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Commentary

The Controversial Beginnings of Neurotology: William F. House's Struggles as a Medical Innovator

This past year, I had the honor of helping Dr. William House prepare his memoir, *The Struggles of a Medical Innovator: Cochlear Implants and Other Ear Surgeries* (1). This brought back my own memories of how controversial the cochlear implant was during the early years of Bill House's clinical program. I and other members of that early cochlear implant team, as well as Dr. House, were literally yelled at when presenting at meetings. Although I hate to admit it, one prominent pediatric otolaryngologist made me cry—primarily with frustration—when, after looking only briefly at one of our scientific posters, he clearly implied that we must be lying. I thought, "Why aren't these people excited about this new possibility of restoring hearing to the deaf?" Instead of examining the data, or even asking to test patients for themselves, they simply proclaimed it unethical and most certainly impossible to get any "worthwhile" benefits.

Although I had personally experienced the opposition of professionals in otology, speech and hearing, deaf education, and the deaf community to the cochlear implant, my work on Dr. House's memoir led to a much greater awareness of how much opposition he had faced throughout his career when trying to introduce new ideas to the medical field. Starting when he was a dentist in the Navy, through his otolaryngology residency at Los Angeles County Hospital, during his early years in otology practice and even after he was a highly respected otologist, William House was constantly mired in controversy for his attempts to introduce new procedures that he thought would help patients.

Both Howard House and William House used to quote a favorite saying of their father, Milus House, D.D.S., "If you're not up on something, you're down on it." One can certainly see this flaw of human nature at work when reading Bill House's memories of how the introduction of some of his procedures "went down" with professional colleagues. I think it might be worthwhile to review some of this history. Perhaps it can encourage us to be more open-minded regarding new ideas and remind us that sometimes we need the perspective of time before judging the potential impact of such ideas.

It is not the purpose of this commentary to "glorify" William House or his work—I am not an otologist and could not begin to know the value of any individual procedure he introduced. Yet, there is no doubt that he was a giant in his field and is often referred to as the "Father of Neurotology." Many of the younger otolaryngology and speech and hearing professionals today may not realize how controversial each one of Dr. House's new otologic and neurotologic procedures was, given that most became standard of practice. His book is a reminder of how stubborn a profession can be when new ideas are introduced. One purpose of this commentary is to have us reflect on an era of great change in the hearing professions and realize what it takes, and what type of person it takes, to make that happen.

First I present some brief examples from Dr. House's memoir, which illustrate some of his major contributions to otology/neurotology and the criticisms he faced each time he introduced a novel approach to an otologic problem. These are presented in the same order with which he addresses them in his book—roughly chronological, although he "worked on different problems not in series but in parallel" (1, p. xi). These brief examples are followed by a more lengthy section on cochlear implants, by far the most controversial of his "new ideas," and the one with which I have the most first-hand experience. This section goes well beyond Dr. House's memoir in reviewing the nature of the controversies associated with implants and the responses to them. But it is hoped that this will make readers, especially those not around in the "early days," more aware of what someone like William House faced in trying to introduce a radical new idea, as well as the long-term consequences of this early opposition.

Ear Microsurgery

After brother Howard bought a Zeiss microscope and Bill first looked through it at a temporal bone, he recognized its potential to revolutionize otology. It was 1956. He reports that, during his first 2 years of practice, he performed a large number of microsurgical ear operations. He remembers that some of Howard's students and visitors were "aghast at such a 'reckless' technique," and several actually told him that they could not understand why a young man with good eyesight needed a microscope just to drill out the mastoid. Eventually, his superior results won the day.

The need to teach others regarding microsurgery led him to seek out an engineer who could make an observer tube for the microscope, which would provide an image that was not upside-down and backward to the surgeon's view, as was the device available at the time. After being turned down by several optical companies because they thought that the product demand would not justify the effort, he found Jack Urban, who, as we all know, ended up being a major contributor to surgical otology through his development of surgical instruments, many in conjunction with

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William House. Jack charged $500 for the work, and that was the last fee that he ever charged Bill House. This innovation, along with the camera system that Jack developed for the operating microscope, led to a temporal bone surgery training facility that was later duplicated by many centers around the world. Jack Urban estimated that it took 2 years from the time that he and Bill House developed something for it to come into widespread clinical use.

