

Industrial Analysis and Product Proposal for an Inexpensive, Quickly Customized
Hearing Aid

by

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S.B. Materials Science and Engineering, Massachusetts Institute of Technology (1988)

Submitted to the Sloan School of Management
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Master of Science in Management

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Abstract

This thesis provides an analysis of the hearing industry and proposes a product to meet the needs of hearing impaired people. Toward that goal, a background is given on the subjects of hearing loss, market size, amplification technology, and customer needs. The paper also describes currently available products, distribution paths, dispenser practices, and manufacturing processes. These descriptions help define the hearing instrument market and demonstrate how that market has the potential to move from the current expensive, custom made devices towards a mass produced, inexpensive, rapidly customized product. The optical market, which made a similar transition in the 1970's, is described for the purpose of comparison.

Thesis Supervisor: Ernst R. Berndt
Professor of Applied Economics

Acknowledgments

Great appreciation is given to Greg Lambrecht for his work on this research project. Much of the work shown here is a result of a joint effort by Alan Devoe and Greg Lambrecht aimed at understanding the needs of hearing impaired customers and developing solutions to current product problems. Mr. Lambrecht's thesis on the same subject is due during the semester following this publication, and that paper will further resolve some of the issues explored here.

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Introduction

Of the estimated 25.8 million people in the United States with a hearing impairment, only six million use hearing aids. The remaining 20 million people presumably prefer to suffer with poor hearing than go through the process of purchasing and actually wearing a hearing aid. And perhaps they have good reason: hearing aids are expensive, difficult to obtain, cosmetically unappealing, and can only improve, not restore, a wearer's hearing.

Technology is being developed, however, that may address some of the unmet needs of the hearing impaired individual. Advances in sound processing technology and the ongoing miniaturization of electronics have made possible a variety of alternative sound amplification devices that could greatly increase the market penetration of hearing instruments and bring major changes to an industry that has developed little since the middle 1960's.

The goal of this thesis is to describe the hearing impaired customer's needs as they relate to hearing aids, to evaluate how well these needs are being served by the currently available products, distribution paths, dispenser practices, and manufacturing processes. Particularly, it tries to define the hearing instrument market and to demonstrate how that market has the potential to move from the current expensive, custom made devices towards a mass produced, inexpensive, rapidly custom fit product. Toward this end, the paper looks at the example of the optical market which made a similar transition with the introduction of the soft contact lens in 1971.

Finally, the paper tries to synthesize the needs of the hearing impaired customer with available, or soon to be available technology to propose a hearing aid that could greatly increase the market penetration of these products. Specifically, a proposal is made to

incorporate tunable micro-electronics into a rapidly customized fitting sleeve in order to produce a device that is inexpensive to manufacture, rapidly fit to the user's ear and hearing loss, and can be completely hidden within the canal of the wearer.

This thesis is presented in four chapters. Chapter One provides the background of the hearing aid industry, including a description of the anatomy of hearing, the pathology of hearing loss, a summary of the hearing aid market, and a description of the hearing instrument customer's needs.

Chapter Two focuses on the existing industry, its history, the major manufacturers, the current technology and products, and the distribution network. As a summary to this section, the mismatch of customer and product and the resulting dissatisfaction are analyzed. This chapter also introduces a number of changes in the industry and in the technology of sound processing that are directed at increasing the satisfaction and interest of people with a hearing loss in hearing instruments. These changes may radically affect the size and direction of the future market by allowing for the mass marketing of an inexpensive, unobtrusive hearing aid with advanced sound processing micro-electronics.

In Chapter Three, the potential future of the hearing aid industry is described by drawing an analogy with the optical industry and the changes it underwent in the early 1970's.

In Chapter Four, the over the counter hearing aid concept is described. This is followed by a discussion of limits of this concept due to the realities of sound amplification technology and the nature of hearing loss. A modified over the counter hearing aid concept is proposed that would take advantage of some of the mass marketed aspects of the contact lens while remaining within the practical limits of the hearing aid framework.

Chapter 1: Hearing and Market Background

The Ear & Hearing Loss

Introduction

As a first step in understanding the sound amplification market and in designing a new hearing aid, it is critical to understand the needs of the hearing impaired individual. This section focuses on the problem itself, on the anatomy of the ear and the pathology of hearing loss, to provide a platform from which an understanding of these needs can be obtained.

Human hearing is a highly developed sense involving the minute structures of the ear, the intricate auditory nervous system, and the complex processing of the brain. At any point along the sound processing path are hidden involved microscopic processes that subtly affect our ability to detect and process the sound information that surrounds us. Any of these processes and structures can break down, leading to a permanent hearing loss. These losses not only affect an individual's ability to understand speech, but also a host of other abilities, from localizing the source of a sound, to detecting hazards, to enjoying the simple pleasures of music.

In the past, sound amplification devices have been applied to all forms of hearing loss. However, because hearing loss has many different pathologies, only some of its forms can or should be treated through amplification.

Below we have tried to summarize the major components of the hearing system as they are currently understood, and to define the major categories of hearing loss. This will provide the basic background necessary for understanding the market size and types of problems of those individuals that are the best candidates for sound amplification

devices. If the reader is familiar with the ear and the processing of sound, he or she should feel free to skip this section.

The Ear

The ear can be divided into three primary functional areas - the outer, middle, and inner ear - which as a whole serve to transduce incident sound energy from the environment into information laden nerve pulses that are sent to the brain for processing. Diagrams of the ear and its critical structures are showing in Figures 1.1 - 1.3 at the end of this section.

The Outer Ear

Anatomy

The outer ear consists of the pinna (ear), the auditory meatus (canal), and the tympanic membrane (eardrum).

The pinna is the outer cartilaginous structure of the ear. It leads to the auditory meatus through the concha, a well shaped cavity on the interior of the pinna.

The auditory meatus narrows as it passes from the fleshy exterior of the outer ear into a hole in the temporal bone at a point called the isthmus, and then widens again toward the tympanic membrane. The canal is commonly straight or slightly 'S' shaped, varies in length from 2.3 - 2.9 cm, and is approximately 0.7cm in diameter.

The eardrum is oval in shape and slightly convex, narrowing proximally toward the head. It is ~9mm high and ~8mm wide and is formed by three layers - skin which also lines the ear canal, a central fibrous layer, and an inner mucous membrane which lines the inner ear. The eardrum has an upper section - the pars flaccida - which lacks the fibrous layer and is loose, and a lower section - the pars tensa. Approximately 2/3 down from the top of the eardrum is the umbo which is the attachment point of the

malleus, one of the three bones of the middle ear, and the point where the eardrum is pulled into the middle ear.

Function

The outer ear has three primary functions - to amplify sound incident on the ear, to conduct that sound to the middle ear, and to provide for sound localization.

The outer ear amplifies sound at the eardrum through acoustic resonances in the pinna, concha, and canal. The horn shaped cavity formed by these three structures provides a gain in sound pressure that varies with frequency, with a primary peak gain at ~2,500 Hz and a secondary peak gain at ~5,500 Hz. The 20 dB primary peak and 15 dB secondary peak are thought to arise from acoustic resonances in the canal and concha respectively. It is interesting to note that the majority of the sound information in speech is carried at these two frequencies and that when the shape of the cavity formed by the outer ear is changed, due to congenital malformities, trauma, or occlusion, significant difficulties in understanding speech arise. One unfortunate drawback of modern hearing aids is that they generally reside in or occlude both the canal and concha, reducing these natural structural resonances.

Sound is passed to the middle ear through the eardrum. The eardrum transduces the acoustical energy of the incident sound wave into the translational (mechanical) energy of the ossicular bones of the middle ear. The oscillations of the eardrum are large for low frequency sound and small for high frequency. Any change in the stiffness, or any perforation or loss of the eardrum decreases the transmission of sound to the middle ear resulting in permanent hearing loss.

The outer ear also allows for sound localization. The acoustical resonances of the components of the outer ear vary depending upon the direction of the incident sound,

a characteristic referred to as spectral modulation. It is thought that these changes in gain are analyzed by the brain to determine the incident direction. Again, if the shape of the outer ear is altered by the placement of a hearing aid in the concha and canal, some of this ability to localize sound is lost.

Middle Ear

Anatomy

The middle ear transfers the mechanical vibration of the eardrum to the oval window of the inner ear. It performs its task using the body's three smallest bones (the ossicles) and its two smallest muscles with associated tendons. The combination of bones, muscles, and tendons are referred to as the ossicular chain and are contained within an air filled cavity.

The three bones are the malleus, the incus, and the stapes (hammer, anvil, stirrup). The malleus attaches to the umbo of the eardrum and is tightly bound to the smaller incus. The incus is loosely linked to the stapes which in turn is attached at its footplate to the flexible oval window of the inner ear.

The two muscles in the middle ear are the tensor tympani and the stapedius muscle. The tensor tympani is attached to the malleus near the eardrum and is controlled by the 7th trigeminal cranial nerve. The stapedius muscle is attached to the stapes and is controlled by the 5th facial cranial nerve. These muscles, when contracted, stiffen the ossicular chain. Contraction can be caused by a loud sound (75 dB above threshold), vocalization, tactile stimulation of the head, and general bodily motion.

Function

The middle ear serves as a low impedance, tunable transducer of sound energy into the mechanical motion of the stapes in the oval window in the inner ear. The middle ear's low impedance characteristics result from three structural properties of its components - the area reduction from the eardrum to the oval window, the lever action of the malleus on the incus, and the cone shape of the eardrum. It is believed that the combination of these factors allow the middle ear to act like a linear amplifier up to ~130 dB. Any permanent change in the ossicular chain affects its ability to transduce and amplify sound resulting in a permanent hearing loss.

The stiffening of the ossicular chain by the contraction of the tensor tympani and the stapedius muscle tends to attenuate low frequency sound while not affecting high frequencies. This both protects the inner ear from loud noise and provides an automatically adjusted gain control on low frequencies up to 20 dB above threshold.

Inner Ear

Anatomy

The inner ear consists of the oval window, the cochlea, and the round window. Within the inner ear, motion of the stapes is converted into the nerve pulses used by the brain to interpret sound.

The cochlea is a set of three coiled tubes, or scalae, separated by two membranes. It is approximately 1 cm wide, 0.5 cm tall, with a coiled length of ~35mm.

The three tubes are the scala vestibuli, the scala media, and the scala tympani. The scala vestibuli and scala tympani which surround the scala media contain perilymph fluid, an electrically neutral extracellular fluid. The scala media is filled with endolymph fluid, similar to intracellular fluid with high concentration of K^+ ions and a resultant charge of ~80mV. The scala media is separated from the scala

vestibuli by Reissner's membrane and from the scala tympani by the basilar membrane.

The oval window is a flexible membrane that sits under the footplate of the stapes and opens onto the interior of the scala vestibuli. The round window is also a flexible membrane and it separates the middle ear and the interior of the scala tympani.

