholds have been used as the basis for setting US environmental policy. Therefore, this type of changepoint data is robust enough to set federal policy. The EPA publication recommends on page 4 that "Future studies should examine for novel or increasing exposures to environmental factors from gestation to at least age 3 for our calculated 1988-1989 birth cohorts". For potential in utero exposures then, we would be looking for something widely, almost universally introduced to pregnant mothers in the years

1987 through Q1 1989. For a childhood vaccine, for instance, recommended to be given between 12 and 15 months of age with up to 20% immunized before 12 months and up to another 33% immunized between 15 and 36 months we would be looking for an event between 1988.4 and 1991.4.

6. The method used by the EPA for changepoint analysis, hockey stick analysis, can identify only a single changepoint in a dataset. More sophisticated analysis methods, called segmented line fit algorithms, are able to identify multiple changepoints in a dataset. Sound Choice has analyzed the datasets used by the EPA, employing this more sophisticated segmented line fit algorithm, as well as additional datasets of US autism disorder, and confirmed the 1988 EPA changepoint and furthermore identified two additional US changepoints, one in 1981 and the third in 1996 (Appendix E). Taken together, the work at Sound Choice and the EPA publication establish three US changepoints for autism disorder; 1981, 1988 and 1996. These data indicate that some widespread, perhaps almost universal, exposure or environmental trigger was introduced that would affect children born in and after 1981, 1988 and 1996.

	Changepoint 1980.9	Changepoint 1988.4	Changepoint 1995.6
In utero exposure	1979 -1980	1987-1988	1994-1995
Birth to 3 years of age	1980.9-1983.9	1988.4-1991.4	1995.6-1998.6

7. The IACC strategic plan states that biological agents may confer environmental risk (Appendix A page 35). What is a biological agent? From the FDA's website the definition of a biological agent is "Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins." There are those who may tell you that the vaccine-autism question has been answered and debunked. However, not only is the US Health and Human Services IACC strategic plan calling for further investigation of the link between vaccines and autism, but they are also calling for investigation of biological agents contaminating the vaccines that we inject into our children. What are these contaminating biological agents? I want to say only one thing about Thimerosal (mercury) in vaccines. I am not saying that Thimerosal is innocuous; however, there were higher levels of Thimerosal in total childhood vaccinations from 1948 to 1988 than there are today. Furthermore, 'changepoints' in Thimerosal levels in vaccines do not coincide with autism disorder changepoints, and levels today are greatly reduced compared to 1999, however, autism disorder has continued to rise.

8. The viruses used in vaccines are produced in cell lines because production in a 'test tube' is inefficient and too costly. Currently, both animal and human fetal cell lines are used by vaccine manufacturers. Production of viruses in cell lines results in residual DNA and cellular debris from the manufacturing cell line in the final product. For instance, as can be found in Merck's Summary Basis for Approval (Appendix F page 3) for the chickenpox vaccine, over 2 micrograms of residual double stranded human fetal DNA are present in each vaccine, which is approximately twice the amount of the active ingredient of the vaccine, which is the varicella virus, a DNA virus. As FDA scientists state in their 2008 publication in the journal Biologicals (Appendix G abstract), the danger of residual DNA in vaccines has been debated for over 50 years, without appropriate studies. The 2008 publication by these FDA scientists demonstrates the real and present danger of human DNA residuals in vaccines, which include cancer, autoimmunity and genomic disruption. As I have already mentioned, the IACC strategic plan summarizes the data demonstrating de novo genomic disruptions at varied sites in at least 10% of children diagnosed with ASD.

