Regulating Cochlear Implants: The Legal Response to a Scientific and Cultural Revolution

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ABSTRACT

This paper is a case study on the cochlear implant device. The inquiry will explore the important aspects of the device's intended use, its legal regulation, and its moral impact. Through this case study I hope to illustrate how this particular technology distinguishes itself from other medical devices that the Food and Drug Administration regulates. I also examine how well the FDA answers the unique scientific and ethical questions that the device poses. This paper looks at the legal response to cochlear implants through the lense of the implant's societal impact.

The research for this paper proceeded in four parts. The first part consisted of reading industry articles, reviews, and manifests in order to understand the hard science of the device. The next part was to understand the regulatory scheme. For that I consulted my Food and Drug law casebook, law review articles that dealt with medical device regulation, and noted cases on the matter. I then tried to ascertain the legal issues that were most pressing to the people who worked directly with the technology. I did this mainly through interviews of clinicians, manufactures, educators, and patients. Finally I consulted books and articles written by or about the leading detractors of the technology, focusing those who oppose it on moral and ethical grounds. This then required me to look towards common law (particularly the field of Family Law) to determine if these detractors had cognizable legal claims.

The paper is basically organized in the same way as my research. Part I explores the hard science of cochlear implants and explains why the are such a revolutionary jump in the way we treat hearing impairment. Part II sets up the basic regulatory framework and explores the legal concerns of those who work with the product.

Part III deals with the moral issues of the device and the appropriate legal response.

INTRODUCTION

The cochlear implant is one of the most exciting new medical devices that has been approved for use with children in the past 30 years. By utilizing the kind of micro-circuitry that today is common in such modern conveniences as the cell phone and the laptop, the cochlear implant can actually stimulate hearing for those who individuals who are born deaf, or lose their hearing later in life. With this device many of the speech problems commonly associated with hearing impaired individuals can be significantly overcome. It is a technology still in its early stages, but it is a technology that has the promise to one day "cure" deafness as we know it.

Since the cochlear implant is essentially a set of electrodes that are implanted into the ear of patients as young as six months old, the device is heavily regulated by the FDA under its medical device authority. The clinical testing requirements necessary to gain pre-market approval are rigorous. Every single change in a particular implant's hardware and most changes regarding the software that runs the device must undergo a daunting and expensive gauntlet of studies and tests before it can be approved for general use. This greatly raises the cost of the product for consumers and delays the rapidity with which new cochlear implant innovations can be brought to the public.[1]

The young age of the usual recipients is itself an important aspect of cochlear implant technology. The FDA has approved the technology for use at the 12 months old. However physicians can (and do) apply for special clearance from the FDA to implant at younger ages. Most clinicians who work with the technology agree

[1] At this point most insurance plans cover the expense of implantation and post implant speech therapy.

that it is most useful the earlier in life it is implanted.[2] The young age further increases the rigors with which the device must be tested and therefore the time and money necessary for innovation.

The cochlear implant also has an ethical and political dimension that make it unique among products that the FDA regulates as medical devices. Most new devices do not come under fire for being the tool for a cultural "genocide." This technology however has been the source of vilification in the Deaf World. Some individuals who were born deaf (or became so early in life) see deafness not as a medical infirmity, but as a cultural distinction. They see implants as a means of stamping out their particular ethnicity because it threatens to prevent naturally deaf children from joining the Deaf community. There is an entire interest group that spends time and money lobbying the FDA to revoke its approval of cochlear implants on the grounds that the device is unethical and subjects innocent children to "violent and useless surgery."[3]

The medical, legal, and ethical issues attendant to this technology make the cochlear implant an interesting case study into how and why the government and the legal system regulates medical devices.

[2]Elizabeth A. Ying. Clinician, Rielly Research Hospital, Indiana University Medical Center.
[3]The Mask of Benevolence. *Harlan Lane.*

PART I

Hearing Loss

In order to understand exactly what a cochlear implant is and what it does, we must first understand the medical condition commonly called "deafness." Hearing loss occurs in about three out of every 1,000 babies.[4] Common risk factors include: extremely low birth weight, cytomegalovirus, German measles, and other post birth treatments that can be life saving (strong antibiotics) but negatively affect hearing.[5] Some hearing loss is also thought to be genetic.[6] Hearing loss can also be the result of tragic accident. The condition is generally progressive.

Common perceptions of what hearing loss is or what deafness actually constitutes are usually inaccurate. Most people think that there is a bright line distinction between hearing loss (which can be ameliorated with an amplification system) and actual deafness (for which there is no "cure"). In fact, hearing loss proceeds on a scale from "mild" to "profound."

Sound is measured along two axis, loudness and pitch. Loudness is measured in decibels (dB) while pitch is measured in cycles per second. The degradation of the sound wave as it emanates from its source is what we perceive when something is thought to be "loud" or "soft." The frequency with which that sound wave passes a fixed point (your ear) is what we perceive as a sound's "quality" or "character" or pitch. When you

[4] Make A Joyful Noise. *The OralDeaf Foundation.*
[5] Make A Joyful Noise. *The OralDeaf Foundation.*
[6] Families whose children are born deaf often undergo genetic counseling and future children are tested at birth.

say "That sounds like a truck" you are making a reference to pitch.[7] Common examples of the difference between the two concepts are the sound a lawnmower makes, which has a high decibel level (100 dBs) and a very low pitch (250 cycles/second) compared with the sound from a digital watch's alarm, which has a low decibel level (30 dBs) and high frequency (2000 cycles/second).

Individuals with normal hearing will start to pick up sounds at around the 0 dB level up to between 150 and 200 dB (at which point hearing damage will occur). However even the best hearing humans can only hear frequencies between about 125 cycles/second and 8000 cycles/second. Thus, there are a wide variety of sounds that humans simply cannot hear (the dog whistle, or the signal from sonar/radar being the most common examples of sounds with a frequencies to high or low for us to hear). For sounds beyond our frequency range no amount of decibel amplification will effect our ability to hear the sound.

Hearing impaired individuals are common thought to be lacking only the ability to hear sounds below a certain decibel level. This is what happens to many adults as they grow older and explains why, for many elderly people, simple amplification (whether through a hearing aid or mere shouting) can be useful. However, for most children who are either born deaf or become deaf through illness or accident, the loss is not only in the ability to hear below a certain decibel level, but also the loss of the ability to hear certain pitches. There are many hearing impaired people who can hear a lawnmower just fine, but could never hear the sound of a watch alarm no matter how loud the alarm was or how close they were to it. For many children this results in very late detection of their hearing impairment, as their parents think that they are "ignoring" the ringing telephone right behind them because the child turns to them when they clap or yell their name.[8] A person who can hear at every normal decibel level, but can only hear a very small section of the pitch range, is often called tone deaf.[9]

[7] The concept of pitch is most commonly applied to music, but the point here is that all sounds have a pitch.

