

What Outsiders Tell Us About the Hearing Industry

by Brent Edwards, PhD

By continuing to develop advanced technology, promoting advances to those outside our industry, supporting evidence-based practice and data-driven development—and acknowledging the success that we are achieving in our industry—we will be poised to be one of the most successful fields to work in among all of the medical device industries.

By many measures, the hearing aid industry is doing very well. Total US sales in 2005 were \$2.8 billion, with worldwide numbers presumably near \$8.4 billion (historically, European sales and the sales in the rest of the world each respectively equal the sales numbers in the US).

While market growth has been flat, several major hearing aid companies experienced double-digit growth in revenue last year and several expect to see similar growth this year. The aging Baby Boomers represent a huge surge in the potential market for hearing aids and will likely ensure sustained increases over the next 20 years. Technology continues to be introduced that benefits hearing-impaired individuals, such as wireless integration, nanotechnology applications, and sophisticated computer graphics in fitting software. On top of this positive news, a hearing aid product was named as one of the “most amazing inventions of 2005” by Time Magazine.

So, What’s the Problem?

Despite all of these positive indicators that our industry is healthy and growing, many people outside of our industry still look upon the hearing aid business as if it were small, antiquated, and uninteresting. These outside opinions affect future customers by influencing their opinion of hearing technology and the process of obtaining a hearing aid. It also affects our industry in more subtle ways: Top university graduates may not be attracted to work in our industry, technology innovators may not be interested to contribute to our industry, and high-tech companies may be reluctant to pursue business opportunities in our arena. These influences can only have the effect of dampening the growth potential for dispensing professionals and companies in the hearing aid industry.

As a contrasting example, consider the Apple iPod and the positive effect surrounding it. The iPod is respected and its value acknowledged by those who have never even owned one, increasing the likelihood that a non-user will eventually become an owner. The Apple iTunes-enabling software is one that people have read about and may have downloaded simply to use as a music player.

The practical impact of this is that those people may eventually purchase an iPod because of their positive experience with iTunes. Hundreds of companies are eagerly developing add-on technologies for iPods, improving the user experience and user satisfaction. The positive reputation of the iPod has increased the sales of other Apple products and has benefited Apple in the financial markets. These are all effects that could occur in the hearing aid industry if our reputation outside of the industry improved.

Understanding how those outside our industry (eg, market researchers, medical device companies, venture capitalists, etc) view us can help us improve our outside reputation. At any level, listening to opinions of outsiders is often a way to become reflective about oneself. These opinions may be uninformed but are also unbiased from the narrow view that one has of oneself. Understanding people’s opinions about our industry can help us analyze what we are doing; true or untrue, their opinions can also tell us where we are failing in promoting our industry, our technology, and our image. In the following, I will summarize the primary opinions I have heard in Silicon Valley and across the country, and I will discuss their validity and implication for our industry’s success.

Good Technology Does Not Necessarily Generate New Sales

A comment I have often heard is that dispensing professionals do not choose hearing aids for their patients based on the best technology available; rather, they select hearing aids based on other business-related decisions—including incentives from manufacturers. Good technology, they conclude, has no impact on a product’s sales.

This statement will come as a great surprise to most people reading this. A simple perusal of trade journals or a walk through the convention floor at the American Academy of Audiology provides more than enough evidence that companies are competing fiercely on technology, striving to produce the best in the industry. Every company I’ve worked for has taken pride in developing advanced technology that they knew was crucial to success, and the dispensing professionals I know take great care to ensure that they are providing the greatest benefit they can to meet the needs of their patient.

Outsiders have also noted that many startup hearing device companies, with supposedly superior technology, have either folded or failed to generate the rapid revenue growth that was expected. To many onlookers, this seems to support the notion that leading technology does not generate sales. Experts within the hearing aid industry, however, understand that the reasons for the cited company failures had nothing to do with an industry-wide unwillingness to embrace the best technology. In my opinion, the reasons for the failures of these companies were varied and included implementing the wrong business plan, developing technology that did not have enough benefit to justify user expense, failing to develop good customer care, and simply being so late to market as to turn an innovative technology into a derivative one. In not one case was the cause of their failure due to the inability of leading technology to generate sales.