Running along the length of the interior of the scala media, resting on the basilar membrane, is the organ of Corti. This organ contains ~15,000 hair cells and 30,000 neurons. The hair cells are divided into two groups - inner and outer. Inner hair cells run the length of the organ of Corti in a single row of cells, while outer hair cells are in rows of from three cells at the base of the cochlea to five cells at the apex. At the top of each cell are a set of tiny hairs called the stereocilia. The stereocilia are made of packed actin filaments. They are packed closely together in a stiff paracrystalline array. The tops of the stereocilia touch or are imbedded in the tectorial membrane, a soft, gelatinous membrane extending out from the spiral limbus above the hair cells. At the base of each hair cell are two types of neurons - afferent and efferent. Afferent neurons carry information from the hair cells to the spiral ganglion and ultimately to the auditory cortex of the brain. 90-95% of these fibers connect to inner hair cells and 5-10% connect to outer hair cells. Efferent neurons are not well understood, but are thought to be part of a feedback loop from the brain.

The vibration of the stapes in the oval window gives rise to a traveling wave in the perilymph fluids of the scala vestibuli and scala tympani. This wave vertically displaces the basilar membrane. This displacement is believed to cause a deflection of the stereocilia atop hair cells in the organ of Corti, resulting in the firing of the afferent neurons.

For a particular frequency, the vibration of the basilar membrane grows in amplitude as the wave travels toward the apex and then dies out rapidly. Low frequency sounds reach peak amplitude toward the apex of the cochlea while high frequency sounds peak toward the base.

Frequency selectivity of the wave is very poor with shallow slopes on the low frequency side and steep slopes on the high frequency side.

It is believed that hearing stems primarily from the firing of the afferent neurons of the inner hair cells. Localized synchronous firing of sets of neurons brought on by a peaking wave in the basilar membrane is probably interpreted as a particular frequency by the brain. Complicating this simplistic model is the knowledge that the outer hair cells actively 'sharpen' the peak of the traveling wave by altering the stiffness of the basilar membrane through a complex, poorly understood feedback mechanism.

Hearing Loss

Hearing losses are categorized either by pathology or severity. This section begins with a detailed description of the two most common pathologies of hearing loss and concludes with a brief review of accepted groupings used to describe severity.

Pathology

The pathologies of hearing losses are currently lumped into four groups - conductive, sensorineural, mixed, and non-organic. Mixed losses have both conductive and sensorineural components. Non-organic loss is due to psychological and not physiological disorder. Currently available hearing aids are being designed to moderate the severity of all losses except non-organic. Following is a description of conductive and sensorineural loss only.

Conductive Loss

Conductive loss is due to a malfunction or malformation in the outer or middle ear. All conductive losses are mechanically based with no neural involvement. The most common conductive losses, their causes and treatments, are given below. All forms of conductive loss, when diagnosed by an audiologist, must be referred to a physician. All permanent conductive hearing loss can be treated with the fitting of a hearing aid.

Outer Ear

Hearing losses related to the outer ear are caused by either blockage of the canal (atresia) or by stiffening (sclerosis) or perforation of the tympanic membrane.

- *atresia* A common cause of hearing loss, atresia can normally be treated medically or surgically, resulting in little or no permanent hearing loss. Some of its more common causes and treatments are:

- 1) Congenital malformations leading to closure or restriction of the canal. This is generally treated by surgical widening of the canal.
- 2) Impacted cerumen or wax which can be treated by chemical or physical removal.
- 3) Otitis externa is an inflammation of the walls of the canal. This can be treated by antibiotics.
- 4) Polyps which can be removed surgically.
- 5) Prolapsed canal is a sagging of tissue in the canal which leads to closure. This more commonly affects the elderly and can be treated surgically.

- *tympano-sclerosis* This is a particular variation of ossicular fixation which also affects the middle ear. It is caused by ossification of the tympanic membrane, is common in people with osteoarthritis, and leads to permanent hearing loss.

- *perforation* Small perforations alter the impedance characteristics of the eardrum resulting in flat hearing losses from 10-15 dB.

Middle Ear

Hearing losses related to the middle ear are due to the presence of fluid in the cavity of the middle ear (otitis media), hardening or fixation of all or part of the ossicular chain (otosclerosis and ossicular fixation), tumors (cholesteatoma), or a breakage of the ossicular chain (ossicular discontinuity).

- Otitis Media* This affliction is due to either septic or sterile fluid buildup in the middle ear. It is particularly common among children and can lead to severe, permanent hearing loss.
 - 1)Suppurative otitis media, which involves septic fluid, can lead to erosion of the ossicular chain and the formation of adhesions which restrict the motion of the ossicles. It can be treated by antibiotics, myringotomy (puncture of the pars tensa portion of the eardrum to allow drainage), tympanoplasty (repair of the ossicular chain), mastoidectomy (surgical removal of diseased cells in the middle ear), or radical mastoidectomy (removal of the entire ossicular chain).
 - 2)Non-suppurative otitis media is the presence of sterile fluid in the middle ear. It is most commonly results from antibiotic treatment of suppurative otitis media coupled with a blocked eustachian tube.
- Otosclerosis* This is the most common form of conductive hearing loss in the elderly, is inherited, and is more common in women than men. It leads to the fixation of the stapes in the oval window and can results in a flat hearing loss of ~ 60-65 dB as well as tinnitus. It can be treated surgically by either stapes mobilization or a stapedectomy (removal and replacement of the stapes with a prosthesis). Both treatments result in permanent, but reduced hearing loss while the latter technique permanently severs the stapedius muscle.
- Ossicular Fixation* This is ossification of any part of the ossicular chain which leads to reduced mobility of the ossicles. It is progressive, results in a flat hearing loss, and is common among people with osteoarthritis.
- Cholestea-* This is the presence of a tumor in the attic of the

toma middle ear. The tumor can perforate the eardrum and invade the external auditory canal. Cholesteatoma are treated surgically and by radiation and chemotherapy.

•*Ossicular* This is generally treated by the removal of all or part of

Discontinuity the ossicular chain followed by the placement of a prosthesis.

Sensorineural Loss

Sensorineural hearing loss is a result of damage to the inner ear, the auditory nervous system, or the auditory cortex of the brain. This type of loss can be caused by acoustic trauma, poisons, ototoxic drugs, congenital defects, tumors, labyrinthitis (inflammation of the inner ear), fistulas in the oval or round windows, arteriosclerosis, central vascular accidents, and lack of oxygen to the brain. Following is a brief discussion of characteristic symptoms of sensorineural loss and a more detailed discussion of two of its most common forms - acoustic trauma and presbycusis (sensorineural loss due to age).

Symptoms of Sensorineural Loss

The most common symptoms are:

- Temporary/permanent threshold shift.*: This reduces the ability to detect low intensity signals, but does not hinder frequency discrimination.
- Phonemic regression.*: Loss of frequency discrimination is a result of damage to outer hair cells and their stereocilia.
- Tinnitus.*: Ringing in the ears can result from acoustic trauma and is generally worst at the frequency of greatest hearing loss. Unlike tinnitus resulting from conductive losses, sensorineural tinnitus cannot be heard by others.

•*Recruitment.*: This term describes a reduction in the range of intensities that are comfortable for a listener. The average young person can listen comfortably to sounds ranging from 0 dB to 120 dB, a range of 120 dB. Someone suffering from recruitment may have only a 10 -20 dB listening range with a large threshold shift and a lowered pain threshold. It is though that recruitment derives from changes in the basilar membrane and damage to the auditory nervous system.

Acoustic Trauma

Explosions or long term exposure to loud noises (>110dB) can result in acoustic trauma which is damage or destruction of the hair cells, the organ of corti, or the basilar membrane of the cochlea. The greatest loss is generally found at the frequency of the offending sound.

Presbycusis

Presbycusis is the most common form of hearing loss. This is partially because the term is broadly defined to include all losses to the sensorineural system that can occur with age. These losses are often broken into four categories:

- Sensory* Damage to the hair cells of the cochlea resulting in a progressive high frequency loss.
- Central* Damage to and loss of ganglion cells resulting in a mild and gradual high frequency loss. Central loss commonly involves phonemic regression, and often is a result of arteriosclerosis. Severe central losses is called aphasia (central deafness leading to loss of communication skills).

- *Metabolic* Defect in the composition of the endolymph fluid which results in a progressive flat loss.
- *Mechanical* Change in the stiffness of the basilar membrane leading to a high frequency loss.

Despite its many forms, presbycusis is generally characterized as a progressive high frequency loss which commonly involves phonemic regression and recruitment.

Hearing Aids & Sensorineural Loss

Hearing aids can be beneficial to those suffering from sensorineural hearing loss only if they do not suffer from:

- phonemic regression
- severe recruitment
- primarily good hearing with a spiked hearing loss at a certain frequency

Severity

Hearing losses, while derived from various pathologies, present themselves as a general inability to hear well. This inability is normally measured by a decibel deviation from an accepted normal Hearing Level or HL. Various societies have published standard HL guidelines across the spectrum of normally encountered sound (between 0 and 8000 Hz).

If a persons can hear sounds between 0 and 25 dB HL, their hearing is considered normal or near normal. Deviations of greater than 25dB HL are considered impairments and can be categorized from mild to profound. A list of the dB HL ranges of the various severities of hearing loss is shown in Table 1.1. This chart was developed by the American Association of Retired Persons, and represents somewhat of an industry

standard.¹ Note that an estimated need for a hearing aid is listed for each group. This is given only to provide information as to the recommendations of the AARP and does not represent the findings of this thesis.

The Hearing Instrument Market

Introduction

The hearing impaired market has been described and tracked by a number of authors, including industry experts, government agencies, and public interest groups. All groups agree that the hearing impaired population is both large and growing. They also agree that few turn to hearing aids for help. In this section we have assembled the various data describing the overall number of hearing impaired people in the U.S., calculated the total market size, and tried to better define the various populations that make up the hearing impaired market. We have also broken out the larger groups of people with a hearing loss that do not own a hearing aid to more clearly describe the enormous untapped market that could potentially be opened by changes in sound amplification technology and a shift in the industry structure.

Hearing Impaired Population

Perhaps the best data describing the size of the hearing impaired market and the demographics of the population with a hearing loss comes from a series of large-sample surveys performed by Sergei Kochkin of Knowles Electronics, a large hearing aid component manufacturer. These surveys, MarkeTrak I, II, and III, were carried out between 1989 and 1991 in an attempt to give the hearing instrument industry a better understanding of their customers and non-customers.

Overall Size

¹ "Product Report: Hearing Aids", AARP Publication, Vol. 1, No. 4, 1989, pg 2

Estimates from the MarkeTrak III survey of 1991 show that the incidence of hearing loss in the U.S. is approximately 274 per 1000 households.² Applied to the general population this translates to nearly 25.8 million Americans, slightly more than 10% of the total population, that were afflicted with some degree of hearing loss at the time of the survey. Similar surveys have been carried out since 1984 and have shown a steady rate of increase in this population of 6.7% per annum.

These numbers are confirmed by the National Center for Health Statistics as well as the National Institute on Deafness and Other Communication Disorders who estimate the hearing impaired population to be between 21.8 and 28 million people.³

Breakdown By Severity

Unfortunately, precise data regarding the degree of hearing loss and the mechanism of its cause has not been gathered for this population. However, as part of the MarkeTrak III survey, hearing impaired respondents were asked to grossly assess the severity of their loss using the categories of mild, moderate, severe, and profound. This breakdown is given in Table 1.2.

Note that a large fraction, 35% or 9 million people, felt that their hearing loss was mild. Currently available hearing aids are generally believed to be most applicable to patients with at least moderate hearing losses. This suggests that the actual market for hearing instruments may be significantly smaller than the total 25.8 million people. More attention will be given to this point later in this chapter.