[8] Hearing in Children. *J.L. Northern and M.P. Downs.*

[9] Here again, music is a useful illustration. A person who is painfully unable to "carry a tune" likely has some form of clinical

The categories used to define the degrees of hearing loss try to take into account this pitch/loudness distinction.[10] Mild to moderate hearing loss means that you have trouble picking up normal "inside voice" conversation (around 40 to 80 dB) but can hear most of the pitch range. Severe and profound hearing loss means that you can't really hear anything softer than an airplane, and that most of your pitch recognition is impaired.

Language

The ability to hear is crucial to the development of language. Put simply, you cannot reproduce what you cannot hear. This is why often the first clue to parents that their child is deaf is that the child does not vocalize as much or in the same way as other children, and that language does not develop. That is not to say that a profoundly impaired child will not communicate. In fact deaf children develop a variety of ways to express what they want and when they want it. They simply to not do so verbally.[11] Even a child that is born deaf can, and intuitively does, learn to read lips (the mouth movement of the word "cup" can be associated with an actual cup almost as easily as the sound "cup"). Obviously sign language is an option for all hearing impaired children and American Sign Language (ASL) has actually achieved status a legitimate foreign language in sixteen states.[12]

Since hearing impaired people do have options in terms of communication (and also because of previous

hearing loss. The frequency of most western "music" is about 1000 cycles/second. Middle "C" on a correctly tuned piano is in fact *exactly* 1000 cycles/second. However, while a "tone deaf" person in the common usage of the term might well suffer from hearing loss in that range, it does not mean that they cannot hear a frequency of 600 cycles/second where which is the sound of most vowels. Heraring in Children. *J.L. Northern and M.P. Down.*

[10] Hearing in Children. *J.L. Northern and M.P. Downs.*

[11] Hearing in Children. *J.L. Northern and M.P. Downs.*

[12] Www.Gauladette.com

technological limitations) the thrust of aids to the hard of hearing has been on the amplification front. A hearing aid might help a deaf person hear the beep of a close automobile, or pick up some auditory clues to piece together a conversation if the person is speaking too quickly to effectively read lips. If a person loses their hearing later in life, an aid might help them retain their language skills. The goal of the cochlear implant is more ambitious than most other hearing aid devices. The cochlear implant seeks to help a hearing impaired people (usually children) in terms of spoken language acquisition.

Language acquisition is an extremely difficult hurdle for a deaf child. Normal hearing people acquire most of their fundamental linguistic skills early in life. Depriving a child of sounds will stunt that process. At some point most normal hearing children will make the connection between a specific word to a specific thing. However before that, they have heard, and reproduced, a much wider variety of the sounds that make up the words they will later use. Those sounds, and their attempted reproduction is what we call "babbling."[13] Severely hearing impaired children do not undergo this process because they have never heard anything worth reproducing.

The effect this has on language acquisition is clear. If you have no concept of what "Maa" sounds like, have not heard the sound 500 times a day since birth, then you will not think to attempt to make the sound yourself. Without the ability to consistently reproduce the sound "Maa" you cannot reproduce the word "Mom." Moreover, if you cannot hear yourself make the sound, if you cannot compare your attempt to the that of another, then you will not be able to subtly correct yourself each time you try. This is why, even if you lose your hearing after you have acquired language skills, those skills will deteriorate over time. The ability to hear yourself and others is the fundamental to acquiring and maintaining oral communication

[13] Make A Joyful Noise. *The OralDeaf Foundation.*

skills.[14]

The loud/pitch distinction discussed above is especially important in terms of language acquisition because the sounds used in language also have a wide variety of frequencies. Most vowels are in the middle frequency which most people can hear. However many important sounds tend towards the margins of the frequency range. Notably, the sounds necessary for "th" "eff" "ka" and "es" are high frequency, while the sounds for "juh" and "mum" are low frequency. Many profoundly deaf children cannot hear these sounds no matter what the amplification. A statement like "I'm fine, thanks" even when blasted at a decibel level they can hear sounds like "eI, eI, ann."[15] They would get the vowels and the rhythm of the speech, but not any of the consonants. Moreover when attempting to reproduce the phrase, "eI, eI, ann" sounds exactly correct to their ears.

Children who wish to gain oral communication using only amplification devices must do so through a painstaking process of rote memorization. Hearing impaired children (and their parents) will spend countless hours in therapy sessions with speech pathologists and clinicians trying to memorize how to produce sounds that they have never heard. It is possible and tremendous achievements have been made. Since most hearing impaired children have all of the vocalization abilities of a normal hearing child they can be taught how to make the "eff" sound, first through trial and error, and then through endless repetition. Hearing impaired children can interact effectively, and orally, with the hearing world using a combination of amplification devices, speech therapy, and lip reading.[16]

[14] Speech and Language: Benefits of Cochlear Implantation. *Ed. Dr. Richard Miyamoto.*
[15] Www.Gauladette.com
[16] Make A Joyful Noise. *The OralDeaf Foundation*

How a Cochlear Implant Works

The cochlear implant attacks language acquisition from a very different standpoint than amplification devices. The device actually receives, interprets, and reproduces sound, and then sends that signal electrically directly to the nervous system and the brain.

In a normal hearing individual sensory hair cells move sound from the peripheral auditory structures (the cosmetic ear and the middle ear) to the central auditory structures (a cluster of nerve endings called the spiral ganglion cells) which then transmit the sound signal to the central nervous system and eventually the brain.[17] The area where the structures of the middle ear meet the endings of the nervous system is called the cochlea. In most hearing impaired individuals the hair cells that make bridge the ganglion cells to the endings of the nervous system have massively degenerated or are entirely absent. There is a literal gap between the inner membrane of the middle ear and the nerves cells that extend into the inner ear which results in the failure of sound transmission to the brain.[18]

A cochlear implant seeks to ameliorate the problem at its source. Electrodes (anywhere from 6 to 24 currently) are surgically implanted in the cochlea in the place of the missing or non-existent hair cells. They are held in place in a specific array by a magnet placed just under the skin behind the ear. In the most simply terms, the electrodes bridge the gap from the ear to the nervous system.

[17] Cochlear Implant Technology. *Blake S. Wilson.*

[18] This is why it is common for people to lose their hearing progressively as they get older. The hair cells do not regenerate or repair themselves so as they are lost or damaged, the amount of sound that the brain receives decreases. A poorly constructed amplification device can in fact increase the problem by overloading and damaging remaining hair cells. - Cochlear Implant Technology. *Blake S. Wilson.*

The electrodes cannot however receive sound waves directly from the structures of the middle ear. Thus the cochlear implant has two more external structures: a computer processor and a transmitter. The processor is worn by the user at about waist level. Through an internal or external microphone the processor receives sound, interprets the sound wave, and reproduces an electrical signal. That signal is then sent (by wire) to the transmitter that is worn just above and behind the ear (the transmitter can be clipped onto the ear). The transmitter then sends a low voltage electrical signal to the internal electrodes, which in turn send an electrical signal on to the central nervous system. The entire device is powered by a battery in the processor that needs to be changed every few months.[19]

The technological leap of this system over previous hearing aid devices can not be overstated. While other systems merely attempt to ameliorate some of the symptoms of deafness, the cochlear implant is the first one to attempt to fix the problem at its source. By attacking the problem at the neural level, the implant attempts to help the user on both the "loudness" axis and the "pitch" axis. Sounds that literally could not be heard before can be with the aid of a cochlear implant.