9. Sound Choice became interested in the potential link between vaccines and autism because we were approached and asked to develop alternative vaccines for parents who objected to the use of human fetal cells for vaccine production. In the US, over 10 vaccines are manufactured using human fetal cell lines, and for MMR II and hepatitis A there are not alternatives available in the US. The vaccine for chickenpox is also produced using a human fetal cell line, and the only alternative anywhere in the world, which some data indicates may be the preferred alternative, is natural exposure. Based on the research we have done, perhaps as many as 3% of parents decline vaccinations primarily due to the use of human fetal cells in the manufacturing. The viruses for the chickenpox and the hepatitis A vaccines are manufactured in the MRC5 cell line (Appendices F and H), which was derived from a normal 3 ½ month male fetus (Appendix J), while the rubella virus in the MMR II vaccine is manufactured in the WI-38 cell line (Appendix I), which was derived from a normal 3 month female fetus (Appendix K).

10. In taking on the mission to provide alternative vaccines to those who object to the use of human fetal cell lines for vaccine production on a moral basis, we began to study the literature surrounding vaccines. The vaccine-autism controversy is difficult to miss, and simply reading the published literature should immediately arouse curiosity in a fresh and objective perspective mind. Firstly, even in the publications that claim no link between MMR and autism, there is an evident changepoint in 1988 (Appendix L figure 2 page 4). The authors dismiss the link between autism and the MMR vaccine, because as they point out, vaccine compliance was already well over 95% in the UK before 1988. However, what the authors documented (page 4 top right) but failed to

investigate, was that the MMR vaccine used in the UK was switched in 1988 and 1989. Prior to 1988 the MMR was produced in animal cell lines, and in 1988 and 1989 three new MMRs were introduced, all of which use human fetal cell lines for the production of at least one of the viruses contained in the MMR (mumps measles rubella vaccine). Having worked in commercial biotechnology and clinical development programs, I was aware of the residuals that would be found in vaccines, and having also worked with 'homologous recombination' and molecular biology, I was also aware that the human fetal DNA introduced in vaccines has the potential to elicit autoimmune responses or to incorporate into the recipient's own genes and disrupt normal protein production.

11. Inflection points, changepoints, are clear by eye in US autism prevalence data from the Department of Education, as well as from the California Department of Developmental Services. This intriguing and perplexing visual assessment of US autism prevalence, together with publications on autism rates in the UK, led Sound Choice to more fully investigate. What we have found is that across continents, and across decades, changepoints in autism disorder (not considering autism spectrum but only autism disorder) are clearly associated with the introduction of vaccines produced using human fetal cell lines. Each time we inject our children with one of these vaccines, we are also injecting them with residual fetal human DNA.

12. US vaccination compliance information was collected by the US Immunization Surveillance (USIS) from 1959 through 1985, by the National Health Interview Survey (NHIS) from 1991-to the present and by the National Immunization Survey (NIS) from 1994 to the present. No data was collected for 1986 through 1991, except by retrospective studies after measles outbreaks had occurred. The CDC Morbidity and Mortality Weekly Report's contain data regarding measles immunization coverage that can be used to fill in this 1986 through 1991 gap. I have already mentioned that the UK 1988 birthyear changepoint in autism disorder is associated with the switch from animal to human fetal produced MMR. In the US, the switch was first approved in late 1979, and by 1983, only the human fetal produced MMR II was available in the US (Appendix T), coinciding with the 1981 birthyear changepoint for autism. In 1989 a second dose of MMR was added to the US vaccination recommendations to be given not less than 28 days after the first dose. We cannot determine the significance of this second dose without accessing each child's immunization record because while it is geared towards 4-6 year olds, the recommendation allows it 28 days after the first dose, and we know that significant numbers of children (up to 20%; Appendix M page 2) receive vaccinations earlier than recommended. More significantly a compliance campaign was undertaken after measles outbreaks in 1988 and 1989 that brought compliance with MMR from as low as 49%, and perhaps even lower (Appendix N) between 1986 and 1989 (birthyears 1984 to 1987), to over 82% in 1991 (Birthyear 1989, NHIS).