Breakdown By Age

²Kochkin, Sergei, MarkeTrak III: Why 20 Million In US Don't Use Hearing Aids For Their Hearing Loss, Hearing Journal, Jan. 1993, pg 20.

³Kochkin, Sergei, Introducing MarkeTrak: A Consumer Tracking Survey of the Hearing Instrument Market, Hearing Journal, Vol. 43, No. 5, May 1990, pgs 17 - 26.

Hearing loss affects people of all ages. Congenital problems can lead to a significant impairment at birth, while progressive diseases and trauma result in gradual losses that worsen with time.

Regardless of the individual, however, our sense of hearing generally deteriorates with age. Over time the gradual depletion of auditory neurons entering the cochlea or the buildup of mechanical damage to the delicate structures of the ear lead to significant impairment. For this reason, hearing loss has largely been a problem of the elderly. In fact, one study estimated that 30% of people over 65, or 9.4 million people in the U.S., suffer from hearing loss.⁴ This number is well supported by the results of the MarkeTrak studies (see Table 1.3) which estimate this population to be 9.6 million or 37% of the total hearing impaired population. Census estimates further report that beginning in the year 2000, the 65 to 74 year olds will be the fastest growing age group in the U.S. The size and growth rate of this older portion of the hearing impaired population has drawn much industry attention and has traditionally been the focus of their marketing efforts.

It is interesting to note, however, that while this group is large, it is by no means the majority, with over 14 million people under the age of 65 suffering from significant losses.

Breakdown By Socioeconomic Status

As would be expected, hearing loss affects all socioeconomic groups. In Table 1.4 the hearing impaired population is segmented by average annual income and employment status. These estimates were again part of the MarkeTrak III study and show that the

⁴Jennifer Day, Census: Current Population Reports PS25-1104, U.S. Department of Commerce, Bureau of the Census, Nov. 1993, pgXXV.

average person with a hearing loss is employed either full or part time and has an annual income of approximately \$35,000.

The deviation from the average salary is significant. 49% of the hearing impaired population, for example, earns less than \$30,000 per year, with 32% earning less than \$20,000. It can be assumed that this group of people have serious limitations on their disposable income and may be reluctant to incur the expense of a hearing instrument until their loss has become either severe or profound.

Hearing Instrument Market

While 25.8 million people represent an enormous market, the portion of this group that currently uses a hearing instrument is significantly smaller. Between 1984 and 1991, the market penetration remained relatively constant at a low 23%, despite increased industry efforts to improve sales through direct marketing.⁵ In 1991, this figure represented 5.8 million people that owned at least one hearing aid out of the total population of 25.8 million with a hearing loss. Most industry experts view the 20 million people who are not hearing instrument owners as an enormous untapped market that will bring massive revenues to the company that catches its attention.

In this section we try to determine what portions of this untapped market represent true candidates for a hearing instrument. We begin by describing the current hearing instrument market size and the market penetration of the various demographic categories discussed above. By making a few assumptions, we then eliminate those portions of the untapped groups that would probably not be significantly aided by the use of a hearing instrument. In the final section we focus on those larger populations of hearing instrument candidates that are not hearing aid owners and give an estimate of the true

⁵Kochkin, Sergei, MarkeTrak III: Higher Hearing Aid Sales Don't Signal Better Market Penetration, Hearing Journal, July. 1992, pg 47.

untapped market.

Market Size and Sales Volume

As can be seen in Figure 1.4, the annual unit sales of hearing aids in the U.S. has been rising steadily, with more than 1.7 million units being sold in 1992. However, between 1984 and 1992 the rate of increase has at best paralleled the increase in the total hearing impaired population, indicating a constant market penetration.

The total market value has been increasing at a rate higher than the growth rate of the hearing impaired population, despite stagnant market penetration. This is a result of steady increase in the sales price of each device. The average price of a hearing instrument increased from \$501 in 1984 to \$717 in 1992, an annual average increase of 4.6%. This translates to an 11% annual market growth rate that has resulted in a doubling of the size of the industry from \$552 million in 1984 to \$1,267 million in 1992.

While this is a large market by any standards, many industry experts allude to the "Billion Dollar Opportunity", a reference to the doubling of unit sales that seems possible when considering the overall size of the hearing impaired market. Ultimately, if all 25.8 million hearing impaired people were reached by the industry, the market would balloon to an annual gross sales volume of more than \$5 billion.

Market Penetration

For a number of reasons to be discussed in the next chapter of this thesis, hearing aids have successfully penetrated only small segments of the total hearing impaired market. In this section we discuss both the demographic groups that have been receptive to hearing instruments as well as those that haven't.

Breakdown By Severity

The primary market of hearing aids have been the moderate and severely impaired customers. As can be seen in Table 1.2, acceptance of hearing aids increases dramatically

with increasing severity of loss, with both moderate and severe categories having better than average device penetration.

Poor penetration of the mild hearing loss group, 35% of the total hearing impaired market, has been an intractable problem for the hearing industry. With only 6% penetration, an estimated 8.5 million people in this category, more than the entire current market, have been consistently resistant to hearing instruments and industry advertising.

Indeed, individuals with mild hearing loss may not be good candidates for currently available sound amplification technology and perhaps should not be included in the potential pool of customers for device manufacturers. One study of one thousand hearing instrument users noted that customer satisfaction as well as improvement in objective hearing test occurred only when the patient's loss was above 34 dB at one and two megahertz, and was greatest for those wearers with losses between 35 and 64 dB HL. This type of loss is generally considered to be moderate to severe, indicating that perhaps hearing instruments sales to people with mild losses are not justified.

If this portion of the market were removed from the total hearing impaired population, the remaining section would more accurately represent potential customers for the hearing industry. The remaining pool would still be large - at 17.3 million people this would still allow for a tripling of the current market value. The effect of removing this market segment would increase the average market penetration to nearly 32%, almost 10% higher than the current perceived penetration.

People in the moderate hearing loss category, the largest segment of the market, have not responded markedly better than those with mild losses. Only one quarter of this population, 3 of 12.1 million, currently use a hearing aid. Even with such poor penetration, this section accounts for nearly 52% of hearing aid users, suggesting that this severity of loss can be successfully mitigated by the use of sound amplification devices.

Reasons why 9.1 million people in this group do not turn to hearing aids are discussed more fully in the next chapter.

The group afflicted with severe and profound loss accounts for about 40% of hearing aid users and only 18% of the total hearing impaired population. Device penetration of this group is higher than average, but is still less than a majority at 49%. This may be a result of device incompatibility rather than poor marketing. Complete loss of hearing, severe presbycusis, sensorineural loss, and tinnitus are all considered severe impairments, but cannot be alleviated through sound amplification. If it is assumed that all 51% of the severely impaired that do not own a hearing aid are not good candidates, an additional 2.4 million people are eliminated from the total hearing instrument market.

In summary, hearing devices have not been particularly successful in penetrating large portions of the hearing impaired population. However, certain forms of hearing loss limit the benefit that a hearing aid can have for a given patient. Particularly patients with mild losses and certain forms of severe or profound loss may not be candidates for hearing aid use and should not be counted as part of the total potential market for sound amplification devices. If these individuals are eliminated from the pool of potential customers, the resulting market is reduced from 25.8 million to 14.9 million people, and the market penetration is increased from 23% to nearly 40%.

We believe these numbers are a more accurate representation of the true hearing instrument market. It is important to note that 40% market penetration is still low and that the opportunity exists to more than double the current annual sales volume for hearing instruments. Further, this analysis suggests that the group that could yield the greatest volume of new customers are those with moderate hearing losses.

Breakdown By Age

Hearing aid acceptance appears to be directly proportional to age (see Figure 1.5). This trend is true even among people with similar hearing losses, suggesting that some factor other than hearing loss is deterring younger people from using hearing aids.⁶

As a symptom of this trend, the average age of the 5.8 million people that used hearing aids was 68.4 in 1991 and had remained relatively constant during the preceding seven years. Market penetration of the 65 and over age group has been relatively high for the industry at a steady 66%.

However, the population of people with a hearing impairment is not predominantly over 65. In fact, the MarkeTrak III survey indicated that this population represented only 37% of the total hearing impaired market.

The remainder of the market, approximately 16.3 million people are under the age of 65. Only 2.2 million people or 14% from this category use a hearing aid. The remaining 14.1 million people represent the large majority, about 71%, of the total untapped hearing instrument market.

Even if allowances are made for the mildly and profoundly impaired individuals in this age group, the resulting undressed market of younger people with moderate hearing loss is still enormous. In the following analysis, it is assumed that the percentage of people in any given age group that suffer from a particular severity of loss is the same as that percentage for the entire population. Based on this assumption, 35% of those under 65 with a hearing impairment suffer from mild losses. An additional 9.3% would have hearing losses so severe or of a sensorineural nature that they would not be candidates for a hearing instrument. If both groups were eliminated from the total

⁶Kochkin, Sergei, MarkeTrak III: Higher Hearing Aid Sales Don't Signal Better Market Penetration, Hearing Journal, July, 1992, pg 47.

population under 65, a sizable market of 9.1 million people would remain of whom somewhat less than 2 million currently own a hearing aid.

This population of moderately impaired people under the age of 65 is poorly addressed by the hearing aid industry and represents a large target market that would allow a doubling of the current market volume.

Breakdown By Socioeconomic Status

Market penetration of any given income range is approximately 23%, with minor variations across the span.

It is interesting to note that while over 50% of the hearing impaired population is fully employed, this group is responsible for only 24% of sales, representing a device penetration of only 11%. Retired persons, on the other hand, are only 22% of the total impaired population, but are responsible for 61% of sales. This may indicate a market focus on the 65+ age group as well as increased acceptance of the product with increasing age.

As mentioned above nearly half of the hearing impaired population earns less than \$30,000 per year. For this group, an average price \$717 per ear could be a barrier to purchasing, particularly if the hearing loss is mild or moderate.

Indeed, an analysis of MarkeTrak III carried out by Kochkin estimated that reducing the sales price of hearing aids could radically increase sales. He predicted that reducing the price of hearing aids to \$100 per ear would result in a doubling of the current market volume. The full results of his study are given in Figure 1.6.

The trend in the industry, however, is moving in the opposite direction. New products released over the past three or four years have emphasized improved technology sold at markedly higher prices, further distancing these products from the middle and lower income portion of the market.

Summary

Currently, hearing aids appeal primarily to the older customer with moderate to severe hearing loss. Penetration of this segment of the market is consistently high, approaching 70%.

Penetration of the remainder of the market is generally poor, leaving potentially enormous sections of the market untapped.

Most industry experts feel that this untapped market includes all 20 million people that are hearing impaired, but that do not own a hearing instrument. We have tried to show that large sections of this untapped market simply are not candidates for currently available sound amplification technology. Specifically, assuming that people on both ends of the spectrum, those with either mild or profound losses, are not good candidates for hearing aids, we have show that a more accurate representation of the potential hearing instrument market is on the order of 14 to 15 million people.

Of this number, the largest untapped and unaddressed market segment are those individuals with moderate hearing loss that are under the age of 65. This population includes more than 9 million people of whom fewer than 2 million currently own a hearing aid.

Additionally, we have shown that people who are fully employed have a less than average acceptance rate of hearing instruments. Reasons for this phenomenon are discussed in more detail in the following chapter.

Finally, it may be possible to reach this untapped market of 9 million people simply by lowering the sales price of hearing instruments.