The implant's biggest benefits come to those who seek oral communication skills. Speech language pathologist Elizabeth Ying explains the benefits of the cochlear implant this way. "The tonatopic arrangement of the cochlea is such that there is better protection for the cells that respond to low and middle frequencies. The vowels. If there is damage [from meningitis or some other infant illness] the high frequency cells are most likely to be destroyed or unusable. The cochlea implant can actually give hearing to children in the high frequencies where most of the hard consonants are. These sounds are not particularly natural and are thus, very hard to teach to a child that has never heard it before. . . . With a cochlear implant a deaf child can be

[19]The number and placement of electrodes, processor speed and voltage requirements are what define one "type" of cochlear implant from another. As will be discussed in greater depth below, each type of implant must receive premarket approval from the FDA.

taught to speak as clearly as their normal hearing counterparts."[20]

For all of its promise and improvement over other systems, current cochlear implants are still a fairly crude reproduction of our internal auditory system. The infinite subtly that can be detected and conveyed by a fully functioning cochlea cannot be simulated by a processor that is bound to only the information a computer programmer can pack into it. Some of the "quality" and "character" of voice is lost. Even a high functioning implant user will still have trouble with certain vocal nuances.[21]

Moreover the signal received is not exceptionally clear. Adults who have been implanted after losing their hearing later in life have compared the signal to, "trying to order food at the drive through window."[22] The problem is exaggerated when there is a lot of background noise (as in a crowded room) and the processor must try to make sense of multiple sound signals (one can imagine that the concept of "hearing two things at once" is much harder for a computer to do than our brains). The key point is that the signal while beneficial is still a reproduction and interpretation of real sound, not a replacement.[23]

Another difficulty arises because the remaining auditory structures (the amount of hair cell deterioration for instance) are different for each patient. The optimal position for the electrodes in each person is going to be different based on the a number of factors.[24] Each processor program (called "maps") must be individualized as well. Since the transmitter is actually sending voltage to the brain a program that is too strong can cause facial twitching and far more serious damage.[25]

[20] Elizabeth A. Ying. Clinician, Rielly Research Hospital, Indiana University Medical Center.

[21] Cochlear Implant Technology. *Blake S. Wilson.*

[22] Cochlear Implant Technology. *Blake S. Wilson.*

[23] Admittedly it is difficult to describe on paper exactly what a person with a cochlear implant is hearing. However, for interests sake, there are a number of websites where you can listen to the unique sound that a implant user hears. My pick would be "http://facstaff.uww.edu/bradleys/radio/library.html" which has links to many downloads that can give one a sense of what it sounds like to be deaf.

[24] A serious problem with older children and adults is "ossification of the cochlea." Bone grows into the vacant space in the cochlea and can make it impossible to even fit all of the desired electrodes into the cavity. Cochlear Implantation in Young Children: The Volta Review. *Ed. Dr. Richard Miyamoto.*

[25] Cochlear Implant Technology. *Blake S. Wilson.*

Due to these limitations, post implant training and therapy is crucial for making the device work. Users, in a sense, must "learn to hear." They must be taught to make sense of the signals and translate them into sounds that are useful and necessary for language. Once the "map" is set audiologists work with patients to change how many electrodes are used, at what frequencies, and for what sounds.[26] Without this post implant vigilance, refinement, and tutelage the advantages of the device are greatly diminished for a hearing impaired person.

[26]Currently the entire speech frequency set can be mapped onto as few as 8 electrodes. In essence however, more electrodes increases the amount of information that can be conveyed to the brain. - Elizabeth A. Ying. Clinician, Rielly Research Hospital, Indiana University Medical Center

PART II

The Basic FDA Framework

Cochlear implants were first approved for implantation in populations of two years or older in 1990. In 1998 the minimum age was lowered to twelve months. In order to implant a child under the age of twelve months, parents and their doctors must apply for special clearance from the FDA.[27] The youngest child to have been successfully implanted was just over 6 months.

The implants are regulated under the authority granted to the FDA in the Food, Drug, and Cosmetic Act and their regulation has been affected by the 1976 Amendments as well as the Safe Medical Device Act of 1990, and the Food and Drug Administration Modernization Act of 1997.[28] Cochlear implant devices meet "significant risk" criteria and the implants are treated as Class III medical devices. They must undergo the most stringent regulations for premarket approval and IRB oversight.[29]

All aspects of the cochlear implant hardware are subject to Class III clinical testing. When innovation allowed for the jump from 20 to 24 implanted electrodes, premarket approval had to be obtained for both the 24 electrode system and the desired placement for those electrodes (called the electrode array). Only electrode arrays that have been through clinical testing can be implanted. The result is that their are currently only a few electrode arrays per number of electrodes that have been cleared for use in children (more have been cleared for adults). Even though the residual hearing structures are different patient to patient, operating surgeons have very little leeway in where they can position those electrodes. Dr. Richard

[27] Cochlear Implantation in Young Children: The Volta Review. *Ed. Dr. Richard Miyamoto.*
[28] Cochlear Implant Technology. FDA Appendix, *Harry Sauberman.*
[29] Cochlear Implant Technology. FDA Appendix, *Harry Sauberman.*

Miyamoto of the Rielly Research Hospital at Indiana University estimates that there are currently 8 clinical trials involving cochlear implants currently being conduct at the university. The topics include such minutiae as the placement of the processor[30] and a device that uses a lower powered, longer lasting battery.[31] The considerable costs of such clinical testing mean that only three companies (Advanced Bionic, Cochlear USA, and Med - El) currently market more than one type of cochlear implant.[32]

There is broad consensus that some type of regulation and clinical testing is necessary. "Basically, you are putting wires into a kid's head, and the charging it with different level's of electricity. You can't make a mistake."[33] All Class III medical devices are subjected to a similar FDA regulatory framework. There is little to distinguish cochlear implant hardware from the other devices that share its classification.

Regulation at the Margins

The FDA's regulation of the external processor program, the computer that tells the electrodes what to do and when, is more controversial. Clinicians tend to call these issues "software" issues, the labeling itself is in a sense the heart of the debate.

As mentioned above, the "map" is the program schema that is part of the computer processor on a cochlear implant. In essence it is an electronic "Rosetta Stone", the template for translating sound waves into the appropriate electric signals. The map however is only the first part of the computer program. The map can and must be refined for each individual patient in order to make the cochlear implant work efficiently

[30] Only one implant has been approved with a processor that is worn on the ear as opposed to the waist, and that has not sold particularly well, so they are testing a more powerful model.

[31] More significant projects include testing on "binaural implants", the implantation of both ears, instead of the standard and approved one ear.

[32] About the Hard Of Hearing. *Jamie Berke.*

[33] Elizabeth A. Ying. Clinician, Rielly Research Hospital, Indiana University Medical Center.

for each user.[34] The map delineates which electrode fires in relation to the others, and which one is the "grounded" electrode (the electrode that receives the signal first in a sequence) among other things. The rest of the program is in charge of issues such as the strength and duration of the signal. How the electrodes signal in relation to each other and how strong that signal is constitutes the basis of what the brain then interprets as "sound." Changing this program therefore directly effects what the brain hears.