Otosclerosis and the Middle Fossa Approach

When William House determined the need to get to the internal auditory canal (IAC) without doing damage to the cochlea or the facial nerve, he began a series of dissections in the morgue that led him to what became known as the middle fossa approach. He first did this hoping that decompression of the cochlear nerve at the IAC in advanced otosclerosis might provide some restoration of hearing. None of the 3 patients in whom he performed this procedure regained hearing, but he presented the cases anyway at an otosclerosis symposium in 1959. He noted his failure to restore hearing but thought that the approach could have other important uses. After he showed a slide of the incision with the patient's head oriented for the surgeon sitting at the head of the table, a discussant stated that it was the first time he had seen a patient operated on upside-down. The audience laughed, and Bill House reports feeling crushed. Another discussant called it "ruthless human vivisection." He tells us that this criticism actually affected his willingness to report on some of his other early work, such as cochlear implants. Even today, it is relatively uncommon for an article to be presented or published in which the author describes failure of a procedure he or she has developed. William House, like other great leaders in a field, was not above acknowledging his failures and learning from them.

"Chronic Ear" and the Facial Recess Approach

> "In 1956, we were entering a complete reappraisal of thinking about management of ear infection ("chronic ear") in light of antibiotics, the application of microsurgery, and the use of dental drills and irrigation suction instead of hammer and chisel for the removal of infected mastoid bone. It was obvious to me that we should now think about cure of the infection rather than just incision and drainage as was the principal of radical mastoid surgery."
>
> William House (1, p. 42)

As Bill House worked on this problem, he came to think that a procedure in which the canal wall could be left intact was necessary. This led him to develop what he called the facial recess approach. The first time he presented this approach at an American Otologic Society meeting in about 1963, a discussant asked what was wrong with the old radical mastoid, and many in the audience cheered. Again, however, he continued his work to improve chronic ear surgery, and others soon jumped in. The facial recess approach turned out to be extremely useful for other purposes such as cochlear implantation and facial nerve decompression.

In describing his work on the chronic ear problem, Dr. House also tells us about one of his "mistakes." Over time, the grafts used for middle ear reconstruction would retract into the attic and form a new cholesteatoma. He tried to solve this by placing a piece of fine stainless steel mesh in the attic to prevent retraction from occurring. He called this the "iron curtain operation." He says, "To my dismay, the skin retraction still occurred, retracting right through the mesh. Now I had a mass of exposed mesh and cholesteatoma to remove" (1, p. 45). He describes how this problem led him to think about air pressure in the ear and the necessity of preserving or recreating the air passage from the middle ear. This is another example of how Bill House was able to admit to and learn from his errors. Interestingly, the "iron curtain" problem has reappeared in modern medicine, with complications and lawsuits arising from use of such a technique for pelvic floor prolapse.

Ménière's Disease and the Shunt Operation

After his usual work in the morgue, Bill presented his endolymphatic sac "shunt" surgery for Ménière's disease at a meeting. An experienced otologist got up and said that he had never seen a patient in his many years of practice that needed surgery for Ménière's disease. Bill House, of course, had already operated on a patient who had earlier seen that physician and been told to learn to live with the problem. More interesting, perhaps, is the fact that the whole idea of introducing a surgery for Ménière's disease met with resistance from colleagues who thought that adding another surgery just added to the cost of medical care. Because many at that time thought that Ménière's disease was a psychosomatic illness, they thought the only reason that someone would propose surgery was to make money.

Although there is still professional disagreement over whether shunt surgery, in particular, has a valid physiological basis, Bill House's insistence on trying to find a way to help patients experiencing this sometimes debilitating problem opened the door for the development of other surgical approaches. Most of these, although more "destructive" than the shunt procedure, became well accepted.