Conclusion

The hearing aid industry has done well marketing devices primarily to older customers as well as to those with severe and profound hearing loss. These groups have fueled an industry with gross annual sales on the order of \$1.2 billion dollars with a growth rate of 11% per year.

The industry has not reached its full potential by any means, missing large sections of the hearing impaired population that would be good candidates for hearing instruments. While this untapped market is probably considerably less than the industry estimate of 20 million people, it is still on the order of 14 to 15 million people. This population could accommodate a tripling of the current market, increasing annual sales from 1.7 to more than 3 million units.

One segment of the market, which includes people under the age of 65 with moderate hearing losses, represents the greatest opportunity for producing new customers. More than 9 million people fall into this group, with fewer than 2 million presently using hearing aids. This portion of the hearing impaired population has been largely ignored by the hearing instrument industry and could provide enormous revenues for a company that better addressed the needs of these individuals.

Customer Needs

Introduction

Products can have an enormous effect on our lives. For the hearing impaired individual, the hearing aid in the proper form can be truly life altering, returning the ability to understand speech and to communicate effectively. For many people, the hearing instrument allows them to re-enter society, to socialize in a manner that they have been unable to achieve sometimes for years.

And yet, for many of the hearing impaired, hearing aids represent weakness, disability and age. The stigma derived from wearing the devices can be so great within

the mind of the individual, that despite their loss and accompanying disabilities, they shy away from the products that could vastly improve their quality of life.

This chapter focuses on the needs that people with a hearing loss have of a hearing aid. Through this analysis, it is hoped that insights can be gained into how to improved both the products and their associated distribution practices to better meet the complex needs of the hearing impaired.

Needs Analysis

There are two basic approaches to understanding the needs of individuals with a hearing loss. The first is to focus on the needs of those that already use a hearing aid, who have experience using the products, and to listen to their feedback. A number of large studies have been performed by the hearing aid industry and the Hearing Instrument Association using this approach. The results provide insight into methods of increasing current customer satisfaction, increasing the frequency of repeat purchasing, as well as improving word-of-mouth advertising.

The second pathway is directed at analyzing the needs of the hearing impaired individual that does not use a hearing aid. Few studies have been performed in this area, but those that have point out some significant difference that may be the key to product, marketing, and distribution improvements that could lead to large increases in overall hearing instrument market size.

Owners

The product related needs of those currently owning a hearing instrument were determined through a review of the available literature and confirmed through in-person interviews with hearing instrument users during visits with a dispensing audiologist.

Product feedback about hearing aids has not been encouraging. Only six out of every ten hearing instrument owners report satisfaction with the performance of the devices.⁷ Indeed, 12% of all hearing aid owners are dissatisfied enough that they no longer wear their instruments.

Satisfaction was shown by an analysis of the MarkeTrak III survey of 2323 hearing aid owners to correlate strongly with the users perceived value of the hearing instrument. Value was heavily influenced by the success of the device in providing improved hearing in a variety of listening environments. Those who were not satisfied commonly reported that their hearing aids failed them particularly in the presence of background noise. A perception of good sound quality was also critical in adding value to the hearing aid. Users that reported their hearing aids provided a "natural sounding" amplification were more likely to be satisfied with their instruments.

Comfort, fit, and lack of feedback were also perceived product aspects that positively influenced the value of hearing aids for their users. Surprisingly, while 21% of all surveyed hearing instrument users felt negative effects from the stigma of wearing their instruments, vanity, product related embarrassment, and hearing instrument size all appeared to have very little correlation with overall product satisfaction. As we will see in the following section, this is nearly the opposite to the perception of the non-owners, suggesting either that the needs of a hearing impaired individual change after purchase or that those that resist purchasing a hearing aid have fundamentally different needs than those that do purchase.

Owner's Needs

⁷Kochkin, Sergei, MarkeTrak III Identifies Key Factors In Determining Consumer Satisfaction, The Hearing Journal, August 1992, pgs 39 to 43.

The needs of hearing instrument owners can be directly translated from factors that influence satisfaction. The resulting list is just such a translation from the factors listed above.

- Improves hearing in a variety of listening situations
- Improves hearing in presence of background noise
- Provides good or natural sounding amplification
- Fits comfortably on or within the ear
- Is cosmetically unobtrusive
- Is inexpensive to purchase
- Is inexpensive to maintain

Non-Owners

The needs of hearing impaired individuals that do not own hearing aids are more difficult both to track and characterize. Few studies of this group have been carried out even though they represent the majority of the hearing impaired market.

Two studies, however, were performed by Dr. Sergei Kochkin to unearth the reasons why an estimated 20 million people with a hearing loss did not use a hearing aid. From his results, conclusions can be drawn as to these individual's needs regarding hearing instruments.

The first study was a survey of 250 hearing aid dispensers. This group of subjects was deemed to have a great deal of experience with potential hearing impaired customers that reject instruments. The survey asked only one question - why they believed the hearing aids were rejected. The four primary reasons in descending order of importance were stigma, price, consumer awareness, and education.

Stigma and vanity were by far the most frequently referenced reason for rejection, accounting for 26% of all responses.⁸ The dispensers believed that many potential customers feared bringing attention to their disability and that wearing a hearing instrument would make them appear older and less capable. As was indicated in Section 1.2, a large portion of non-owners are both younger and employed. This group may be particularly subject to the effects of stigma, with fears about possible repercussions on their careers or social lives resulting from the use of a hearing aid. Some of the direct quotes from the survey that were very telling about the concerns of these individuals:

"The stigma attached to hearing aids is still very much a factor in our society. Hearing aids are associated with old age, deaf, dumb and retardation."

"Their concerns are, if I get a hearing aid, it's a sign of weakness... what will the other guys think of me, if they see a hearing aid in my ear? Will it indicate some kind of frailty that I have. Could I lose my job because of that?"

"They feel they are losing something of themselves. That they are less of a person, less intelligent, less attractive, closer to the grave."

"It's the negative image that a hearing aid has. A visible sign of old age and loss of abilities."

The high cost of hearing instruments accounted for another 22% of responses. As discussed in Section 1.2, nearly half of all hearing impaired people earn less than \$30,000 per year. The surveyed dispensers pointed out that between \$700 and \$1,000 per ear was a high price to pay for people with this level of income, particularly when

⁸Kochkin, Sergei, "Hearing Professionals' Views On Market Expansion", Hearing Instruments, Volume 42, Number 12, 1991, pgs 6-7.

they were already reluctant to purchase for other reasons. Typical of these response is the following:

"You can pay \$700 for a refrigerator and appreciate its use, but the same price for a small electronic aid is resented."

The last major groupings of reasons for non-purchase were awareness of loss and consumer education, totaling 17% and 12% of all mentions respectively. The dispensers believed that many in the hearing impaired population knew they suffered from a hearing loss, but were unaware of its severity. These and other potential customers were also often unaware of available hearing aid technology, how to purchase an instrument, or what price they could expect. This lack of consumer awareness presents a significant barrier to potential hearing aid customers, particularly if their hearing loss is either mild or moderate.

The responses from the dispensers were largely confirmed by results from the MarkeTrak III survey. As part of this massive study, 677 hearing impaired people that did not own a hearing aid were surveyed. Common among nearly all subjects, more than 96%, was the belief that their hearing loss was not severe enough to warrant the use of a hearing aid.⁹ This high percentage may be a symptom of the generally held belief that hearing aids are only for severe or profound losses. Not wanting to be categorized as elderly or handicapped, many people with milder or moderate losses may be avoiding purchase until their loss is severe enough to greatly restrict their lives. This assumption is backed by the response of 44.1% of those surveyed mentioning stigma issues as a primary reason for non-purchase. Overly high cost was also mentioned by 43.6% of those surveyed.

Non-Owner's Needs

⁹Kochkin, Sergei, "Why 20 Million People Don't Wear Hearing Aids", *The Hearing Journal*, April 1993, Volume 46, No. 4, pgs. 36 to 37.

The following list of needs held by hearing impaired individuals that resist purchasing a device were interpreted from the reasons for non-purchase given above.

- Good Sound Quality - Particularly For Less Severe Losses
- Cosmetically Unobtrusive
- Inexpensive To Purchase
- Easy To Obtain
- Easy To Use

Table 1.1: AARP Guidelines For Hearing Loss

Level of Loss	Description	Effect	Need for Hearing Aid
25 to 40 dB HL	Mild	Difficulty understanding normal speech	Needed in specific situations
41 to 55 dB HL	Moderate	Difficulty understanding loud speech	Frequent Need
56 to 80 dB HL	Severe	Can understand only amplified speech	Needed for all communication
81 dB HL or more	Profound	Difficulty understanding amplified speech	May need to supplement with speech-reading, or sign language

Table 1.2: Hearing Impaired Population By Severity of Loss

Degree of Hearing Loss	Total Impaired Population	Penetration	Population	
			Non-Owner	Owner
Mild	9 million (35%)	6%	8.5 million	0.5 million
Moderate	12.1 million (47%)	25%	9.1 million	3.0 million
Severe & Profound	4.7 million (18%)	49%	2.4 million	2.3 million
Total	25.8 million		20 million	5.8 million

Table 1.3: Hearing Impaired Population By Age

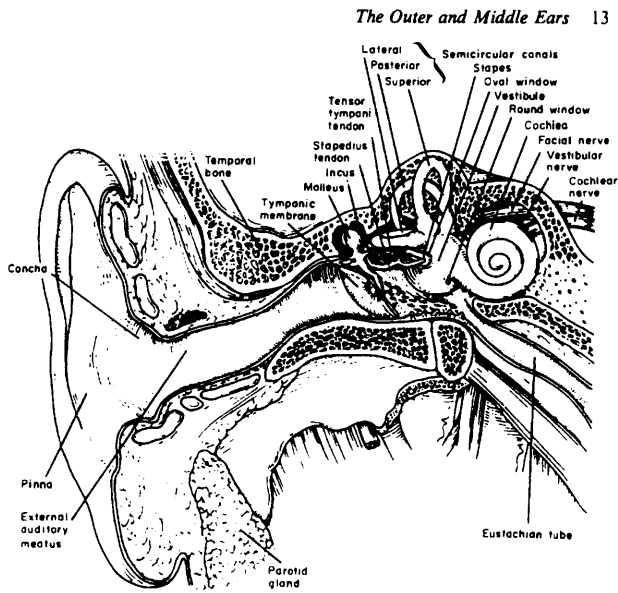
Age Group	Total Impaired Population (000)	Penetration (%)	Population (000)	
			Non-Owner	Owner
1 - 17	326	15%	276	50
18 - 34	3,032	6%	2,838	194
35-44	4,223	7%	3,908	315
45-54	3,989	13%	3,481	508
55-64	4,643	21%	3,680	963
65-74	5,887	34%	3,874	2,013
75-84	3,101	47%	1,648	1,453
85+	599	56%	264	335

Table 1.4: Hearing Impaired Population By Socioeconomic Status

	Total Impaired	Penetration	Population	
By Income			Non-Owner	Owner
Less than \$10k	3,171	28%	2,279	892
\$10 - 19k	5,073	28%	3,676	1,397
\$20 - 29k	4,541	24%	3,451	1,090
\$30 - 39k	3,844	19%	3,097	747
\$40 - 49k	2,812	17%	2,323	489
\$50 - 59k	2,083	19%	1,677	406
\$60K	4,276	19%	3,467	809