According to the FDA "when a computer product is a 'component, part, or accessory' of a product recognized as a medical device in its own right, the computer component is regulated according to the requirements for the parent device." If however the computer product is deemed to be a medical device onto itself, it is to be regulated "with the least degree of control necessary to provide reasonable assurance of safety and effectiveness."[35] For this device the FDA has determined that the map is a component of the larger cochlear implant. The reasoning being that the electrodes implanted in the cochlea would be rendered useless without an operating program.

This means that every map must undergo the same rigorous clinical testing as any other Class III medical device. Engineers and clinicians have the latitude to alter some of the program specifics to individualize the program, but only under the guiding template of a pre-approved map (currently, for each electrode array and number, there are about two to four maps.).[36] However since the map is a crucial step in individualizing the signal received, Class III regulation of the map in essence greatly diminishes the amount of "tweaking" that a clinician or engineer can do with an implant. A useful analogy under the current regulatory framework is

[34] Cochlear Implantation in Young Children: The Volta Review. *Ed. Dr. Richard Miyamoto.*
[35] Food and Drug Law; Cases and Materials. *Peter B. Hutt & Richard A. Merrill.*
[36] This process is usually done one or two months after implantation, and continual monitored.

to that of a car engine. Having map "A" or map "B" is like having a V6 or a V8 engine. Patients (through their doctors) can do things like add a turbo charger or get a tune up, but they cannot switch from a V6 to a V8 and, even more importantly, are not allowed to work off of a V 7 template.

Jane Madell, Director of Audiology at Beth Israel Hospital in New York City feels the current legal framework negatively impacts her ability to treat patients. She states "I have a patient who was implanted with an eight electrode array and mapped accordingly in the mid 90's. Now there is a mapping program out there for the 24 electrode array [it is apparently common to implant more electrodes than one intends to use] that would be much better for him. I can't use that map because the map hasn't been approved for use with eight electrodes."[37] The map would have to go through the entire premarket approval process with the specific number of implanted electrodes before Dr. Madell could use the program, an option which Dr. Madell says "is wholly unrealistic" because of the costs involved. The parents of the patient in question are now faced with the choice of proceeding with a the pre-approved yet sub-optimal mapping program or putting their child through another surgery to implant 16 new electrodes.[38]

This distinction that the FDA makes between the map and the rest of the program is not merely a bureaucratic oversight. As the template for the way in which sounds are changed into signals, the map is "the thing" that makes the cochlear implant what it is as much as or more so than any other component. If a map were so ill conceived as to overload an electrode it could cause serious damage and (at the very least) render the device altogether useless.[39] The crux of the legal distinction seems to turn on whether or not the map should be viewed as a component or a device unto itself. Given that the device cannot function without the map, and that the map has no medical value without the electrodes, transmitter, and the rest of the

[37]Dr. Jane Madell. Chair, Beth Israel Audiology Department.
[38]Dr. Jane Madell. Chair, Beth Israel Audiology Department.
[39]To my knowledge and that of my interviewees, this has never happened and is only a theoretical possibility.

processor program, the mapping program has many of the elements of a component part, and relatively few of the elements of a medical device unto itself.

An equally important attendant issue to the science of the map's classification is the practical result of FDA regulation of the map in Class III. This classification naturally increases the costs of developing new mapping programs. Cost inflation caused by the regulation not only raises the specter of economic inefficiency, it also fundamentally places the innovative power in the hands of companies and not doctors. Manufacturing companies are ill suited to expand the software options, even though the software is important to the overall effectiveness of the product.

The cost of developing the hardware in a cochlear implant are high. Since that hardware is useless without the mapping programs, companies combine the two into one testing process. This results with each new implant system coming to market with a few maps. Companies however make their money off of the new hardware, not the computer programs. The economic incentive for companies is to develop a more diverse set of mapping programs is simply not there, the testing is just as costly yet the end product is going to be useful (purchasable) by only the segment of cochlear implant users who will benefit from the new map significantly more than some other map. Compare that to the economic possibilities of a more advanced number of electrodes, or a faster more powerful processor, or even a longer lasting battery. These innovations have potential use for all cochlear implant users, and cost the same in terms of clinical trials as one map. "From the corporate perspective, maps are secondary to the hardware. But to the audiologist and the patient, the quality of the map and its individual fit is the most important thing" claims former audiologist Janet Pierro.[40] "We've gone from 6 to 24 electrodes in thirteen years. What I'd like to see is 24 maps for

[40]Janet Pierro. Regional Director for the Hard of Hearing, New York Board of Education.

an 8 electrode device."[41]

"Hardware" manufactures can be expected to focus on the nuts and bolts of the invention and not the software that runs it. All of the companies that make cochlear implants employ a medical advisory committee. A typical committee constitutes engineers, research scientists, and surgeons. While accomplished researchers, these boards are not stocked with practicing clinicians. "Some of these people have never even spoken to a child who uses one of their products, [or] never been in a therapy session."[42] Its not that the manufactures' medical teams are oblivious to the importance of the mapping program, however the software is not necessarily their field of expertise.

The solution would have to involve untying the production and approval process for maps from the larger implant system. Allow hardware companies to focus on the system, while creating a market opportunity for a companies that would only produce maps. If the FDA treated the mapping program as a medical device unto itself, and classified the program in a less stringent category, you could maintain a level of clinical testing and postmarket surveillance, while lowering the costs to producers.

The legal problem here is that neither the FDA's definition of medical device nor component part accurately reflect the category of a mapping program. In the FDA's regulatory guidelines on the issue, the agency notes "many software programs known as 'expert' or 'knowledge based' systems that are not used with existing medical devices and that are intended to involve competent human intervention before any impact on human health occurs (eg. Where clinical judgment and experience can be used to check and interpret a system's output). These systems are exempt from registration, listing, premarket notification and premarket approval

[41] Janet Pierro. Regional Director for the Hard of Hearing, New York Board of Education.
[42] Dr. Jane Madell. Chair, Beth Israel Audiology Department.

requirements."[43] This the map is an "expert" or "knowledge based" system that just happens to be used in conjunction with a medical device. It *can only* be used where human intervention is intended to occur before an impact on human health. Yet the FDA currently regulates the program as rigorously as the rest of the Class III medical device.

In essence, the FDA needs to establish a new category for computer programs that are components of medical devices. The approval process for these programs should be separated from its parent device. As technology continues to produce smaller and faster computers and our skills in micro-circuitry improve, we can expect an increasing number of medical devices that work in conjunction with computer programs that are made patient specific. Treating these programs as component parts and thereby subjecting them to the highest regulatory scrutiny will vitiate the individualized treatment these programs promise to convey. The FDA's regulations here have stunted innovation and detracted from the quality of patient care. The answer is not for the FDA to abdicate its responsibility for the public health and safety. Instead the agency should maintain flexibility and update categories and definitions so its law can incorporate new technologies and possibilities.

