



still frame of Dr. Petitto discussing the dangers of implanting children (see link below if video box is not embedded)

<https://www.youtube.com/watch?v=7gU7a1EH2jo>

Title Frame: Panel of Experts Review Pediatric Implanting

[Dr. Laura-Ann Petitto wears a V-neck red knit-shirt with buttons along the forearm's sleeves. She has shoulder-length dark brown hair, and wears short drop earrings, and a necklace. She's sitting in a corner with pictures and a vase of flowers behind her. She looks down to her left and then looks up smiling.]

That has been a very hot topic in my life. I lived through that experience, I was there, I know what happened, but the information about that has now disappeared.

Title Frame: Excerpt of Interview with Dr. Laura-Ann Petitto, Cognitive Neuroscientist

What happened was that during that year (subtitle text: 1980s), 12 children died from the cochlear implant surgery. The 12 children who died, died from complications from the cochlear implant surgery itself. It was the operation itself that caused the children to die. The children did not die from meningitis. NO! They died due to a number of complications related to the surgery and related to the procedures associated with the surgery, the post procedures and/or the follow up procedures as well as psycho-socio reactions/result to the implantation. They died from many of these such things.

So the White House, the FDA, NIH, and NSF funded agencies were anxious about these deaths. Consequently, the FDA, NIH and NSF called for meeting that included 13 panelists to collect and review all of the evidence from those surgeries during that year. Furthermore, Dr. House, as well as many of his doctors who did this surgery, came before the panel to present their best of the best work related to the cochlear implant surgeries. The panel functioned like a jury; we listened to the evidence and had discussions. Then after those who 'testified' left, the panel worked together to decide what should be done. That is, should cochlear implant surgeries for young children continue or should the surgeries be stopped until more evidence is gathered so that they can be determined to be safe? Clearly, if 12 children died, then the surgery is not safe.

It was appropriate that the FDA be concerned about what to do about this. The panel gathered all this evidence and discussed it thoroughly using four categories or areas to analyze the different types of possible risks. Looking at the evidence in each of these categories convinced us that the surgery was not safe. Therefore, the panel's decision was that the cochlear implant surgeries needed to stop for three years until there was more evidence collected to show that it was truly safe.

Title Frame: Four Concerns

Title Frame: #1 Medical Concerns

There were complications associated with infections. At that time, they had no antibiotics to treat or cure these infections. This meant prior to the cochlear implant surgery they knew that if the child got an infection as a result there would be a percentage they would not be able to save. This was due to the fact that they didn't know how to cross the blood-brain barrier (subtitle: blood-brain barrier), and our regular antibiotics could not treat the infection in the brain caused by the cochlear implant. The doctors already knew before implanting that they did not have the medicine to treat these types of infections. The doctors knew when they did the cochlear implant surgeries that they had no medications to cure the infections children might develop. So the doctors were aware of this risk even before they did the operations.

We also already knew at that time that it was harmful for a child to have two operations with heavy doses of anesthesia. This could cause cognitive and processing disorders in children.

Title Frame: #2 Technical Concerns

The second area related to technical concerns. The person who invented the cochlear implant itself, Dr. Loeb (subtitle: Dr. Loeb), he stood up and explained that a cochlear implant was not meant to become like 'an ear;' that is, it doesn't give you language. Cochlear implants, he explained, had technical limitations. He said that even 25 years in the future with multiple channels developed for cochlear implants, that technology would still never permit a human to hear like the ear does. He warned us and said be careful how you use my invention because you are utilizing it erroneously if you think it is meant to replace the ear. It was meant to be a very fancy hearing aid and never meant to be marketed as a human ear. So Dr. Loeb was upset about this.

Title Frame: #2 Psycholinguistic Concerns

The third area we looked at was the psycho-linguistic effects of cochlear implant surgery. Dr. Klatt, a famous MIT psycholinguist, stood up and explained psycho-linguistic perception of letters in human speech and he said that the device doesn't actually hear letters in English (or any other spoken language) instead it simply gives stimulation in the areas of the basal membrane. Still, a human child would need to be rigorously trained to perceive like the letter "e." One must be trained because the child is only getting raw stimulus in crude categories. So perception of that letter 'e' would require a lot of training, and of course it is training in isolation not being able to perceive entire words.