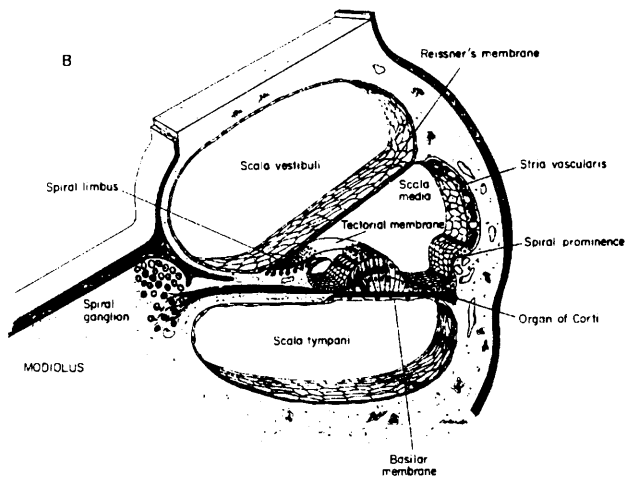
By Employment				
Full-Time Employment	11,547	12%	10,165	1,382
Part-Time Employment	2,371	20%	1,899	472
Unemployed	2,805	16%	2,356	449
Retired	9,079	39%	5,552	3,527

FIGURE 1.1: ANATOMY OF THE HUMAN EAR



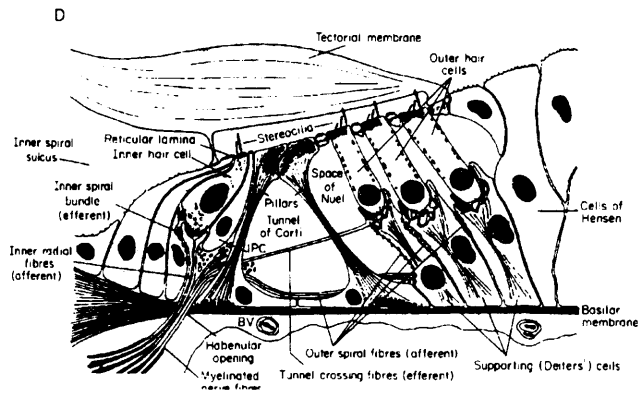
Source: Pickles, 1988.

FIGURE 1.2: ANATOMY OF THE COCHLEA



Source: Pickles, 1988.

FIGURE 1.3: ANATOMY OF THE ORGAN OF CORTI



Source: Pickles, 1988.

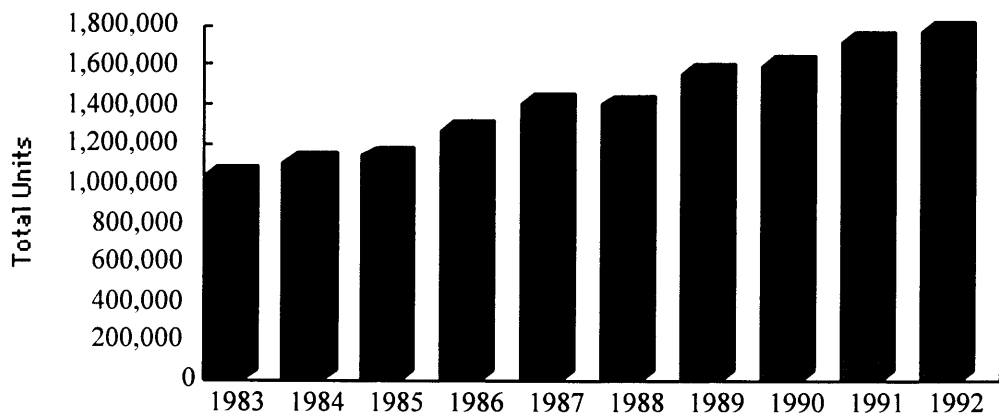


FIGURE 1.4: HEARING INSTRUMENT UNIT SALES (U.S.)

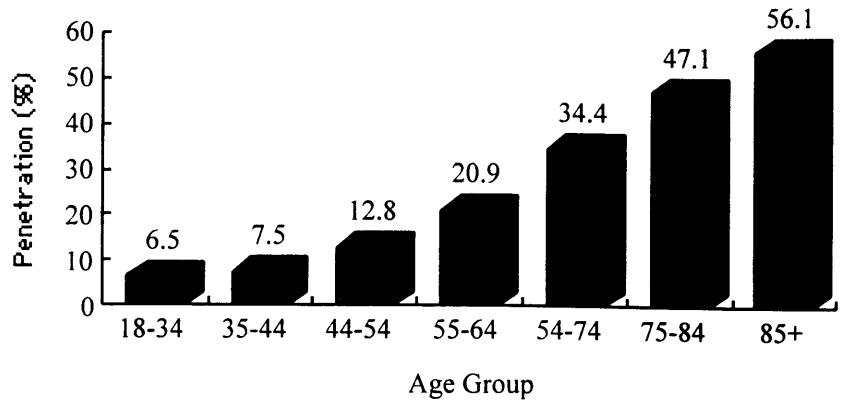


FIGURE 1.5: HEARING INSTRUMENT MARKET PENETRATION BY AGE

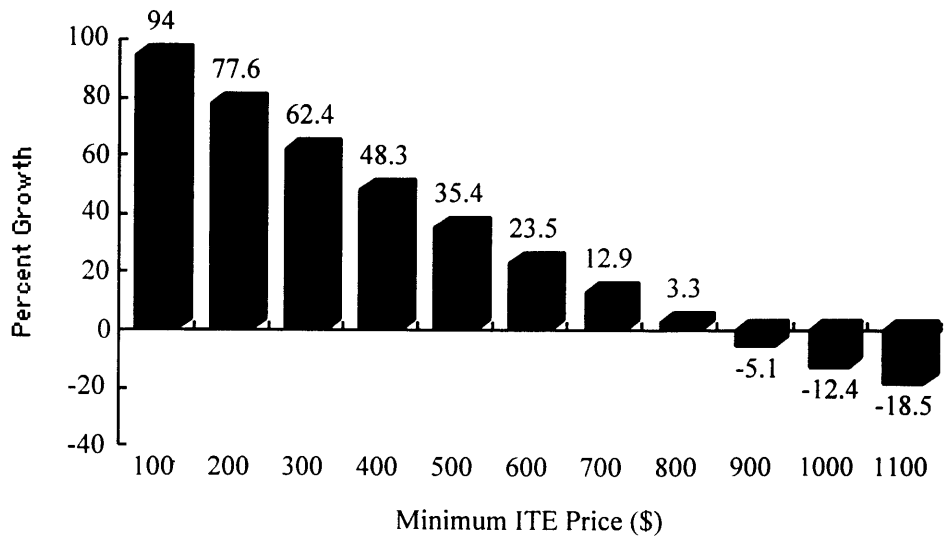


FIGURE 1.6: GROWTH IN UNIT SALES WITH CHANGING UNIT PRICE

Chapter 2- Technology and Manufacturer Background

Product History

The earliest hearing aids was simply a horn used to collect sound and funnel it toward the ear. The open area of the horn was larger than that of the pinna, allowing it to focus a large amount of sound energy, and the most effective horns were those which reduced size slowly as they funneled sound toward the ear. Some horns offered an increase in apparent loudness at certain frequencies due to resonance within the horn. Even the earliest users of hearing aids tried to hide their hearing loss, as was shown with the drawing of a “horn in a hat” in a text by Williams and Wilkins.¹⁰

The first electrical hearing aid was sold at the turn of the century and was an outgrowth of work by Alexander Graham Bell. The hearing aid used a carbon type microphone, called a transmitter, a magnetic earphone, called a receiver, and a battery. The device was simple yet clever in its function. Within the microphone was a diaphragm and a back plate, separated by carbon granules or dust. When a battery was hooked across the carbon, with one terminal attached to the diaphragm and another to the back plate, sound wave vibration of the diaphragm changed the resistance of the carbon granules, thus converting sound energy into an electrical signal. To convert the signal back into sound, a receiver was used which contained a permanent magnet, an iron pole, a copper coil and another diaphragm. As the signal moved through the copper coil, the iron pole moved back and forth and sound was produced at the diaphragm. A maximum amplification of 10 to 15 dB was achieved in this type of hearing aid, although higher

¹⁰Watson, Leland and Tolan, Thomas (1949) Hearing Tests and Hearing Instruments, The Williams and Wilkins Company, Baltimore, MD.

levels could be produced by using larger microphones. The drawback of this device was the distortion produced by the carbon microphone, which reduced clarity of the sound.

The first amplifier used the same principles as the carbon microphone and the magnetic receiver, and allowed reduction in size while still giving increased hearing aid amplification. The amplifier consisted of an intermediate module which “boosted” the original signal, and because of this amplifier large microphones were no longer needed. The disadvantage, however, was that distortions due to the carbon granule mechanism were even more noticeable, lowering the intelligibility of the amplified sound. From the time of these earliest devices, customers have been dealing with the trade-off between size and sound quality.

Miniature vacuum tubes were used for hearing aids beginning in 1938 and provided improvement in amplification volume and sound quality. The vacuum tube took a small input signal and magnified it to a much larger output signal; usually several tubes were used in succession to get greater output. Crystal microphones and receivers became common in this period, their advantage being that they were small and lightweight, but these were eventually replaced by miniature magnetic microphones and receivers. Together the new devices were called the “wearable” vacuum tube hearing aids and had amplification on the order of 30-60dB.

Modern transistor hearing aids arrived in the early 1950’s and soon replaced the vacuum tube versions. Transistors require less power to operate, are more rugged, and take up less space than vacuum tubes. By the mid 1960’s integrated circuits were being produced which contained transistors, resistors and conductors all on a tiny chip, making more sophisticated sound manipulation possible.

Current Technology and Products

This section will describe the styles and components of currently available hearing aids. An understanding of these components is an essential background for later discussions of customer dissatisfaction and the opportunities which result from technological improvements, and also for the product design portions of section 6. Numerous sources describe the detailed function of each component, but that information goes beyond the aim of this paper; the goal of this section will be to provide a concise description of the most important elements of hearing aid technology.

Hearing Aid Styles and Features

The categories for hearing aids from largest to smallest are Behind The Ear (BTE), In The Ear (ITE), In The Canal (ITC), and Completely In the Canal (CIC). The different styles represent an evolution of electronic miniaturization, with the earliest hearing aids having been BTE's, and the most recent being the tiny CIC's. Recent statistics estimate that BTE's represent 17% of the market, ITE's represent 44%, and ITC's represent over 26%.¹¹ (See figure 2.1) ITC's are the fastest growing market segment at around an 18% annual rate; this figure reflects the way customers value small size.¹² Which device a patient chooses depends on the needs and desires of the patient, as well as the limitations of technology. Hearing aids choices are often made based on the following features:

Power

Some patients have a severe hearing loss and therefore need a large dB gain from their hearing aid; the BTE is well suited for this purpose. The case has room for the large

¹¹Cranmer-Briskey, Karen, "Hearing Instrument Dispensing- 1991", Hearing Instruments, Volume 42, no. 6, 1991, pg 9.

¹²Kranmer, Karen, "Hearing Instrument Dispensing- 1991", Hearing Instruments, Volume 42, no. 6, 1991, pg 9.

battery which is needed to drive the receiver. Also, the microphone for a BTE is usually located far away from the receiver, which reduces the chances of feedback between the two components. Many ITE devices can also provide large amounts of power, but feedback may be more difficult to control, and only smaller size batteries may fit into the device.