Implanting the Young

FDA regulations of cochlear implants are of crucial importance because this cutting edge technology has proved most useful to the very young. This puts the FDA in an vice that is similar to balancing the act the FDA goes through with potentially lifesaving drugs for terminally ill patients. The relative youth of

[43] Food and Drug Law; Cases and Materials. *Peter B. Hutt & Richard A. Merrill.*

the cochlear implant population poses two problems as the FDA tries to determine the effective level of regulation.

When the FDA goes forward with clinical testing for a new cochlear implant product, that testing starts on consenting adults, even though the product will be primarily used on children. Only after successful testing has occurred in adult populations does testing for children begin. On one hand this procedure is self evidently prudent. It would seem reckless to start testing on children before even basic viability tests on adults have begun.

The necessity of clinical trials starting with adult populations before testing proceeds to children greatly increases the time it takes for a new product to get to market. While the amount of time it takes to approve new implant technology does not place potential patients in the same dire straits as terminally ill patients, the time spent in trials does affect the usefulness of the technology to children.

There is overwhelming scientific evidence that cochlear implants are much more effective the earlier a hearing impaired child receives it. A recent study basically proves this issue. According to the report: "Children implanted prior to the age of two years of age had significantly faster rates of receptive vocabulary and language development than later implanted children. Furthermore, children implanted prior to age two had superior expressive language abilities compared with those implanted after that age."[44] The benefits to early implantation are not simply relevant because of the extra time a child has to learn how to use the device. Early in life the brain is more able to adapt to the plethora of new stimuli that accompany infancy. If the brain learns to rely on the electrical signals from the implant early on, quite simply, it does so better and more effectively

[44] Cochlear Implantation in Young Children: The Volta Review. *Ed. Dr. Richard Miyamoto.*

The measurements of spoken word recognition and vocabulary as well as expressive language abilities where significantly higher for children in the 0 -2 age group than for either the 2 - 4 or the 5 and over age groups. What's more, the study showed that the rate of improvement in these skills for children implanted before the age of two was greater than rates for children implanted at later stages of development.[45] This means that children do not only gain language skills more quickly when implanted early, but that the gap widens two and three years after implantation. The age at implantation plays a significant role in the overall oral functionality of the user. Potentially, a patient implanted at 12 months will be on par with her "normal hearing" classmates, in terms of language production and recognition, by age 5. Conversely a child implanted at 5 will not be on par with his counterparts at 9 or even 10.

This overwhelming scientific evidence lead to the FDA's reduction of the minimum age requirements to twelve months old in 1998. While cutting edge advocates wish for the age to be lowered even further (to six months, or have no minimum age at all) one would assume that as this technology becomes more and more common, any hearing impaired child will soon have the option to receive an implant as soon as the hearing loss is recognized. The FDA seems to have recognized that implanting children as soon as possible maximizes the effectiveness of the product.

That time is of the essence is understood by FDA lawmakers. However the timeliness concern should be carried over into the realm of clinical testing as well. A delay of a year or two has such a significant effect that it isn't reasonable for a parent to wait until an experimental device finishes the gauntlet of testing it must go through to get approval. Parents would be well advised to take the best implant readily available at the time their child's impairment is recognized. However the cochlear implant is not a device that can be removed and upgraded with ease.[46] Having implants go through adult testing first makes good moral sense

[45]Cochlear Implantation in Young Children: The Volta Review. *Ed. Dr. Richard Miyamoto.*

[46]The importance of the binaural study alluded to above is that implanting the other ear would give previously implanted

on paper, but in practical terms looks like bad policy in a field on the cutting edge of technology. Even a cursory glance at the websites for the three main manufactures suggests the truth that this is a product that is predominately focused on children, is intended to be used by children, and gives the greatest benefit to children.

The regulatory paternalism of adult testing is certainly well intentioned, but it causes significant further delay in getting these products to market where they are intended to help babies and infants far more than profoundly deaf 30 year olds. If we are truly settled, both as a legal system and as a society, that the parents are the proper decision makers for the deaf children, than we should also trust those parents to decide if it is best for their children to receive an experimental device. This is another example where the regulatory process need not be completely scrapped, merely brought up to speed with the realities of the technology.

children the option of accessing more recent technologies without removing the first (and potentially outdated) implant that they have become accustomed to.

PART III

Deaf Culture

Most of the political and legal issues surrounding an FDA rulemaking or regulation centers around a familiar set of flash points. How dangerous is the proposed technology? What is the right balance between public safety and life changing innovation? Do the proposed regulations cost too much for producers, or consumers? On most matters there is some broad consensus that the FDA should have some oversight function, the questions being how much and how costly should that oversight be.

In the realm of cochlear implants however there is a large and politically vocal community that believes that the FDA should not regulate the device at all. They do not believe this because the regulation is too strict or too costly rather they believe that any government regulation amounts to state sanctioning of an unnecessary and immoral procedure. By setting standards for premarket approval, the FDA also saying that cochlear implants are devices that improve the public health and safety, and should be made available to the public at large.

The interest group that believes cochlear implants are far more dangerous than a simple new technology is widely referred to as the "Deaf World" or "Deaf Culture." The upper case D is significant as it is used to signify an identity with a shared culture, rather than individuals grouped by a medical condition.[47] They view deafness as a distinct minority group, an entirely different community with its own language, its own values, and all the other trappings of a distinct cultural entity. They oppose cochlear implants so strongly

[47] Culture and Cochlear Implants. *John Niparko.*

that they view the technology as a means for committing "genocide" on their way of life.

Personally, I was first exposed to this argument as a young teenager. My mother was then and still is a speech pathologist and I had always grown up in full awareness that, with training and teaching, a hearing impaired child could achieve a level of language skills and functionality on par with any of my normal hearing schoolmates. The notion that deaf children should not be taught to communicate orally seemed wholly preposterous to me. Why in the world would you not want to help an impaired child?

The assumption that deaf children are "impaired" is exactly the contention that Deaf Culturalists rail against. Noted proponent of Deaf Culture Harlan Lane claims that the labeling of deaf as an infirmity is a prejudice towards Deaf Culture that has always been a part of society. He notes a leading physician at the Paris school for the deaf adequately summed up this prejudicial treatment in 1853 when he said "The deaf believe that they are our equals in all respects. We should be generous and not destroy that illusion. But whatever they believe, deafness is an infirmity and we should repair it whether the person who has it is disturbed by it or not."[48] According to Lane, the entire history of deaf education has been to obliterate an entire cultural group simply because the majority culture is made uncomfortable when interacting with the hearing impaired.