We also saw much psycholinguistic evidence concerning the people who best utilize and the only people who do well the cochlear implant. All of the data pointed to a particular type of candidate—adults—“postlingually deafened” adults. So all the push was for early, early implanting when all the evidence showed that children didn't do well, it was the adults--Adults such as a 22-year-old Hearing man who suffered hearing loss after a fall from his motorcycle. Cochlear implants could help him improve in locating and identifying environmental sounds. But even in this situation, his speech perception would not necessarily improve without a tremendous amount of training and he would still need visual clues (not speaking while covering the mouth). And this situation, with a postlingually deafened adult, is the best evidence, the best success of cochlear implant.

This is an example of the kind of evidence that Dr. House gave us. This would be considered his best evidence and he gave us all of his best of the best evidence, which truly was very weak.

The panel was astounded by what was presented as best evidence of success, which occurred only after intense training to perceive particular isolated sounds by postlingually deafened adults.

Title Frame: Psychological, Social & Emotional Concerns

The group of psychologists, therapists, social workers and family therapists came and told us horrific stories concerning what had happened to the children after the cochlear implant surgery. They described the children as becoming psychotic, over-stimulated and the children were unable to understand what was

happening to them. The adjustment/mapping of the cochlear implant was difficult to get just right with children. Some children developed fears and paranoia. Others couldn't sleep or dream.

The group of psychologists and therapists described how everyday life was disrupted due to problems sleeping or physical limitations such as being unable to shower, swim, or other routine activities due to needing to be careful of the implant.

A few children were even described as having pulled the cochlear implant out of their head, as these early models had wires that went from the ear to the back of the skull. A few children died from this because they then got infections that couldn't be cured.

Title Frame: Panel's Decision Based on Evidence

Evidence was given in all four categorized areas of examination (medical, technical, psycho-linguistic and psycho-social) to the panel. Dr. House himself provided the panel with the best evidence he had collected. We discussed and analyzed all this evidence. We also had surgeons who had performed cochlear implantations from Massachusetts General Hospital in Boston. The panel collected all of this evidence and those who testified left.

After all of the evidence was discussed over a period of three days, there was an unanimous decision by this panel of 13 experts--each who was at the top their various fields: Doctors, psycholinguistics, Language acquisition experts, Psychosocial experts all highly regarded experts-- unanimously decided that cochlear implant surgery should be stopped immediately for children. The panel defined children as under age 12 and it was our decision to ban cochlear implantation on children under the age of 12.

The panel determined that there should be a 3-year moratorium on cochlear implant surgery until sufficient evidence would be collected to show the surgery as being safe.

And I will repeat, that that year 12 children did die from cochlear implant surgery. Because of those deaths, the FDA, NSF, and NIH called this meeting. The FDA, NSF, and NIH were responsible because taxpayers' money supported the research. Imagine if 12 children died from your tax dollars! So THE FDA said we needed to evaluate this so they called 13 experts to form a panel and that was our decision.

However, what happened after this was complicated. The 3M company, which is big business, invested a lot of money. That year, 3M company had already invested over 25 million dollars in the cochlear implant business, an investment they did not want to lose.

The FDA accepted the decision by the panel to stop cochlear implant surgeries in children in the USA. And while FDA stopped cochlear implantation on children in USA, the FDA could not control the 3M company outside of the United States.

This was a terrible irony.

The 3M company was free to implement cochlear implant surgeries in children throughout the world in countries considered third world. How could that happen?! Incredibly, Canada was considered third world, for economic reasons based on some economic principle I don't understand.

So I arrived back from the FDA panel in Montreal where I was a professor at McGill University. That Monday's newspaper had an article about some company, it was 3M but they had a different name, granting millions of dollars to the children's hospital in Montreal for cochlear implant surgeries. Accompanying the article was a doctor who was describing the cochlear implant surgery as "a miracle that would make children hear again."

If you would look at the historical documents, you would notice that there was an immediate and aggressive increase in cochlear implant surgeries all over the world in places like the English Commonwealth countries Hong Kong, Australia, England and Canada. You could actually map this out

and see the hot spots where the surgery was taking place during the three years where there were no surgeries in the US. This aggressive promotion of cochlear implant surgeries in the British Commonwealth nations like Canada, Hong Kong, New Zealand all came from 3M company that gave money under different names. You can see the hotspots of where cochlear implanting of children was taking place around the globe.

During this time in the United States, the 3M company got a very serious lobby group and they began to put pressure in various places. This is why later, the moratorium was lifted and cochlear implant surgeries were once again being done with children.

It may be difficult to find the records now, but it is impossible to deny that for three years in the United States cochlear implant surgery in children was stopped. I was on that panel, I lived in that room for three days, and **we did stop it.**

However, during that time the 3M company aggressively lobbied for cochlear implant surgeries and vowed to overturn the moratorium. They said, "We will see you in three years," **and they did overturn it.**