Acoustic Tumors

William House's work on new approaches for the removal of acoustic tumors (now, of course, known as vestibular schwannomas) is well known in the history of otology and, as usual, was met with considerable opposition. In this case, much of the opposition came from another field, neurosurgery, which thought that otologists were not trained to enter the intracranial areas. Bill House always worked with a neurosurgical cosurgeon. But when he first presented the translabyrinthine approach by TV projection at a course that he and his colleagues gave on acoustic tumor surgery in 1963, the neurosurgeon announced to the audience that he did not agree with the approach and would take no responsibility if the patient died. Luckily, Bill House met Bill Hitselberger, a young neurosurgeon who was much more

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open-minded. Many of you have heard the story told, most often by Howard House, regarding the "showdown" at St. Vincent Hospital in which the staff neurosurgeon attempted to forbid House and Hitselberger from performing acoustic tumor surgery, issuing a "them-or-me" ultimatum at a meeting with the hospital administration and the Sisters of St. Vincent. Howard House stood up and returned the ultimatum to resign if his brother was not allowed to proceed. The committee decided in favor of the Houses, and the neurosurgeon resigned from the hospital staff.

These were a few of William House's contributions to otology that met with considerable initial resistance from others in the field. But once he had established a precedent and shown that the idea had potential, others followed—adding modifications of their own so that, today, there are many variations on these and other related procedures that evolved based on these first steps.

COCHLEAR IMPLANTS

Cochlear implants are now an accepted form of rehabilitation for an ever-expanding selection of deaf individuals. Energies are currently focused on making improvements in the hardware and software and extending the use of cochlear implants to a greater variety of patients. But, the road from idea to practical clinical application was not smooth. I would like to repeat here some history that Dr. House and I wrote about in an earlier publication, describing the nature of the attitudes toward and controversies over cochlear implants (2). The original publication on this topic was in chronological order by decades—the 60s, 70s, and 80s—and I have tried to follow that theme here. I will also include a few "tidbits" from Dr. House's memoir regarding his personal experiences of criticism and his fight to win acceptance of the idea of using electrical stimulation to restore hearing to the deaf.

Early Years—the 1960s

In addition to William House, Robin Michelson at the University of California, San Francisco, and Blair Simmons at Stanford were actively pursuing both animal and human research on cochlear implantation in the 1960s. Simmons later wrote:

> "While skepticism engendered by claimed miracles is healthy, outright denial that a genuine research problem exists is not. While my 1964–65 experiments were in progress I contacted at least six of the most prominent researchers in speech coding and others in auditory psychophysics. None of these persons were willing or interested in suggesting experiments which might have helped define speech coding strategies for the future. I got a distinct impression, perhaps colored by a little personal paranoia after the first few rejections, that most everyone was either incapable of thinking about the many problems involved or would rather not risk tainting their scientific careers. I do not believe this problem has disappeared completely in the subsequent 20 years" (3, p. 4).

Dr. House describes this same experience. First, he went to a leading authority on the physiology and electrophysiology of hearing, Hallowell Davis, who said that he did not believe in what Bill House was doing and could not actively work with him because it would stain his reputation. He suggested instead that some information might be gained by approaching people at cocktail parties and asking questions. Merle Lawrence, an expert who performed animal studies of the cochlea and hearing nerve, told him that the work with cochlear implants was useless because the inner ear and hearing nerve in deaf people were deteriorating and would be further destroyed by electrical stimulation. Hal Schucknect in Boston, a world authority on pathology of the ear, simply told him that what he, William House, was attempting could only be accomplished if he had a team of neuroanatomists, neurophysiologists, electrical engineers, and lots of money. In other words, all of the experts he approached gave him reasons why he could not succeed but did not offer advice that might help. Even the president of the Deafness Research Foundation at the time made it clear that they would not provide grant money for that type of research because being associated with such "off-the-wall" human experiments would stain the Foundation's reputation.

A practical limitation led to delaying much more clinical investigation until the end of the 1960s and that was the lack of availability of biocompatible insulating materials. After the development of such materials for pacemakers, electrode brain implants in animals, hydrocephalus implants, and so on, Dr. House was ready to start his cochlear implant work again.

Beginning the Clinical Era—the 1970s

By the 1970s, critics of the implant work said "it won't work," "it's not perfect so we shouldn't use it," "it will destroy the auditory system and won't continue to work in the long run," and so on. Despite this, William House and his team proceeded to develop complete clinical programs for implantation, including development of materials and methods for device fitting, rehabilitation, and assessment.

In 1973, the American Otological Society meeting held a session on cochlear implants. Printed by the journal as an attachment to the House and Urban article are discussion comments by others present at the meeting (4).