Prejudice and ill treatment of the disabled certainly has long history in western society. Whether because of medical misunderstanding about the nature of the ailment or base disrespect to those with special needs, the hearing impaired have long been associated with being "dumb" "deviant" or anti social. However the discrimination that Lane and others see is not merely the kind of disrespect that has historically been heaped on the disabled. Lane analogies the prejudice to racial plight of African or Latino - Americans and views cochlear implants as a state sanctioned attempt to exterminate a valid minority ethnicity.[49]

[48] The Mask of Benevolence. *Harlan Lane.*
[49] The Mask of Benevolence. *Harlan Lane.*

The crux of the Deaf World argument centers around the contention that American Sign Language is not only a viable communicative option, but that ASL is also a preferable option for deaf individuals. Advocates argue that ASL can encompass feelings and emotions that spoken language struggles to reproduce. The appropriate analogy here is the oft mentioned anecdote that one form of Inuit language utilizes multiple words which all translate back to English simply as "snow." Proponents of ASL point out that skilled users can do symbolically what oral linguists accomplish by changing the tone of their voice. Furthermore, by the use of distinct symbols, ASL users can cut out much of the misunderstanding that often happens in oral communication.[50]

The pitch recognition problem that is common with most forms of hearing impairment feeds right back into the contention that ASL is a preferable mode of communication for deaf people. Even with the best cochlear implant device currently available, a user is still likely to have problems picking up the subtlety of voice inflection because of the very nature of deafness as discussed above. The indescribable shift in vocal quality that can change an benign statement into a threatening one is something that can often be lost on even a very high functioning cochlear implant user. Lane argues that deaf people should not be doomed to a life of trying to approximate a mode of communication that they will never be able to get quite right when there is a completely viable alternative available that they can succeed with.[51] In the same way that some defend the right of Spanish speakers not to have to learn English, or the more novel argument of Ebonics as a viable language alternative, the Deaf World contends that ASL users should not be forced to assimilate the language of the dominate culture. They believe that the positive feedback of becoming a skilled ASL user is an important part of a deaf child gaining the self confidence in a world that treats them as defective.

As a corollary to this argument, Deaf Culturalists contend that cochlear implants, for all their promise, simply

[50] An ASL user does not have to wonder if the girl was angry at him, or just tired. - The Mask of Benevolence. *Harlan Lane.*
[51] The Mask of Benevolence. *Harlan Lane.*

do not work. They contend that scholastic achievement and vocational opportunities are not significantly greater for children who were implanted early in life than they are for children who have chosen non-oral options.[52] While implanted children test well "on paper" in terms of language acquisition skills, many still lag behind their normal hearing counterparts in the classroom. Even when exposed to predominately mainstream (normal hearing) environments and schools, children with cochlear implants do not do as well, and require consistent and costly special attention. Even though cochlear implants promise to "eradicate" hearing impairment, detractors contend that the product still falls far short of it's supposed potential.
The contention that cochlear implants are somewhat ineffective is certainly a minority viewpoint. The suggestion that no significant scholastic gains have been recorded due to the device border on blatant inaccuracy.[53] The overwhelming scientific evidence suggests that cochlear implants do greatly enhance the ability of deaf children to function in a hearing environment on par with their normal hearing brethren.

Much of what uncertainty there is about the effectiveness of the technology stems from two key factors. As stated above the device is virtually useless without the correct mapping program and rigorous training in the use of the device. Human input has such a great impact on actual outcomes that human error or merely a different teaching method produce very different results. Critics will point to the children who do not do as well while advocates will focus on only the highest functioning individuals. In this area the truth can not really be ascertained from simply looking at the outcomes of cochlear implant users. For instance a user does need a mainstream environment that is sensitive to their needs. The availability of such an environment can neither serve as an unqualified victory for the technology, nor as a condemnation of its usefulness.

The second factor is that the technology is still in its relative infancy. FDA approval only came in 1990 so

[52] Culture and Cochlear Implants. *John Niparko.*
[53] Culture and Cochlear Implants. *John Niparko.*

we are dealing with something that has been widely available for a statistically short amount of time. The first child to be implanted (Katiland in 1990 when she was five) is only now entering college.[54] When we talk about career opportunities, there is currently no way of studying how implanted children will do compared to non-oral children. We do know that children such as Katiland have the opportunity to go to college and participate in that community just like any normal hearing teen-ager. Does this mean that Katiland will get a better job, or make more money, or do something that we label as more "successful" than ASL users of her generation? Does such a distinction need to be made before we decide whether cochlear implants are effective or not?

The statistics can be bent to fit whatever viewpoint you are advocating. To the extant that there is such a thing as "hard facts" those facts suggest that cochlear implant users can gain all of the language skills of a normal hearing person. What an individual does with those skills is beyond the purview of this technology. The Deaf World argues (correctly) that the FDA is making a decision as to the societal benefit that this technology confers. By regulating cochlear implants the FDA is saying that it believes that deafness is an infirmity that should be fixed. If the FDA did not believe deafness was something that should be repaired if possible, the government would essentially be sanctioning invasive elective surgery on an infant based on the parent's cultural preference. This is clearly not what the government is doing. The FDA treats this issue much like the abortion issue. It makes no statement as to the ethical or moral validity of this procedure; its the parent's choice. However if a parent chooses to go this route, then the FDA outlines the way in which the route can be taken. In this way the agency tries to stay somewhat "above the fray" of the political and cultural debate that rages as to the ethics behind this technology.

But the FDA can't really stay out of the political quagmire on this issue because what we are dealing with here is truly a technology that will likely someday be able to "cure" deafness. If there are prevailing cultural

[54] Make A Joyful Noise. *The OralDeaf Foundation.*

and minority rights based issues here, the FDA does not merely decline to speak on the issue by allowing implants to continue in accordance with parental choice. Our laws do not generally allow for majority to concerns to ride roughshod over minority rights. The FDA cannot merely rely on parental choice without making a finding as to whether that choice is in conflict with the best interest of the child. By sanctioning cochlear implants, the FDA is ruling on whether Deaf Culture is minority culture that should be protected, or if it is an infirmity that should be corrected where possible.

Conflicts Between the Hearing Parent and the Deaf Child

Giving the Deaf World legal status as a minority culture or a disadvantaged group under the Civil Rights Act would have far reaching and largely undesirable legal effects. In fairness Deaf Culture does not really advocate for protections that go much beyond dutiful enforcement of the Americans with Disabilities Act and much of the "disadvantaged class" rhetoric stems from discomfort with the term disabled. Disadvantaged class status would only serves as a step in their fight to claim third party status in the "best interest of the child" decision making process.

The traditional legal structure regarding medical decisions on behalf of minors gives high deference to parents. Numerous doctrinal strands coalesce on this issue of parental deference. The notion that citizens have a right to privacy and that therefore parents have a right to raise their children as they see fit, cuts heavily against third parties from interfering with that choice. While the State does have a compelling interest in the well being of children, given two reasonable alternatives of "well being" courts will almost always defer to parents.

The basis for the Deaf World's legal arguments comes from the Supreme Court holding that, despite the deference that should be accorded to parents, minor children do have rights that can and should be protected. The court has concluded that "a child, merely on account of his minority, is not beyond the protection of the Constitution."[55] The court did not go so far as to argue that the child's rights "trump" the rights of parents. However they did suggest that the child's Constitutional protections could not simply be ignored by their parent.

[55] Bellotti v. Baird, 443 U.S. 622, 633 (1979).