Poorly analyzed case studies aside, what’s clear is that our industry suffers from an inertia of reputation. Many of these current misconceptions had truth to them over a decade ago but are no longer valid. While these old characterizations have been invalid for years, they still linger among people less familiar with the changes to our industry.

These misconceptions will disappear as our technology continues to advance, with the application of such developments as nanotechnology and wireless technology capturing the interest of those who once shunned our industry as being unsophisticated. This perception of our industry will continue to improve with publicity such as the placement of digital hearing aids in CNN’s list of the top 25 technological developments of the past 25 years and the inclusion of wireless hearing aid technology in Time’s top innovations of 2005, but we must continue to work hard to promote our achievements in the public domain.

The perception of the hearing aid industry as having fast-moving and exciting technology will allow us to compete with the computer industry and telecom industry, among others, for the brightest university graduates and, of course, help to reduce people’s unwillingness to seek out hearing help.

Our Industry is Not Like Other Medical Device Industries

An investor and executive at a hearing aid company—someone with decades of medical device experience but who was relatively new to the hearing aid field—stated at a recent conference that the hearing aid industry was a difficult one for him to understand. He’s not alone in his frustration with trying to grasp the intricacies of our field. Medical device experts in general encounter difficulty with the hearing aid industry because of how its characteristics differ from those of most other medical device industries, such as cardiovascular devices. These difficulties result in a reluctance on their part to become involved with our field. There are three areas in particular where our industry gives them trouble:

Hearing aids as Class I devices. Hearing aids are Class I devices and therefore product development does not have the same regulatory requirements and does not fit into the usual medical device development model. In most industries, new technology must undergo a series of clinical trials that are costly and can take years to complete before a product is brought to market. Clinical trials are designed to satisfy three important constituents: the FDA, the doctors working with the device, and reimbursement agencies such as Medicare. The fact that we don't fit into their product development model affects their intuition about how the business works.

The FDA, doctors and reimbursers require legitimate data from multiple well-controlled and designed clinical trials that demonstrate statistically significant benefit of the new product over past ones. This leads to the second problem for medical device experts analyzing our industry.

Evidence-based audiology. A clear correlation between clinical data and product success exists in most medical device industries. Success or failure of a company can depend on the results of a clinical trial. A company's target customer—the doctor—demands valid data demonstrating increased benefit for their patient or they will not waste their time learning a new procedure and training their staff on the product.

This is not always done in our industry. Claims from manufacturers are often obfuscated with marketing jargon. Real patient benefit is often not discussed, nor is it requested. I have seen extensive literature on a new product published by a hearing aid manufacturer that does not contain a single data point on patient benefit.

This lack of hard data is problematic to those looking to enter our industry. It may also influence decision makers in government agencies and other arenas. In the early 1990s, the FDA imposed restrictions on the hearing aid industry as a result of unsubstantiated (and, in some cases, false) claims of patient benefit made by hearing aid companies. Those restrictions have since been relaxed after years of our industry's abidance to the FDA regulations and what is arguably a fairly effective system of industry self-governance. However, supporting all claims of patient benefit with accurate and meaningful clinical data is vital to the well-being of the industry and hearing health care profession.

Discussion has increased in our community on the need for evidence-based practice. Robyn Cox, PhD, has pointed out that many audiologists tend to select technology based on belief or expert opinions rather than published data that supports the benefits claimed by the manufacturer.^{1,2} Too often when data is presented by a manufacturer, the methods behind the data acquisition or even the source of the data is obscured, sometimes with a footnote indicating that the manufacturer will tell you more details if you contact their representative. This approach to clinical data support of product benefit will always hurt our industry in the eyes of medical device experts outside of it, and their opinions will propagate down to the consumer who is considering whether or not to become a hearing instrument wearer.