Dr. Merzenich of the San Francisco group made the following comment:

> "Dr. Kiang's remarks suggest little or no discriminative hearing can be generated from a single electrode pair. However, it should be pointed out that these subjects do have some discriminative hearing in the sense that small differences in stimulus frequency can be detected. And subjects describe sounds which they hear as 'tones.' This must be faced up to and explained" (4, p. 13).

Dr. William House said:

> "Now, what are our goals?…Well, let us take the example of a patient who has no leg. Shall I wait until our tissue transplantation has progressed far enough that I

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> can transplant a leg on him that will work as well as yours and mine or shall I offer him a peg or a wooden leg? I shall offer him a peg or wooden leg and that is where we are at this point in our cochlear implant work. We are entering a new era of otology. For the past thirty years we have been in the conductive hearing loss era…but we are now entering the era of the sensory hearing loss…I believe we, as doctors, should meet this challenge and form groups all around the world, groups of engineers, otologists, rehabilitation experts and anybody who has anything to offer, who will study this problem intensively. …If we do not do this, we shall have been remiss in our efforts as otologists" (4, p. 14).

Finally, the last discussant, Dr. Dobelle said:

> "I cheerfully confess that I do not know why stimulation of the auditory cortex results in subjective sensations of sound, Dr. Kiang. However, I agree with Dr. William House's approach. If such stimulation results in the sensation of sound—and it certainly does—I will be delighted to take advantage of the phenomenon even if I do not understand the underlying physiological mechanisms…If it works, I will take it. Auditory physiologists…can then try to explain why" (4, p. 14).

A few months after the American Otologic meeting, a conference was held titled, "The First International Conference on Electrical Stimulation of the Acoustic Nerve as a Treatment for Profound Sensorineural Deafness in Man." In the foreword to the printed proceedings published in 1974, it states that the purpose of the conference was "To demonstrate to the scientific and otolaryngologic community the very marked limitations of the present devices (essentially only sound perception)" and "Their [Michelson and Merzenich's] work also suggested that the remaining obstacles to a practical implant, namely; multiple electrodes, multi-channel receivers, etc. could be solved in a relatively short time using standard neurophysiologic techniques and laboratory animals" (5, p. vii).

In his book, William House recalls that Jack Urban was not invited to participate in this meeting, although other engineers were. He got this omission corrected. At that time, Jack was one of a very few engineers who had actually produced an electrode system for implantation in humans, developed a complex electrical generator box to provide a wide variety of stimulation patterns, and spent countless hours testing several human subjects.

As an aside, Jack Urban died in 1981. He had devoted his time and the facilities of his company to the development of the "House" cochlear implant at no charge. He is perhaps the single most underacknowledged figure in the history of cochlear implants. Apparently, because this engineer, whose basic cochlear implant design was used in large numbers of profoundly deaf adults and children, was not in an academic setting and/or because he was an unknown to the basic hearing science community, he was never credited with the expertise that he possessed or the contributions he made to the field of cochlear implantation. Jack had a long and admirable history in engineering before beginning his work with William House, but it was primarily in the field of optics, where he performed work for many years for the National Aeronautics and Space Administration. His original, hard-wired, multielectrode implant was used by William House in 1969 to 1970, and Jack tested stimulation schemes not unlike those later used by others in their multielectrode devices. He then took the best of the results and developed the first wearable cochlear implant processor.

Charles "Chuck" Graser, one of these patients tested by Jack Urban, provided the feedback that led to development of that first wearable device and was the first to walk out of the laboratory wearing it. Dr. House took Chuck with him to the 1973 meeting specifically so that participants could talk with him themselves. Chuck was not invited to speak, and according to Dr. House, none of the participants seemed interested in talking to him!

One consequence of the meeting was a view that multichannel devices were "just around the corner" and that implantation of single-electrode cochlear implants should be stopped because they would never provide full speech discrimination. In fact, many seemed to think that it had already been demonstrated that multiple-electrode implants were the only practical approach. Keep in mind that, at this time, there were only a few patients using single-electrode implants and none using multielectrode stimulation.