The state can step in as an advocate on the child's behalf. We see this structure all of the time in the family law setting. During a divorce or a child abuse hearing the state will often appoint a guardian and a legal advocate to articulate the child's rights and interests, even when that child is too young to legally ascertain what it wants.[56]

The highly contentious debate over abortion has opened up fissures in this traditional structure of parental deference as courts try to forge a balance between the rights of minor children, and the rights of parent's to raise those children as they see fit. The case of Hodgson v. Minnesota is typical of the balancing logic. In that case the court affirmed a 48 hour waiting period for minors seeking an abortion. Furthermore the court upheld a mandate that during the waiting period, both parents had to be informed of the impending abortion. The court did however decline to insist that parental "consent" be obtained, and allowed for a judicial bypass of the entire procedure where the minor could explain why their parents should not be informed of the abortion.[57] In this opinion we see both the court's deference to the right's of parents, as well as protection of the rights of minors.

The effect of this Solomon-esque attempt to please two different doctrinal strands does not really differ all that much from traditional standards of parental deference in actual practice. Under this holding, the right of a minor to have an abortion is not nearly as important as the parent's right to child rearing autonomy. In many abortion situations parents will be able to effectively stop an abortion, even though the court does not specifically recognize a veto. This opinion tries to provide for remedial structures in case the parents grossly disregard the welfare of their children; but the power of discretion still fundamentally rests within the parental authority.

[56] In Prince v. Massachusetts, 321 U.S. 158 (1944) the court outlined the state's interest in the "well rounded growth of young people" and some circumstances where that interest allowed in the state to interfere with parental choice.

[57] Hodgson v. Minnesota, 497 U.S. 417 (1990).

The opening exposed in the abortion case is one that Deaf World advocates are seeking to exploit. It is a convoluted argument. The abortion cases that mitigate parental rights vis a vie their children all involve relatively mature children. In the cochlear implant context, we are dealing with infants. They are wholly unable to express a preference for one option or another. In cases like Belotti the protection of children's rights are asserted in the context of clear parental abuse. A determination about the appropriate communicative path for an infant seems very different than a case of abuse, neglect, or a difference of opinion between parent and teen-ager.

When the court does intervene in the raising of a child, it is in furtherance of an articulated compelling state interest, and thus in the name of state action. Deaf World advocates are suggesting intervention not as state actors, but as a private interest group. The state interest at issue could only be the preservation of Deaf Culture based on non-oral communication. However that decision turns completely on the determination that non-oral communication is something that the state would want to support. Compared to the general consensus that the state has an interest in the well being and safety of its youngest citizens, the support for Deaf Culture as the desired alternative to oral communication is one that does not have the broad based support necessary to justify judicial interference with parental choice.

Undaunted, Deaf Culturalists notice that a common thread in the cases supporting children's rights has been an implied or overt conflict of interest between the parent and the child. The entire basis of parental deference is the belief that the parent is the authority most suited to ascertain and act in their children's best interests. When that paradigm seems to break down (in a messy divorce, in an abortion situation) the courts have been much more willing to step in.

The potential for conflict would arise if hearing parents are seen to be favoring cochlear implants simply because of their discomfort with interacting with a deaf child. Deaf World advocates argue that such selfish discomfort is the main reason parents choose oral communication strategies. They suggest that that parental

decision making process in regards to implantation is "ill-informed, ill-prepared, ill-advised, ill-founded, and ill-fated."[58] Deaf World advocates claim that parents are *unable* to understand the circumstance of a deaf child. They suggest that trying to make deaf child "hear" is like trying to make a black child white.[59] Without being fully educated about, or amenable to, the opportunity for a life within the Deaf World, hearing parents are said to disadvantage their children. Parents are said to be unqualified to make the decision for their children because of their own self interest. They want to keep their children in the hearing community to which they belong, disadvantaging their deaf offspring. The argument that "in the broadest sense, a human being, hearing or deaf, is better off having rich, meaningful, and satisfying dialogues with only 100 individuals than to have superficial, parrot like, and stifled dialogues with 10 million individuals" suggests that the court should intervene in the parent's decision.[60]

Even if a court was willing to recognize a conflict of interest between hearing parent and deaf child, the Deaf World argument suffers from a fatally problematic legal hurdle. If there is a conflict, who should be in charge of settling that dispute? Deaf Culturalists argue that Deaf Culture, as a community, is qualified to represent the best interest of the deaf child. The suggestion that an entire minority community is in a better position to know what is in the best interest of any individual child is not persuasive.

First of all, the deaf community is hardly unified on the issue of cochlear implants.[61] Even before implants were approved, millions of deaf people around the world opted for hearing aids and various training in oral communication. If being deaf is some kind of birthright that irrevocably puts you into a community, than certainly the views of these deaf individuals should count for something. For the purposes of the cochlear

[58] Who's Child Is This, Hearing Health (May 1993) *Larry Fleischer.*
[59] The Mask of Benevolence. *Harlan Lane.*
[60] Who's Child Is This, Hearing Health (May 1993) *Larry Fleischer.*
[61] Defiantly Deaf, N.Y. Times, Aug. 28, (1994). *Andrew Solomon.*

implant debate, it seems that the only deaf voices that are supposed to count are the ones whom believe in non-oral communication. In his book on this point, Harlan Lane places a lot of emphasis on one survey that found that 86% of deaf individuals would not want an implant. He suggests that this proves that deaf children would not opt for implants given the choice, and an inherent conflict between the children and their parents.[62] This is exactly the kind of statistic that has no legal or moral relevance. What is at issue is not the percentage of adults who have become comfortable with being deaf. The issue is that it is nearly impossible to pinpoint a community that can or should have the legal standing to oppose the views of a parent.

Should a court find that some particular sector of the deaf community has standing on this issue, the decision would be a radical legal departure. It would open the door wide for all sorts of "communities" defined by their shared political point of view to claim standing in issues of personal and private decision making.[63] The suggestion would be that a deaf person is more of a "parent" then the biological progenitor of the child.[64] A state imposed deaf advocate that could supersede a parent's fundamental child rearing decision simply has no analogy in American jurisprudence.

Should we want to recognize a conflict of interests between parent and child, we would have to do so on the grounds of compelling state interest. The government, acting out of the best interests of the entire community, is the only authority that has the right to step in and frustrate the will of parents. Once one recognizes the need for state interest in order to justify intervention, the conflict of interest argument basically collapses upon itself. Whatever conflict there might be between parent and child, it would not rise to the level necessary to trigger state intervention on behalf of the child. This would be so whether you felt that deafness was an infirmity that should be eradicated, or a cultural difference that should be preserved.

[62] The Mask of Benevolence. *Harlan Lane.*

[63] We see these kind of arguments advanced by certain African-American activists, seeking to enjoin white parents from adopting black children.

[64] Defiantly Deaf, N.Y. Times, Aug. 28, (1994). *Andrew Solomon.*

If deafness is an infirmity than there is no potential for a conflict of interest between a deaf child and a parent who chooses the best available technology to help that child. If deafness is a cultural difference then any potential conflict would exist not between the parent and child, but between the parents and the state. The state would have to step in a deny parents their traditional rights in the interest of preserving the deaf community. Alternatively the state would step in to prevent harm and "needless surgery" on otherwise healthy children. Again, whether the child would want to be deaf, or if being deaf is in the best interest of the child would not be the issue. Rather the determination would be that the Deaf World is a culture that is under attack from cochlear implants, and that the state has to step any and preserve this cultural difference.[65]

Exploiting the judiciary's willingness to act where there is a conflict between parent and child simply does not take Deaf World advocates to where they want to go. Their legal argument cannot get away from a fundamental state determination as to the nature of deafness. Without finding that hearing impairment is a classification that should be immutable because of the great societal value in having a hearing impaired community, it is hard to see how a court could interfere with parental choice. The judiciary would basically have to elevate the Deaf World to an above the law status that no other community enjoys.