Exit strategies. The lack of industry-wide evidenced-based development, and subsequent lack of evidence-based sales, leads to a third difficulty seen by a medical device expert looking at the hearing aid industry: the lack of a reasonable exit strategy for founders and investors. In other industries, a typical exit strategy for a company that develops and sells a product supported by clinical data of improved benefit is to be acquired by a large medical device company (eg, Boston Scientific, Medtronic) for \$200-\$300 million. This is how investors make a profit on their investment and is a common goal for any medical device startup.

The hearing industry has not shown this type of acquisition behavior. One reason is that new hearing aid technology is cheaper to develop than other medical devices due to a lack of extensive clinical trials, and therefore high acquisition costs are inappropriate. Additionally, the lack of clinical data-driven sales makes the value of a technology difficult to evaluate; even if clear benefit data existed, whether that data will drive sales in our industry is unclear to outside observers. The widespread application of evidence-based development and practice could enable a thriving pool of technological development by innovative entrepreneurs.

Are There Any Remedies?

Can anything be done to address these three difficulties with understanding our industry? Let's examine them one by one:

Hearing aids fit the definition of Class I products. The first difficulty, that our product development process does not fit the typical medical device model, will not change because hearing aids fit the FDA's definition of a Class I medical device. Class II and III devices require extensive clinical testing as a part of product development to ensure safety and effectiveness. According to the FDA, Class I devices "present minimal potential for harm to the user," and therefore are not subject to rigorous regulatory requirements. Thus far, new hearing aids pose no change in risk to patients over previous hearing aids, making extensive clinical testing for device safety irrelevant for product development of a traditional-style hearing aid.

Move toward evidence-based audiology. The second difficulty, that clinical data does not always play a role in product development or in how an audiologist assesses products, can be changed. The effort to move our industry towards evidence-based product development and evidence-based practice will go a long way to alleviate this concern. We do not have to go to the extent that exists in other medical device industries where clinical trials are extensive and multi-staged, requiring several sites and thousands of patients. We should, however, develop a clinical process that supports all patient benefit claims, that is transparent, and that could satisfy any independent review of protocol and data integrity.

Rewarding successful high-tech start-ups. The third difficulty, that a technology licensing and corporate acquisitions do not exist to give founders and investors a return on their investment, will be addressed once evidence-based development and assessment is universal. This will allow companies to accurately assess the value of new technology with the confidence that the positive clinical data result in product success in the marketplace.

Outside Opinion Does Matter

Perhaps the most surprising "fact" discussed above is the misconception that advanced technology does not drive sales and therefore is not important to our industry. This can only be explained as a result of the industry's lingering reputation that is still resonating from over a decade ago among those who don't know any better. A reputation is difficult to change, and our industry must work hard to promote the advances that we have made. This responsibility partly lies with the manufacturers who must continue to promote our innovations to the outside world, but responsibility also lies with the audiologists and other dispensing professionals. Many offices have not improved along with technology and have the appearance of being unchanged since the 1970s; people walking into them would have no idea that hearing aid technology is as advanced as the products that they see on the shelves of mass merchandizers. Business practices need to change along with technology, and the appearance and capability of practices go hand-in-hand with technology to promote our industry.

Hearing aids are not as severely regulated as other medical devices, so in one sense our business will never appear similar to other medical devices industries. However, we can embrace the aspects of other industries that are likely bring about positive change and that promote the integrity and quality of its products and services. Valid clinical data that demonstrate product benefit should become a part of product development industry-wide. This clinical data should be made openly available to audiologists and other dispensing professionals, and these professionals should embrace the evidence-based practice approach. Hearing care professionals should know what benefit new products provide to patients, should demand supportive data from manufacturers, and should be cautious when they see claims that are vaguely worded with no supporting data. This approach is understood by everyone outside of our field, and by embracing these standards industry-wide, we can only increase support for our industry among government, health insurance companies, health care professionals and potential patients.