The second attitude was that only animal work was needed to solve the major problems. This perspective fueled the controversy over human implantation. Third, a judgment was made by scientists and professionals with normal hearing that the benefits demonstrated at that time were of little value, i.e., "only sound perception." This theme recurred frequently—that anything less than provision of true speech discrimination is not worthwhile or, at least, not worth the risks of surgery. However, those of us who had actually worked with or spoken to patients receiving these early single-electrode cochlear implants knew that this was far from true. I personally did my master's thesis on the importance of human contact with the environment through hearing, which included research testing of some of the House single-electrode implant patients. And it was obvious that the improvements in speechreading ability provided by those early devices made a substantial difference in quality of life to our deaf patients. Dr. House's memoir contains a chapter with excerpts from letters written to him in 1981 by 82 patients from around the country who had the House single-electrode cochlear implant (some were patients of coinvestigators and had not met Dr. House). Read these and tell me that these patients were not benefiting significantly from their implants.

In the mid 1970s, the National Institutes of Health (NIH) sponsored an independent evaluation of the patients then implanted with single-electrode implants. How did this come about? Dr. House recalls that after his daughter, Karen House, filmed the reactions of a young congenitally deaf woman on first stimulation and it got shown on the Barbara Walters show as Drs. Howard and William House were being interviewed, a number of people called their congressmen and asked what NIH was

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doing regarding this new breakthrough. Howard and Bill were "summoned" to Washington for a meeting with the Secretary of Health, Education, and Welfare, who then turned to the head of NIH at the time and asked him to look into it and provide a report on the findings. In his memoir, Bill House gives us a feeling for what the atmosphere was like surrounding the consequent meetings and the NIH-sponsored study. It was not friendly.

The results of the study of 11 subjects using the House-Urban implant and 2 subjects using the Michelson device were published in 1977 as a journal supplement, often referred to as the "Bilger report" or "the Pittsburgh study" (6). The study generally confirmed the clinical findings that had been reported by the implanting clinics: the implant provided detection of sound over the entire frequency range, patients could identify environmental sounds, speechreading was improved with the implant on, patients could better monitor their own speech productions, and patients thought their quality of life was improved.

From the perspective of history, it is interesting that these positive findings took a backseat publicly to 2 "negative" findings, which were widely cited by implant critics. First, implant patients were bothered by noise. In particular, they found traffic noise bothersome when in an automobile on the freeway. How surprising—a hearing-impaired listener is bothered by noise! Yet, some professionals argued that the noise problem was a function of "1-channel" listening. Second, increased postural instability on one or more measures, as measured by a posturography platform (a new device at the time), was reported to occur with stimulation from the implant (although none of the patients noted any clinical vestibular symptoms on implant use). Those who cited this finding typically failed to point out that there were multiple measures in the study and that there was also *improved* stability on one or more measures in all patients. Later studies found no evidence for increased postural instability, and this issue has long since disappeared.

Even this first "independent" study of implanted subjects was influenced by the attitude of the times. In an overview of the study, the authors discuss the study design:

> "The psychoacoustic protocol was designed primarily to specify the nature of auditory discriminations possible with present-day auditory prostheses and did not stress tasks that would require the subjects to provide an absolute identification of the stimulus (e.g., repeat the word), since it is well-accepted that subjects using auditory prostheses cannot understand speech with them" (6, p. 4).

They go on to say, "Above all, a single channel auditory input will not provide a speech input that either sounds speech-like or is understandable" (6, p. 4). Although the number of subjects who had cochlear implants at the time was very small, and speech recognition was not actually tested, this study continued to fuel the existing assumption that no speech understanding was possible with any single-"channel" device (which inappropriately took on the meaning, "single-electrode device"). Work with more patients and a variety of single-electrode devices has shown that this assumption was not entirely accurate (e.g., Hochmair-Desoyer et al. [7] and Berliner et al. [8]).

Use of the term *channel* was introduced to the cochlear implant field in the Bilger report by those who made analogy to information processing theory. It was assumed that 1 electrode was analogous to 1 channel and that, therefore, performance expectations for a single-electrode device could be based on what was known about the capacity of 1 channel. Yet, it is not really self-evident that a single wire equates to a single channel in the information processing theory sense. In the normal ear, we have only 1 tympanic membrane, 1 set of ossicles, and 1 oval window membrane. Yet, each of these elements along the sound reception pathway is able to receive and pass on complex signals. It may or may not be possible for an electrical stimulus presented on a single wire to maintain a significant level of complexity, but because of the assumption behind use of a specific term, *single channel*, this possibility has gone unexplored.