Put simply, it is highly unlikely that an American court would ever find a state interest strong enough to trump the long standing tradition of parental deference on this issue. To this point there has not even been a judicial mandate that requires doctors to fully inform parents of non-implant options. No attempt has ever been legally made to force parents to even consider the non-oral option if they do not wish to do so.

[65]Lane's analogy here is to religion, where at a certain age the child chooses which religion (if any) to associate with. It is worth noting however that even in the religious context, parents are allowed to have their children baptized or can force them to go to conformation classes or have a Bar-Mitzvah.

FDA in the Center

It is perhaps a tacit and unspoken acknowledgment to these considerable judicial hurdles that the Deaf World has focused the main of their efforts not towards bringing "test cases" in court, but on lobbying the Food and Drug Administration. Focusing on the FDA allows advocates to center their argument on simplified, ethical grounds. The thrust of the lobbying has claimed that there is relevant medical uncertainty about the effectiveness of the technology, and that it is unethical to operate on a healthy child.[66]

The medical effectiveness argument is easily disposable from the FDA's perspective. This technology has undergone the most rigorous testing and approval process that the agency has to offer. To revoke the cochlear implant on medical effectiveness grounds would call into question many approved products. The ethical concerns are more difficult to dispense with. If the FDA feels that the Deaf World is a viable alternative, then advocates argue that they have a duty to prevent needles operations on healthy children.[67]

One common response is that the previous viewpoint misapprehends the nature of the FDA's role in our executive structure. It is not for the FDA to decide what is morally or ethically acceptable. The agency's pivotal role is to determine if a product is safe for human use. Such a response however, oversimplifies the FDA's role. There are many instances where the agency authorizes or rejects a product not simply based on the hard science of the potential effects on human health. The FDA engages in risk management techniques where it attempts to balance the potential risks of a product against its proposed usefulness.[68] If the agency truly felt that Deaf Culture was an acceptable alternative it might not approve implants for children, and

[66] The Mask of Benevolence. *Harlan Lane.*

[67] Defiantly Deaf, N.Y. Times, Aug. 28, (1994). *Andrew Solomon.*

[68] Pesticide regulation is an example where the FDA approves products that are clearly dangerous because of the societal good they do in terms of bigger crops for farmers and cheaper prices for consumers. While the FDA tries to mitigate the health risks from these products, it does allow for a certain level of danger that it finds acceptable.

certainly wouldn't lower the age minimum further and further. The fact is that the FDA does make a determination as to the ethics of cochlear implants.

That determination is that cochlear implants are important because hearing impairment is a disability that can be ameliorated. Both sides in this debate believe that language acquisition is of vital import to the lives of children.[69] In this way both sides believe that being born deaf, or losing hearing at a very young age, is poses a problem that needs to be overcome. The FDA is comfortable labeling this problem a "disability" and cochlear implants are but one of many medical aids that the FDA has authorized for patients to use in order to overcome that disability. While the FDA makes no statement concerning whether parents should choose cochlear implants as the best treatment option, they do recognize that the implant is an option that is a safe and effective given their interpretation of the medical problem at issue. This is an ethical choice made by the FDA based on the agency's judgment of the societal benefit of the technology.

[69] Culture and Cochlear Implants. *John Niparko.*

Conclusion

The cochlear implant is one of the more intriguing technologies that the FDA regulates. It terms of its medical effectiveness, the device is truly revolutionary. Before this technology hearing impaired individuals were consigned to amplification devices that ameliorated only some of the symptoms of deafness, and did nothing towards the actual causes. This technology has the promise to actually cure hearing impairment and allow people to hear sounds and tones that were previously impossible to duplicate.

The impact on language acquisition arguably the most exciting aspect about the device. Communication is no longer bound to sign language and lip reading, even for profoundly deaf individuals. For children who are born, or become, both deaf and blind oral communication is vital to their ability to interact with the world. The emerging evidence from children that were implanted young and are now entering their teens is that these children will be able to compete on par with normal hearing peers in any and every endeavor that they choose. As our social awareness of hearing impairment increases, the possibilities for full mainstreaming for the hearing impaired seem closer now than ever.

What the hearing world view as possibilities, the Deaf World sees as a threat. They worry about the marginalization of their culture and retrenchment on the gains made in bringing American Sign Language to the point of a bona fide alternative mode of communication. They see being deaf as a ethnicity, not a condition, and they view this grand new technology as a mechanism for destroying that ethnic group.

In a sense the debate over cochlear implants is a real world, modern day application of the debates that have raged in science fiction novels and intellectual "thought experiments" for years.[70] Where is the line between correcting hearing impairment and enhancing normal hearing? Is there a difference between allowing a par-

[70] One of Advanced Bionics most popular implants is named "The Bionic Ear."

ent to improve their child's hearing and changing their child's pigmentation? How we answer these questions will go a long way towards determining the shape of this century.

I think that a line can be drawn between the cochlear implant and other possible forms of eugenics. Communication is an essential part of the human experience and our society is reliant upon oral communication. The cochlear implant hopes to give children the ability to speak. Whether its being able to participate in class, or order fast food, that ability is vital. This intent can be contrasted with other technologies whose goal is to increase human performance beyond normal capacities or allow parents to have "boutique babies." The distinction between a remedial device meant to correct a problem and an enhancement device meant to tinker with normal functions should result in the continued development of technologies like cochlear implants without destroying the differences that make each person unique.

I think that it is also a distinction that the FDA can follow, and in a sense already adheres to. There is a reasonable moral and political argument that can justify the implantation of an infant so that she may achieve a level of normal hearing. Will there be as persuasive an argument for a parent who wants to give their child hawk like vision so that he can see a baseball better than the other kids? There is a usefulness requirement that the FDA is aware of. In Public Citizen v. Young the court upheld the Congressional requirement that the FDA could not list as safe color additives that might cause cancer in humans or even animals.[71] The reasoning behind this affirmation seems to be that court simply viewed color additives as not very important to the social good. Conversely, the same clause at issue in Public Citizen were specifically not applied to pesticides residues under the Food Quality Protection Amendment. Here pesticides served some important social good that color additives did not. As technology continues to expand the limits of what is possible, the legal system in general will have to continue to make distinctions between products based on an interpretation of what are appropriate social goods, and what are not.

[71] Public Citizen v. Young (D.C. Cir. 1987).

Cochlear implants are important social goods because they have the potential to cure deafness. The FDA should continue to deny the entreaties of those who claim that oral communication has no independent social value. Furthermore the agency should take a look at just how far the technology has come, and make sure that its approval process is in keeping with the development of the technology.