Telecoil

Telecoils allow the hearing aid to receive information which is broadcast by a special transmitter, usually in an airport or in a specialized classroom. Telecoils add volume to the hearing aid, so they are most commonly found in ITE or BTE devices. In addition to the telecoil itself, the hearing aid usually has an external switch for turning the feature on and off.

Ease of manipulation

For many elderly, small hearing aids are too difficult to manipulate, either adjusting the volume or inserting the device into the ear. Lack of mobility of the fingers or loss of sensitivity in the fingertips can cause these difficulties. Despite these problems, many of these patients still want small hearing aids which are not noticeable in the ear. An audiologist must often explain that instead of an ITC hearing aid, an ITE or BTE with larger controls is a better choice.

Miniaturization

Small size is found in ITC devices, which can just barely be seen at the entrance to the ear canal, and CIC devices, which are completely hidden within the canal. Some tradeoffs can occur in the choice of small size, such as battery life, ease of use and possibly sound processing technology, and usually there is a price premium.

Sound Processing Technology

There has traditionally been a trade off in sound processing technology versus size, but this has recently become less of a problem. Manufacturers used to have to put only their simplest circuits into ITC devices (these circuits will be described in the next portion of this chapter), meaning that customers sacrificed sound quality when buying the small hearing aids. Recently, however, sophisticated chips like the K-AMP circuit have become available for use even in CIC's, eliminating most of this trade off. The Resound circuit, which is the most sophisticated in the industry, is still only available in ITE styles because of the large size of its electronic components.

Hearing Aid Components

Hearing aids consist of a microphone, a receiver (this is the industry term for a speaker), an amplification circuit, and a battery. These parts are contained within a plastic case. The hearing aid operates by first converting sound waves into a voltage signal at the microphone, then amplifying and manipulating that voltage signal in the amplifier section, and finally converting the signal back into sound at the receiver. Usually the hearing aid will have several small electronic trimmers on the plastic case to control features like volume or type of amplification.

Earmolds

Earmolds are the lucite housing which contain the hearing aid electronics. Earmolds are produced by first taking an impression of the concha and ear canal of the patient, then creating a plastic shell to match that person's ear shape. The impressions are made by the hearing aid dispenser, who injects a fast drying silicone putty into the ear. After hardening and removal from the ear, the impression is sent to the factory where a lucite copy is made using a spin casting procedure. The hearing aid electronics are then put into the case, and a vent tube is left connecting the ear canal to open air.

The vent tube provides an important function in the hearing aid by allowing low frequency noise to leave the ear canal. Without adequate venting the patient's own voice will seem too loud, similar to the effect of a normal person speaking with his or her ears plugged. Too much venting, however, allows feedback in the hearing aid, a process by which amplified sound from the receiver travels back to the microphone and is amplified again; the result is a high pitched whine.

Earmolds can also be made of silicone, although this is less common. Silicone earmolds provide greater comfort because they are softer and more flexible, and also provide a better seal against the ear canal which can reduce feedback. One drawback of silicone is that it attenuates high frequency sound that would be carried through by a lucite mold; this can reduce the clarity of the a hearing aid which does not amplify above 4 to 6 kHz.¹³

Microphones

The most common type of microphone is called the "electret" microphone, a name which refers to the material used to convert sound to voltage. Electret microphones work by transforming sound into vibrations of a very thin, charged diaphragm which is mounted above a permanently charged electret material. The diaphragm-plate configuration acts like a capacitor, with a capacitance that varies with the vibration of the diaphragm, thereby converting the sound into a voltage signal. The microphone can be given a high frequency emphasis by placing a hole on each side of the microphone chamber, thus filtering out low frequency sounds which arrive on both sides of the chamber simultaneously. Knowles EM receiver is currently the smallest available, at .00018 in³.¹⁴

¹³Letowski, Thomasz, "Study Finds Greater Sound Attenuation with Silicone than Lucite Earmolds", Hearing Journal, Sept.1991, pg 28-22.

¹⁴Knowles product literature.

Receivers

The receiver functions to transform an electrical signal into acoustic energy. The receiver creates sound by using the amplified electric signal to drive an electric coil, which contains an iron armature. This armature is actually positioned between two magnets and separated from them by an air gap; the armature can easily oscillate when a signal is applied. This vibrating armature is also connected to a diaphragm, which in turn vibrates to produce sound. Knowles makes the smallest receiver currently available, the EH style with a volume of .0034 in³.¹⁵ Some receivers are quite sophisticated, containing a Class D amplifier within the receiver housing (types of amplifiers are explained later in this section), such as the Knowles ES receiver with a volume of .0056 in³.¹⁶

The method of mounting a receiver in a hearing aid is important because it affects device performance. If the mount is too hard, the receiver could transmit mechanical vibration back to the microphone, causing feedback.

Batteries

Batteries have the simple but important task of supplying electrical energy to hearing aids. Batteries are optimized to hold as much energy as possible for hearing aid operation (measured in milliamp-hours), but must stay within the constraint of small size. A variety of combinations exist, providing just the right amount of size and energy for each application. A powerful BTE might require quite a large battery, while a tiny CIC, whose receiver is very close to the ear drum, might operate well with a very small battery. Zinc-air and mercury batteries are the leading types.

Trimmers

¹⁵Knowles product literature.

¹⁶Knowles product literature.

Trimmers are an electronic device used for setting the hearing aid parameters, such as volume or frequency response. A typical BTE or ITE hearing aid might have one large trimmer for controlling the volume, which can be adjusted with the tip of a finger. It might also have two tiny trimmers for fine tuning the acoustic characteristics of the hearing aid, which can be adjusted with a small screw driver. Each trimmer contains a variable resistor which changes value as the knob is turned, and this in turn influences circuit performance. On smaller hearing aids where there is only limited space for trimmer components, efforts are made to eliminate them; these methods will be explained in the Digital Programmers and Remote Controls sections.

Amplifiers

What might commonly be thought of as amplifiers actually include two distinctly different devices. The first, the amplifier circuit, takes the audio signal and amplifies it before it enters the receiver mechanisms. This device will be discussed here. The second device, the pre-amplifier, accomplishes the signal manipulation which is a key to hearing aid performance. The next section will be devoted to explanation of pre-amplifiers.

Analog amplifiers (as opposed to digital, which will be described later) are available in four types, although only three are commonly used in hearing aids. The major features of these were described in an article by Thomas Longwell.¹⁷ They are the following:

Class A

This amplifier is the most commonly used in the industry. It also has the distinction of being the simplest to make and the smallest, but also the most wasteful of power and the lowest in sound quality. This amplifier operates by modulating a constant

¹⁷Longwell, Thomas "Fitting Strategies for the 90's: Class D Amplification", Hearing Journal, Sep. 1992, pg 26-31.

average value of current in conformance with the input signal. Battery power is used whether or not sound is being amplified. This type of operation gives a maximum efficiency of 25%, which leads to a shorter battery life than other types of amplification. In addition, the output voltage is limited by the battery to 1.3 volts peak to peak, which gives clipping and distortion of loud inputs.

Class B

This type of amplifier is more sophisticated than the class A and overcomes some of the Class A's problems. The device has two active transistors which conduct current on alternate cycles, and when there is no signal neither circuit draws much power. This improves the amplifier efficiency to 78%, increasing battery life. The use of two transistors also provides less distortion at high gain.

Class C

Class C amplifiers are used in applications like radio transmitters and are not useful for hearing aids.

Class D

Class D amplifiers are the most sophisticated available and have many advantages. The theoretical efficiency of the device is 100%, giving long battery life. It gives excellent sound quality, which people describe as "clearer", "more natural", of "richer quality", and having "less distortion". Knowles Class D integrated receivers are self contained units, containing both the amplifier and receiver components.

The amplifier achieves efficiency and sound quality through use of a high frequency carrier wave and the use of transistors which are either fully on or fully off. Specifically, a high frequency (100kHz) square wave is pulse-width-modulated to match

an audio input signal.¹⁸ As the audio signal goes more positive, the average value of the square wave also goes more positive. The average polarity of the signal is then applied to the receiver coil, creating the audio output signal. The inductance of the receiver coil rejects any high frequency components from the pulse-width-modulated signal.

Types of Pre-Amplifier Circuits

Pre-amplifiers perform the function of signal processing within the hearing aid, and the approach used in this circuit can be simple or very complex. Simple pre-amplifiers raise only the decibel level of the incoming sound, usually within a desired frequency range. More complicated circuits raise the decibel level to varying degrees depending on the level of incoming sound and the frequency. Additional features act to block out sudden loud noises, such as clanking dishes or slamming doors. With increasing sophistication of signal processing, however, there are tradeoffs in size and cost, and this helps create a wide demand for different circuit styles.

It is interesting as one reads about pre-amplifier circuits to think of them in terms of their strategies for accomplishing sound amplification. The strategies used have evolved over time as researchers learned how the hearing impaired ear functions and improvements occurred in the state of the art of electronics. These considerations can be observed in the products which follow.

Linear Circuits

Linear pre-amplifiers are the simplest type, operating by increasing the sound level of the incoming signal. For example, a person with 30dB of hearing loss in a given frequency range might use a linear hearing aid which added 30dB to any incoming sound.

¹⁸Longwell, Thomas "Fitting Strategies for the 90's: Class D Amplification", Hearing Journal, Sep. 1992, pg 26-31.

The advantage of a linear circuit is that it is inexpensive and has a small size. The main problem with this circuit is the quality of amplification at the high end; a loud noise entering the microphone may produce an output signal which is too large for the electronic circuit to amplify clearly, or for the ear to understand comfortably. The circuit handles this is through peak clipping, in which the portion of the signal which is above the power capability of the output stage is cut off. This method is not desirable because it results in distortion, which is noticeable by the patient. An improved method of solving this problem is soft peak clipping, or peak rounding, where the signal amplitude is reduced in a gradual way. This method offers less distortion. The level at which the peak rounding begins is called the knee point.

Fixed Frequency Response (FFR) Circuits

Fixed Frequency Response (FFR) circuits offer improved sound quality over linear preamplifiers. One example uses a technique called Automatic Gain Control (AGC) to reduce the gain at the highest levels. Instead of using peak clipping or rounding in the presence of loud sounds, an AGC circuit reduces the gain of the amplifier (equivalent to the volume) and thus better preserves the quality of the amplified sound. The term AGC comes from the idea that in the presence of loud sounds, the wearer would like to turn down the volume of the hearing aid in order to avoid the distortion which comes with peak clipping. The benefit of AGC is that the circuit can perform this function quickly and conveniently. The term Fixed Frequency Response is used because this AGC function is applied to the entire incoming signal, regardless of frequency, a distinction which will be understood better in the next section.

Logarithmic compression is another type of FFR circuit, this one based on placing the total range of incoming sound into a smaller dynamic range. This approach has

advantages because many patients have both a lower threshold level and an upper comfort level for hearing, and are best served if the hearing aid places the amplified sound within this range. A logarithmic compression circuit takes soft sounds and amplifies them more than loud sounds. For example, in a quiet room this hearing aid might amplify all sounds by 30 dB, but in a loud room the hearing aid might only amplify sound by 10dB. Again, the circuit is classified as FFR because the logarithmic compression applies across all frequencies.