Unfortunately, the historical prejudice regarding this topic (open-set speech recognition with single-electrode implants) has remained so strong that there has been little acknowledgment or use of the findings that some patients had considerable open-set discrimination with a single-electrode device (Dr. House provides some data on 3 long-term House implant users in the Appendix of his book). This is truly lamentable because scientific curiosity should, at the least, lead us to wonder how we can fit theory to the facts and explain the phenomenon. The belief that single-electrode cochlear implants could not provide speech discrimination had lasting effects on device development. It greatly narrowed the perspective of workers in this field and excluded from pursuit many possible approaches to signal processing.

One common attitude at the time is represented by this statement: "An experimental neurophysiological study-addressed itself specifically to the problem of the handicap of patients with single-wire prostheses" (9, p. 11). Some, particularly the scientists, compared the less-than-perfect hearing provided by the implant to normal hearing and perceived the "handicap." Others, particularly those clinicians working with the implant and profoundly deaf patients, compared implant performance to deafness and perceived the benefits. These contrasting perspectives, I believe, were a major part of the barrier to understanding that seemed to exist between these 2 communities.

Of course, not everyone had a negative attitude toward the idea of cochlear implantation, as exemplified by Ralph Naunton, M.D.:

> "Once in a great while our surgical specialties can point to a single dramatic advance in surgical technique, outshining in importance all other developments in the area. Such a revolutionary advance is now taking place in otolaryngology, an advance offering for the first time a means of improving the communicative abilities of postlingually profoundly deaf subjects" (10, pp. 33,35).

Given the atmosphere at the time, Dr. House was afraid that it might be a long time before he could get otologists

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in the United States on board with cochlear implants or that the NIH or other organizations might try to get the program shut down (some members of the Pittsburgh grant research team expressed feeling great pressure to report negative findings). Therefore, the first implant course given by Dr. House and his staff in 1977 was for international surgeons and their teams. He hoped that some progress could be made in other parts of the world if not here. Many of those who attended did start cochlear implant programs, and some even developed their own devices to use. Most certainly, this was the start of a worldwide effort that greatly expanded the research on this topic and made cochlear implant devices available to deaf patients in many countries.

In 1979, Dr. House and his implant team gave another cochlear implant training course. This time, a select group of otologists from within the United States was invited to become coinvestigators in a multicenter study of the House cochlear implant in adults. They were required to bring with them to the training course a complete cochlear implant team, including an audiologist and a psychologist. The pattern set by this course and its requirement for a multidisciplinary cochlear implant team has continued to dominate the clinical approach to cochlear implantation. In addition, this was the start of what was probably the first major clinical trial in otology. The next year, the U.S. Food and Drug Administration (FDA) medical device regulations went into effect and we submitted an Investigational Device Exemption (IDE) application, which was approved.

Practical Clinical Application—the 1980s

Although there was continued controversy, vigorously renewed by the implantation of children, the 1980s brought some level of acceptance. Two major meetings specifically on cochlear implants took place in the first half of the 1980s. The first conference was held in 1982 by the New York Academy of Sciences. The second, held in 1983, was the 10th Anniversary Conference on Cochlear Implants: An International Symposium. Proceedings of both of these meetings were published (11,12). The difference between the Preface to the book resulting from the 10th Anniversary Conference and that from the 1973 Proceedings (see above) illustrates the major change in attitude toward cochlear implants that took place in the early 1980s. This later Preface says:

> "Studies on the development and application of cochlear implants represent an exciting, unprecedented multidisciplinary endeavor in otolaryngology…It is clear that the current generation of cochlear implants are of benefit to carefully selected deaf individuals. It is likely that future cochlear implant devices, particularly those that have multichannel capabilities, will provide substantially greater benefit. Cochlear implants are rapidly becoming a major treatment modality for the deaf…" (12, p. v).

The House/3M cochlear implant had a significant impact in the treatment of the profoundly deaf, even while in the investigational stage (13). Patients previously turned away as "untreatable" were provided with a new option. Furthermore, the professionals—otologists and audiologists—had a new set of tools, including assessment and rehabilitation materials, to use in dealing with profoundly deaf patients. These patients could now be provided more effective care whether they obtained an implant or a hearing aid. Finally, the introduction of this device stimulated (no pun intended) the development of better devices, better assessment tools, and other alternatives.