Finally, our industry has not been as bad at meeting the needs of hearing-impaired people as what is suggested by the frequently quoted the 20% market penetration statistic. In truth, we are engaging a much larger percentage of our viable market, one that is going to experience tremendous organic growth over the next two decades. By continuing to develop advanced technology, promoting advances to those outside our industry, supporting evidence-based practice and data-driven development—and acknowledging the success that we are achieving in our industry—we will be poised to be one of the most successful fields to work in among all of the medical device industries.

Market Penetration Statistics vs Market Reality

It is often cited that only about 20% of the hearing-impaired people in the United States (7 million out of 31 million) have purchased a hearing aid.³ Those outside of the hearing aid industry, and perhaps even those inside the industry, look at this low percentage and believe that we have failed in our job to provide a compelling solution for the hearing impaired. They also believe that a different business model—or even perhaps a different product—than what we have today is needed to reach the larger target market of 24 million hearing-impaired people who presumably want some form of hearing help but have rejected hearing aids.

The mistake with this line of thought is that the 80% number is a myth, and the 24 million potential hearing aid consumers don't exist. Here's why.

The numbers above are based on the frequently cited statistic that approximately 10% of the US population has a hearing loss of over 25 dB PTA. Recent analysis indicates that this total number is more than 31 million people. This means that approximately 31 million people in the United States can be officially diagnosed as having a "hearing impairment." The mistake in determining the potential market size for hearing aids is in assuming that all 31 million of these people are potential consumers for hearing aids. The flaw in this thinking can perhaps be understood by considering the potential market size of a company that has been considered (until recently) a successful one: Palm.

When Palm first entered the market as the Palm Pilot under US Robotics, they were an electronic PDA with simple functionality: datebook, to-do list, contact database. When Palm analyzed their potential market size—the number of people who might reasonably buy their product if they made the product appealing and were successful with their marketing—they did not simply count the number of people who used a datebook, a to-do list, or a contact book. That would have been every adult in the US, or 220 million people. Had Palm used that number, they would have set their sales department up with an unrealizable goal. 220 million was not their potential market; it was simply the number of people who met their minimum requirement to be a potential customer.

Palm's actual market was better described as those who had a need for a portable electronic device with the Palm Pilot's functionality that connected to their computer and who were also willing to pay a lot more for it than for a paper calendar and book of contacts. The number of people who had a compelling need for Palm's product was a lot lower than 220 million—that lower number was their potential market size.

Palm ended up selling products to 15 million households out of a total 108 million households in the US. That would be a small 14% market capture if one assumed that every adult was their potential market. In fact, Palm's market capture was significantly higher than 14% because not every household had a compelling need for their product and therefore were not a part of their potential market.

In a similar manner, the hearing aid industry is not failing in their responsibility by seemingly reaching only 20% of its potential market. There may be 24 million people with a PTA of greater than 25 dB HL, but certainly not all of those 24 million have a compelling need for a hearing aid.

So, what is the actual potential market size for hearing aids? Historically, the percentage of the US population that has been estimated to have a hearing impairment has been approximately 10%, and this total number has been assumed to be the total potential market size for hearing aids. Recent MarkeTrak data published by Sergei Kochkin, PhD, indicate that the number has grown to 31 million people, with 7 million hearing aid owners and 24 million non-owners.³ Kochkin analyzed this population in MarkeTrak IV and found that, of the 24 million hearing-impaired people who didn't own hearing aids, only about 7 million of them actually had enough of a significant need for hearing help to make them potential consumers.⁴ Also as a part of the same MarkeTrak study, Kochkin found that 32% of non-owners thought that their hearing loss was severe enough for an aid, indicating that approximately 8 million recognize a need for hearing help but reject purchasing aids for other reasons.⁵ These 7-8 million people are the non-owners who are potential users of a hearing aid if one were designed and marketed to their requirements.

Thus, rather than reaching only 20% of its potential market, the hearing aid industry has reached nearly half of the market potential—a number much more in line with other industries. With 7 million current hearing aid owners and 7-8 million viable potential customers, the hearing aid industry has room for improvement but has been successful so far in its penetration. The challenge ahead is to reach the more demanding baby boomer market and make the industry grow along with the demographics.



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