Level Dependent Frequency Response (LDFR) Circuits

Level Dependent Frequency Response circuits are the most sophisticated available, giving high sound quality in the loudness range and frequency range needed. The circuits accomplish this by taking the concept of logarithmic compression (soft sounds are amplified more, loud sounds are amplified less) and applying it to two specific frequency channels. For example, suppose that a person has high frequency hearing loss and this leads to difficulty hearing soft, high frequency sounds. In a quiet environment this patient might benefit from 30dB amplification of high frequencies, but no amplification of the low frequencies. In a louder environment, however, the patient might benefit from only 10 dB of amplification of the high frequencies, and no amplification of the low frequencies. The term LDFR then is used because the frequency response of the circuit (meaning how much each frequency is amplified) varies with the loudness level of the incoming sound.

Circuits of the LDFR type were classified in an article by Mead Killion in *Hearing Instruments*.¹⁹ He recommended the following categories:

¹⁹Killion, Mead, "Classifying Automatic Signal Processors", *Hearing Instruments*, vol. 41, no. 8, pg 24-25.

BILL-- Bass Increases at Low Levels. In this type of circuit, the bass amplification increases at low sound levels, giving more response for soft sounds than for loud sounds. An example of this type is the Manhattan circuit.

TILL-- Treble Increases at Low Levels. This type of circuit was described in the example above. It provides more treble response for quiet inputs than for loud inputs. An example of this circuit is the K-AMP circuit by Etymotic Research.

PILL-- Programmable Increase at Low Levels. This circuit can be programmed to give either BILL or TILL response, or any combination in between, giving the most versatile design of this type. The example of this circuit type is the Resound device.

An important term which has not been mentioned until now is automatic signal processing (ASP). This refers to any circuit which automatically performs some task which the patient would like to perform, but cannot do quickly or conveniently. An example is adjusting the volume control, which is the idea behind AGC circuits, or the adjusting of the tone control depending on loudness, which is the idea behind LDFR circuits. In fact, any FFR or LDFR circuit can be said to be an ASP circuit.

Additional Features: Programmability

Digital programmability was first introduced in the 1980's and has the potential to improve hearing aid fitting and operation. Programmers function by replacing the trimmers with a silicon chip which can accomplish the task. Digitally programmed hearing aids can give more reliable and easier fittings than traditional hearing aids because the device can be tuned while in the patient's ear. An audiologist can make tuning changes and get feedback from the patient without ever removing the hearing aid from the ear. Simple programmers are often called "electronic screwdrivers".

One important benefit of programmers is that they can allow various programs to be called up as needed. The usefulness of this is based on the idea that one setting for gain and frequency response may not be best for all listening conditions: the listening environment at home may be significantly different from that at a cocktail party, which may be different from that at a baseball game.

Programmers are useful in reducing the size of a hearing aid, especially on canal aids where there is little room for trimmers. The programmer overcomes this by having a wire connection which is used during fitting and then removed for normal operation. A drawback to current programmable designs is that there is little standardization of support hardware. A dispenser wishing to offer programmable aids must purchase expensive equipment from each manufacturer. This issue has slowed acceptance of the feature in the market.

Additional Features: Remote Control

Remote controllers provide convenience to users and are becoming common accessories. The remotes are usually pen shaped or palm sized, and control features such as the on/off switch, volume, and the preset program choice. These remotes operate by emitting an infrared or ultrasonic signal which is received by the hearing aid, and the aid then beeps to let the user know that it has received the message. Use of remote controls allows successful design of small hearing aids where there is little room for volume control trimmers, and helps people with dexterity problems work with small hearing aids.

Technology Summary

Significant changes have taken place in hearing aid technology making possible the device described in section 4 of this thesis. In the area of size reduction, improvements have been made in all component areas: microphones, receivers, batteries, and preamplifiers. Remote operation has become more common, allowing some hearing aids

to avoid use of a manual volume controls, thereby shrinking the size of the device and overcoming some of the challenges of dexterity. Sophistication of amplification has also improved greatly with the advent of programmable aids, which can hold several settings for different environments, and LDFR circuits, which better match the needs of the hearing impaired ear. Finally, convenience and success rate can both benefit from the introduction of programmable circuits, which can easily be fine tuned while inside a patient's ear, leading to a more satisfied patient.

Major Players

Starkey

Starkey is said to be the largest seller of hearing aids in the world, and the example of Starkey's success is an important lesson in the hearing industry. The company is interesting because of its rapid growth and emphasis on marketing instead of technology. The company is just 25 years old, started in the basement of William Austin's home in 1968.²⁰ The original business was a hearing aid repair shop called Professional Hearing Aid Service, which offered a new product: a flat rate repair warranty. The company was successful even in its first year and bought an earmold company called Starkey Laboratories. Two years later the company was the largest hearing aid repair shop in the country.

In 1973 Starkey introduced its first hearing aid, a custom molded ITE, with some very attractive warranties. The company offered a 90 day trial period, during which the customer could return the hearing aid for a free refund, also a one year period in which the aid would be replaced in case of loss or damage, and finally a warranty which covered the instrument in case of changing hearing requirements. By 1976 Starkey had grown to be the largest seller of the new custom hearing aids. Starkey expanded globally

²⁰ "Autographs: Starkey Laboratories", Hearing Journal, July 1993, pg 46.

in the following years through purchase of manufacturers or distributors; the expansion included: United Kingdom in 1977, Canada in 1980, Germany in 1981, France in 1982, Australia in 1984, Switzerland in 1985, Hungary in 1990, and Japan in 1992. The expansion also included several sites across the United States. Starkey is known in the industry for its parties at trade shows and its give-aways to distributors who reach certain sales goals. The lesson from Starkey is that industry sales leadership belongs to the company with the best marketing abilities.

Dahlberg

Dahlberg sells the most hearing aids in the United States, focusing especially on small ITE and ITC devices, and it has accomplished these sales through a large network of Miracle Ear stores. This company is known for its strong focus on marketing, especially through commercials on late night cable television, and this provides another example of what is important to achieving large sales in the hearing industry. Dahlberg has over 1000 stores, including franchise shops, the Sears network, and recently a chain of Australian optical shops. The company was bought in 1993 by Bausch and Lomb, who was already a minor supplier of hearing aids. Dahlberg currently has problems with the FDA due to its aggressive advertising practices over the past several years; the company seems to have been the worst offender in the industry. These problems are discussed more in the FDA section of this paper.

Resound

Resound is the sound processing technology leader in the hearing industry. The company began in 1987 with venture capital financing and uses a patented sound technology from AT&T. 1990 was its first year of sales, by 1992 sales had grown to \$15 million, and by

1993 sales had reached \$35 million.²¹ Financial analysts predict that the company may grow to \$100 million dollars in the next several years. The company offers the industry's only PILL circuit, which gives a dramatic sound quality improvement over linear or FFR circuits. As a result, audiologists report that selling Resound hearing aid is much easier when the person has owned a hearing aid before. The price of Resound units is around \$2000 per ear, and this price along with large size may be the biggest limitations to Resound sales.

Philips

The Philips XP Peritympanic is the most widely sold CIC device. The product was first demonstrated in France in 1989, offered for sale in Europe in 1991, and offered in the United States in 1992. During its first year the product sold 5,000 units.²² Philips has stated that its goal is to establish market share in the U.S. which is equivalent to the status Philips holds in Europe, and it plans to do this with the XP hearing aid and its remote control.²³ The problem with this deep canal instrument centers around fitting: it is difficult to get a comfortable fit deep in the ear canal. The cost of the device is especially high because of these fitting problems, up to \$1500 per ear.

One drawback in this type of hearing aid is the need for deep impressions of the ear canal. Most dispensers are uncomfortable about injecting silicone so near to the ear drum, where an accident could result in serious medical problems for the patient.

Additional Companies

The hearing industry has many more companies which make innovative products, but they will only be mentioned briefly here.

²¹ 1993 Resound Annual Report.

²² Hearing Journal, "Autographs: Philips hearing Instruments Corp.," Hearing Journal, July 1993, pg 46.

²³ Hearing Journal, "Autographs: Philips hearing Instruments Corp.," Hearing Journal, July 1993, pg 46.

- 3M-- This company is a leader in programmable designs and makes a variety of product styles.
- Siemens-- This company also has broad experience in programmable hearing aids. It received notoriety in the late 1980's when President Reagan bought a Siemens product.
- Knowles-- Most microphones and receivers used in the industry are made by Knowles, an industry leader who continues to offer smaller and more advanced products. Knowles sponsors the Marketrak studies of industry performance.
- Etymotic Research-- This company has achieved great success with its K-AMP pre-amplifier, which operates using an LDFR approach. The product is attractive because it is for sale to the industry as a whole, keeping high technology amplification within reach of even small companies who have no R&D budget.
- Gennum-- This Canadian company also sells circuits to the industry as a whole. It has a wide variety of products, including programmable models, and has complete facilities for producing electronic hybrids.

FDA Actions Since 1993

Beginning in early 1993 several groups started to criticize the hearing aid industry, including the FDA and the American Association of Retired Persons (AARP). These criticisms resulted from consumer dissatisfaction with the hearing industry and took the form of television exposes, bad press in the newspapers, and written criticisms by the FDA. The result for certain companies may be fines or other penalties (the problems with the FDA have not yet been resolved), and the industry as a whole suffered a loss of prestige and public trust. The actions affected the industry's financial

performance in 1993 and may continue to influence it in the future. The history of these recent actions is important to understanding how the FDA and the public view hearing aids. This section will describe the events which began in March 1993.

Emerging problem

During March and April the hearing industry was hit with several public criticisms of the way it operates. The one which was most vividly played up on the news was an investigation by the AARP. The group sent a woman named Doris Lomax to visit hearing dispensers in Florida and found several major problems in the way she was treated. In one case the hearing evaluator did not look into her ears to see if wax build-up might be the cause of hearing loss. In another case she reported that “They seemed more interested in selling me a hearing aid than considering my situation. I wouldn’t go back to have my hearing checked at most of these sights.”²⁴ Overall the AARP report was highly critical of the methods and training of hearing aid dispensers, and it said the largest problems were overpromising and the quality of the hearing tests.

FDA takes action

The FDA issued a strong warning to the hearing aid industry around this same time, further contributing to the industry's problem. Their warning focused on the advertising claims of specific hearing aid dispensers, including Dahlberg, Starkey, Siemens, Omni, Beltone, and Electone. FDA commissioner David Kessler was worried about “advertising, promotion and labeling that mislead the public by creating unrealistic expectations” for hearing aids. “Our concern is that the claims these manufactures are making overstate the value of these devices.” “Many of the claims say that the devices do things which they simply cannot do. No hearing aid can distinguish between speech

²⁴ Vick, Karl, “Senate Panel Hears Hearing Aid Scams”, St. Petersburg Times, Sep. 16, 1993, pg 1A.

and background noise. And yet some of the advertising says that it can do exactly that. That's misleading." The result, said Kessler, is that "many of these devices get bought and end up in people's bureau drawers."²⁵

These written warnings, which were sent to each of the companies mentioned, were just one of the steps the FDA planned to take in strengthening hearing aid regulations. The agency also planned to demand formal clinical testing before companies could make claims about performance. Any claims not supported by clinical data "will not be allowed," said David Kessler.²⁶ The offending companies were given fifteen days in which to change or remove their advertising claims or face regulatory action, and most of these companies immediately cancelled all of their television and newspaper advertisements. Even companies who were not targeted specifically by the FDA, including Resound who makes the most highly regarded product in the industry, recalled promotional literature from the offices of dispensers.