But William House's implantation of children beginning in 1980 did ignite another firestorm. In a 1984 news magazine article, a well-known pediatric otolaryngologist was interviewed on the topic of cochlear implants in children. Here's what the magazine reported that he said:

> "There is no moral justification for an invasive electrode for children."…Speaking for himself, he says he finds the cochlear implant a costly and "cruel incentive," designed to appeal to conscientious parents who may seek any means that will enable their children to hear. "It's a toboggan ride for those parents, and at the end of the ride is only a deep depression—and you may hurt the kid." (14, p. 34).

In November 1984, the FDA announced on national television a premarket approval for the 3M/House Cochlear Implant in adults as the first medical device to replace a human sense. And, despite the criticisms, FDA had granted an IDE for clinical trials of the 3M/House implant in children. Although it is not well known, the FDA advisory panel did also eventually recommend to FDA that the device be approved for use in children aged 2 to 17 years. However, rights for the device were sold by 3M to Cochlear Corporation, and the final conditions for approval were never pursued.

Impact of the FDA

The Medical Device Amendments to the Food, Drug and Cosmetic Act in the United States gave the FDA authority to regulate new medical devices. The law basically required that safety and efficacy be adequately demonstrated through clinical investigations before a device such as the cochlear implant could be marketed. Specific regulations were published in January 1980 to go into effect near the end of that year. The FDA regulations had an impact that I think many in the professional and scientific communities failed to appreciate, at least at the time.

To use a device at all in human subjects required submission of an IDE application for approval by FDA. The purpose of an IDE study, from the perspective of the FDA, is to gather clinical data on safety and efficacy to eventually be submitted for review for marketing approval by FDA. That is, implicit in the process is the goal of large-scale clinical trials in human subjects to eventually result in commercial marketing. This added, perhaps, a different perspective than that held by the research community. Yet, it was necessary to proceed at all with cochlear implant research or development of any scale.

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The IDE had to include a detailed protocol for gathering the safety and efficacy data. This protocol could be changed, but doing so required formal submissions and the consequent time lags to approval. Once a study had been underway for some time, changing the protocol would produce a significant setback in compilation of consistent data to submit for required reports and for marketing approval. That is, it became impractical to change the assessment measures that one was using every time a new measure had become available and had garnered popular endorsement.

During the FDA-approved clinical trial, use of an investigational device was limited to a small number of approved sites, but such use could not continue indefinitely on an investigational basis. That is, the very nature of the regulations required an eventual move to make the device generally available for use by the professional public, something that did not go over well with many critics of cochlear implants.

Lastly, large-scale clinical trials require staff such as regulatory personnel, clinical specialists to maintain data and ensure adherence to protocol, and a team to train and support investigators. They further require extensive data handling and analysis, report writing, and travel for meetings with investigators and FDA. In other words, clinical trials are expensive. Moreover, the more patients who have been included in the clinical trials, the more patient needs become the time-consuming priority. Thus, performing appropriate FDA-approved clinical trials may deplete resources (both time and money) to the extent that other questions of "mere" scientific curiosity must go unexplored or must be delayed.

The IDE regulations did encourage the use of multicenter clinical trials, a rather unique approach in otology. In the case of cochlear implants, this involvement of a number of different centers helped to lend considerable credibility to the claimed results. And, of course, it makes a new device more geographically accessible to patients than if only 1 investigational site is involved.

HISTORICAL CYCLES

Probably typical of most new innovations in medicine, the cochlear implant passed through several stages with regard to prevailing attitudes. The cycle is repeated with each foray into a new dimension of the problem.

When Dr. House began cochlear implantation in human adult subjects, it was considered highly unacceptable by large numbers of the scientific and professional communities. When it became clear that cochlear implants were not going to simply fade out of the picture, that some patients were undoubtedly benefiting, and that newer devices would eventually become available, the attitude changed, albeit gradually, to one of acceptance. This whole cycle started again with the first implantation of children.