Introduction of a second recommended dose in 1989 and the compliance campaign correlate with the 1988 calculated autism disorder birth year changepoint. MMR vaccination rates increased from birth years 1987 to 1989 by at least 20% and as much as 30-40%, and the changepoint is calculated to be 1988.4. In 1995 the chickenpox vaccine was approved in the US and correlates with the 1995.6 autism disorder birthyear changepoint. The rate of chickenpox uptake corresponds to the post 1995.6 birthyear changepoint slope (Appendix E and O).

13. Similar associations between autism disorder changepoints and human fetal DNA containing vaccines are evident for Canada, Denmark, Japan, and several South East Asian countries. The US Vaccine Safety Database contains data regarding immunizations and autism disorder for hundreds of thousands of children, and careful analysis of this data comparing autism rates prior to 1995 and after 1995, as well as comparing autism disorder prevalence in children vaccinated or not vaccinated with the chickenpox vaccine after 1995, will provide significant information about the potential association between the use of human fetal cells for vaccine production and autism prevalence. Sound Choice is preparing a proposal to gain access to the Vaccine Safety Database to conduct this analysis. We are partially funded through a grant from the Murdock Charitable Trust and are looking for additional funding to conduct these types of studies. I also need to say that it is important that independent groups conduct these types of analyses, and several groups should independently examine each question, so that children are finally helped and protected. One of the key scientists funded by the CDC to do studies into MMR and autism links, studies used to dismiss the MMR-autism hypothesis, was indicted on April 13th this year, 2011, on 13 counts of fraud and 9 counts of money laundering. Furthermore, Dr. Thorsen had also already been cited for academic misconduct by Aarhus University in Denmark and was charged with embezzling a $1 million grant from the Centers for Disease Control (CDC) (Appendix P).

14. There are also viral contaminants from the human fetal cell lines used to produce the vaccines present in the final product. Human endogenous retrovirus K is present in the MMR II, the Meruvax (a monovalent rubella vaccine that is no longer produced) and the chickenpox vaccines (published in the Journal of Virology in 2010 Appendix Q). HERVK is a virus related to the MMLV virus, a virus that was used to deliver gene therapy in clinical trials for boys with SCID disease (severe combined immune deficiency also known as Bubble Boys). The MMLV virus caused inappropriate gene insertion and subsequent somatic gene mutations in 4 of 9 boys that led to the development of cancer (Appendix R). So, not only was human fetal DNA introduced to our children with the MMRII and chickenpox vaccines, but a retrovirus capable of enhancing genomic insertion was also introduced in these vaccines. Sound Choice is focusing our work on quantifying the genomic integration of human DNA fragments into

human recipient cells and on epidemiologic studies to evaluate the temporal link between human fetal cell produced vaccines and worldwide autism prevalence. Additional safety questions about the use of human cell lines for vaccine production include viral contaminants such as the HERVK. There are clearly several safety issues with our current vaccination program that have not yet, but need to be addressed, which may also include the number of vaccinations delivered to children over short time periods. Most importantly, solutions are readily available. Merck has monovalent animal produced mumps and measles vaccines that could be re-activated within a few months, and Japan has several animal produced MMR vaccines that could be brought to the US rapidly. The monovalent measles vaccine was discontinued by Merck for economic reasons in December of 2008. What are we going to do for pregnant women in the event of another measles outbreak? They should not be given the MMRII, as the rubella virus in that vaccine crosses the placenta and can infect the fetus. This is just another example of where vaccine policy has not been based on the best interests of the patient.

15. The vaccine-autism issue evokes strong emotional responses from people, and the use of human fetal cell lines for vaccine production may stir up pro-choice defenses. However, this issue is not about Andrew Wakefield or about women's reproductive rights. Most pro-choice women are philosophically opposed to injecting their children with vaccines containing human fetal cell DNA. This issue is about the health of our children and what we give them in vaccines, and politics has no place when we think about the health of our children and a devastating disease like autism. I would like to close with a quote from a father of two boys with autism: "Policy makers and medical professionals ought to be more motivated by a true desire to know more, rather than ideology. As a parent, I don't care about ideology; I just need research to help me choose between therapies that work and those that don't."

Thank you for your time and your attention.