As active members of a professional or scientific community, we are often called on to voice our opinions on new ideas or practices in medicine. Our frailty is that once we have taken a highly visible public position on an issue, we are hesitant to concede a change in opinion. In the arena of cochlear implants, the introduction of newer, more complex devices provided a mechanism for "cognitive dissonance reduction" and a public rationale for a change in perspective. Thus, although most of the original concerns regarding damage to the auditory system, long-term effectiveness, growth and development in children, and so on were at least as relevant for new devices as for the "old" devices, these concerns were suddenly pushed aside in a new wave of acceptance.

In this cycle, we tend to forget that innovation does not often leapfrog directly to the ultimate answer. Without the steady, daily work of starting with the first step, in this case, the single-electrode cochlear implant, and developing the clinical application (e.g., selection criteria, equipment and procedures for fitting and adjusting the device, rehabilitation techniques, patient information brochures, professional training materials and courses), we would not have the present "state of the art." Dr. William House put great emphasis on these "ancillary" aspects, hiring almost immediately an audiologist to develop a testing and rehabilitation program and using consulting clinical psychologists. When he began to think about implanting children, he expanded the professions involved to include speech/language pathologists and educators of the deaf. This was, in itself, a rather unique contribution to otology—the multidisciplinary approach to what might have been seen by physicians as a "medical" problem.

Because of the mechanism of change in attitude, there is often little acknowledgment of the possible continued need for the "old" along with the "new." As Dr. Michael Glasscock noted in his recent Letter to the Editor in this journal, there is still an important niche for a simple-to-use, simple-to-set-and-adjust, affordable cochlear implant device for millions of deaf individuals around the world (15).

William House intentionally never patented his idea for the cochlear implant or any of his other innovations. He thought that doing so might restrict others in pursuing this promising lead in the conquest of deafness. He says in his memoir that he does not regret this decision, although had he obtained a fundamental patent on cochlear implants, he might be a little richer today.

DISCUSSION

Times have changed, perhaps making it more difficult for the current generation of physicians to engage in the innovative types of clinical research undertaken by Dr. House and others of his era. Regulatory requirements, the shift from private funding to government grant funding with all of its associated rules, timelines and paperwork, and, of course, the litigious atmosphere in modern medicine all conspire to make truly novel approaches to patient care difficult to develop and apply clinically unless you are part of a large, well-funded research facility. Some of the things Bill House and others at the time did might even be considered unethical by today's standards. But aside from

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these external factors are the "internal" things that make someone like Bill House able to have such a huge impact in his field. He is a creative thinker with a self-assured stubborn personality but is able and willing to listen to others, admit and learn from mistakes, and always keep the good of his patients in mind. He clearly thought that a good idea was a good idea whether it was his or someone else's. His history also shows us that advancements may not always be a matter of being "right" but of taking the first step.

From my own experience working with Bill House, he is an exceptionally unpretentious and unselfish person. He was an active participant in every aspect of the cochlear implant program. He hired specialists but wanted to know and understand everything they were doing. For example, he wanted to know about the psychological tests that were being administered to the adult implant patients. Because I was the one giving the tests, he asked me to test him, and I did so. He would get many invitations to speak regarding cochlear implants at meetings or to write articles for publication, and he passed on some of these opportunities to me and others. He never insisted on being first author on an article.

Both Bill and Howard House believed in sharing their knowledge and insights and in training others so that new procedures would be more widely available to patients across the United States and worldwide. To this end, they offered temporal bone surgical dissection courses, started a clinical fellowship program in otology, and opened the doors of their practices and research institute to visiting physicians and students from all over the world. Nothing was kept "secret." In his book, William House describes "traveling the world." Over the years, he demonstrated surgical procedures or lectured in Australia, Hong Kong, Thailand, India, Nepal, Vietnam, and China as well as, of course, many European and South American countries, thus influencing the practice of otology on a worldwide basis.

Bill House was always happy to teach or give advice to younger colleagues, once saying:

> "To understand the management of any otologic problem, you must continue long-term observation of the patients and do your best to try to help them. This commitment to clinical observation constantly pressures you to face the limitation of the present management of a particular clinical entity and think the problem through. You will be amazed at how this approach leads you to new solutions to difficult cases. Realize there will be criticism, but overcome this by keeping your eye on what you are trying to achieve…The constant challenge to find new solutions to seemingly impossible problems will keep you from the burnout of monotony and make you proud to be a healer" (16).

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