The FDA gave several specific examples of advertising practices it wanted changed. One of these was the claim that a hearing aid "focuses on the things you want to hear," implying that the product could distinguish between speech and background noise. Another false claim in the eyes of the FDA concerned one product being better than another. Hearing aids all use basically the same technology, Kessler said, so it was misleading to claim that one was significantly different than another. A third problem concerned claims that a hearing aid could restore hearing to that of the patient's youth. This type of advertising was clearly misleading and only led to dissatisfied customers.

²⁵ Schwartz, Karl, "FDA Warns Hearing Aid Firms To Avoid Misleading Ad Claims", The Washington Post, Apr. 27, 1993, pg A6.

²⁶ Reuters news service, "Health Agency tightens hearing Aid Rules", Reuters, July 9, 1993, AM cycle.

The combination of the AARP and FDA reports raised quite a bit of attention in the press, and many newspapers ran articles about the poor state of hearing aid dispensing. Television also focused on the issue, with shows like Nightline and 20/20 doing specials and exposes. Senator Cohen of Maine was quoted widely in newspapers when he said that some payment plans for hearing aids charged as much as 27% annual interest.

Responses

There were numerous responses by industry groups and professionals, some supporting the efforts of the FDA and AARP, and others disagreeing with their conclusions. The International Hearing Society (IHS), which represents over 3000 hearing specialists, said that the AARP report was flawed because it was “anecdotal in nature” and showed “blatant experimenter bias.”²⁷ This was based on analysis by Ayres D’Costa, a Professor of Educational Services and Research at Ohio State University. In addition, the IHS pointed out that the number of complaints recorded as a percent of sales with the Better Business Bureau was lower than any other consumer products category, at .05%.²⁸ The group also suggested that most buyers were satisfied with their purchases.

Many industry members did, however, support the intentions of the move, including the IHS which had criticized the method of the AARP study. The IHS responded to public concern by proposing improvements to state dispensing laws, especially in the area of the “waiver” system. The waiver system is the method by which a patient chooses not to visit a medical doctor for an ear examination, and instead is tested only by an audiologist. Additional industry members expressed support in letters

²⁷ Kramer, Steve, “Hearing Specialists Challenge AARP Findings”, U.S. Newswire, Sept. 15, 1993.

²⁸ Kramer, Steve, “Hearing Specialists Challenge AARP Findings”, U.S. Newswire, Sept. 15, 1993.

to industry journals: one audiologist wrote to the Hearing Journal saying that “the commercials were actually hurting the customer” by raising customer’s expectations.²⁹

Others thought the FDA was misinformed in their conclusions concerning what hearing aids could and could not do, and brought up technical issues to support these claims. One Washington attorney said that the “FDA seems not to be aware of a large body of data and industry technology that substantiate these claims.”³⁰ It did in fact seem that the FDA was not familiar with current methods of signal processing. Voices are made of higher frequency sound than many background noises, so that by amplifying high frequencies a hearing aid can do a reasonable job of improving the desired sounds. Other sounds, however, like the clanking of dishes or additional voices in a room, cannot be filtered out by a hearing aid. Each group was partly correct.

Many people also questioned the FDA’s statement that advertising claims are not supported by data. Industry members had plenty of data, but according to the FDA it was not valid. The FDA usually offers strict criteria about how testing is to be performed, but in this industry it had never offered such guidelines. Even by the end of 1993 the FDA had still not finished preparing testing guidelines, leaving the industry in a bad position; it could not make strong claims until it completed FDA testing, but the FDA had not issued any guidelines. Miracle Ear began television advertising again in early 1994, but the commercials emphasized only the small size of the product.

There also seemed to be questions about what authority the FDA was using in its attacks on the hearing industry. The FDA used an obscure rule covering “Misbranded Drugs and Devices,” section 502(r), to make its claims. Under this rule, the absence of

²⁹ Schwartz, Karl, “FDA Warns Hearing Aid Firms To Avoid Misleading Ad Claims”, The Washington Post, Apr. 27, 1993, pg A6.

³⁰ Dickinson, James, “Extending FDA Drug Ad Restrictions to Medical Devices”, Medical Marketing and Media, June 1993, pg 56.

data on file at the FDA is evidence of illegal claims. Few or none of the manufacturers had data on file at the agency. There were also suggestions that the actions of David Kessler were not based on real problems in the hearing industry. Kessler had used high profile attacks on the pharmaceutical and other industries, and now he was trying it in the field of medical devices. A Washington lobbyist, interviewed for this paper but who wished to remain anonymous, was highly critical of David Kessler personally. The lobbyist thought that half of the FDA's actions since Kessler had become commissioner were politically motivated, with one possible motivation being to maintain a large budget for the FDA in the face of government cutbacks.

Effect on Dahlberg Acquisition

One of the biggest effects of the controversy was its influence on the Dahlberg (Miracle Ear) acquisition by Bausch and Lomb. The large optical company was interested in hearing aids because the product fit in with its other health products, and it chose Dahlberg specifically because of its 1000 store franchise network. When the FDA actions occurred, and when Miracle Ear was pointed out as a major offender, the purchase seemed to be in question. Bausch and Lomb went ahead with the purchase after negotiating a \$20 million price reduction. In addition to the FDA letter, the FTC threatened at the same time to file a complaint against the company and its officers for violating a 1976 order on advertising claims. Dahlberg stated that the \$20 million price reduction reflected the economic impact of the "increased governmental regulation within the hearing industry," but it must have reflected also the specific problems between Dahlberg and the FDA.

Conclusion

The resolution of the current FDA actions will have a significant guiding influence on the hearing aid industry. In one area, Dahlberg continues to struggle with

the FDA and FTC. In January of 1994 the FTC filed a civil suit against Dahlberg, seeking substantial penalties for what it said was false advertising between 1988 and 1992. Dahlberg has tried to countersue, alleging that the FTC does not have the right to oversee a medical company such as itself. The arguments may not be resolved in the near future, but one result is clear: Dahlberg laid off 17% of its workforce last October, mostly in manufacturing and assembly positions.³¹

In another area, the FDA is getting close issuing guidelines on clinical testing of hearing aids. The administration distributed preliminary copies of a protocol in March 1994 and asked for comments to be returned by April. In June 1994 the FDA plans to have a general meeting on the subject, and a final protocol will be issued some time after that. The protocol outlines the type of tests which will be done, and includes requirements such as a minimum of 25 persons per test, and double blind test procedures. It will not be clear until the process is further along whether the FDA desires to be cooperative or adversarial with industry members, but the answer to that question is be important. The relationship between industry and government will end up dictating whether small companies can afford to come out with innovative products, and how quickly existing companies can bring out their own new products.

Distribution

Dispensing Path

The distribution of hearing aids is both complex and labor intensive. Each hearing aid must be specially fitted to the customer's ear, both mechanically and acoustically. The mechanical fit begins when the hearing professional prepares a mold of the patient's ear canal by injecting fast curing silicone. The professional then removes

³¹Frederickson, Tom, "Dahlberg Cuts Workforce by 17%", Minneapolis-St. Paul City Business, Oct. 15, 1993.

the mold and sends it to the hearing aid manufacturer. Often a second mold is made in case the manufacturer has a problem. The manufacturer takes the mold and uses it to make a spin cast acrylic case, which fits the ear canal exactly. The proper electronics are put into the case and it is returned to the dispenser.

An acoustic prescription, called an audiogram, must accompany the silicone mold to the manufacturer so that it can pick out the correct circuit. This audiogram must be created by an audiologist in a careful test, and experience of the audiologist is important toward getting a reliable audiogram.

When the hearing aid returns from the manufacturer, the patient must return to the office for the instrument fitting. Adjustments are necessary to tune the device to the patient's hearing, and instructions are given for care of the hearing aid. The size of the hearing aid vent tube must often be adjusted to change the amount of occlusion in the patient's ear. Dispensers meet with the patient for several hours during this first fitting of the hearing aid in order to help the patient become comfortable with the device. Meetings in the following weeks take place for a variety of reasons: customers don't understand the use of batteries, aren't comfortable with the amount of occlusion, or are unsatisfied with the sound amplification. Improvements in the dispensing path are a major part of the cost savings opportunity in producing a quickly fit hearing aid.

Types of Dispensers

There are three types of hearing aid dispensers, as described in annual dispensing surveys by Hearing Instruments magazine. These are: hearing instrument specialists (HIS), dispensing audiologists in private practice (DAP), and dispensing audiologists in a clinical setting (DAC). As will be seen in the following sections, these groups each have a different emphasis in sales and marketing. (All dispensing data in the following section

was taken from 1991 and 1992 survey articles appearing in Hearing Instruments magazine,^{32, 33} except where noted.)

HIS: Hearing instrument specialists are state approved dispensers of hearing devices who usually work in either an independently owned and managed shop or a franchised shop.

DAP: Dispensing audiologists in private practice are professionals who hold a master's degree in audiology. These audiologists also work in a small shop setting, and often own the business.

DAC: Dispensing audiologists in clinical practice have the same training as above but work in a setting associated with a hospital or Ear, Nose and Throat (ENT) practice. This association strongly affects advertising and the number of referral sales for the shop.

Dispensing

As mentioned earlier, the average price for a hearing aid is \$717. The price varies by style, however, with smaller hearing aids costing a premium. In 1992, the average price for a BTE was \$644 and the average price for an ITC was \$814, about a \$170 premium. Instrument prices overall are more expensive at an HIS; In The Canal products can cost up to \$80 more than the average.

Dispensers vary on how many instruments they sell per month, but according to data the average dispenser is relatively small. Among HIS, 60% of dispensers sell less

³²Cranmer-Briskey, Karen, "1992 Hearing Instruments Dispenser Survey Results", Hearing Instruments, vol. 43, no. 6, 1992, pg 8-13.

³³Cranmer-Briskey, Karen, "Hearing Instrument Dispensing-- 1991", Hearing Instruments, vol. 42, no. 6, 1991, pg 6-13.

than 20 units per month. For audiologists in private practice, the number sold is similar, and for audiologists in clinical practice, 70% sell less than 20 units per month. For all three types, gross revenue per year is around a quarter million dollars or less. Of survey respondents, the DAP showed the highest revenue at \$259,000, and DAC showed the lowest revenue at \$162,000.

Waivers

It is recommended, but not required, that a patient visit a physician before having a hearing exam. Even though it is in their own interest to see a doctor, many people sign a waiver in order to avoid the hassle and expense of visiting the doctor. Additional problems exist with this system: as reported in the FDA section of this paper, a 1991 survey in Vermont found that 55% of customers waived the doctor's evaluation and 20% of customer files contained neither a waiver nor a doctor's evaluation. It is likely that future industry reforms or regulations will focus on this issue.

Returns

Most company's offer a return policy if the customer is not satisfied, and this is used somewhat frequently. For BTE instruments, 3% were returned for credit in 1992, and for ITE instruments 6.7% were returned for credit.

Many more instruments must be returned to the manufacturer for adjustment. At HIS dispensers, 14.5% of hearing aids must be returned to help solve fitting or feedback problems. At DAP dispensers, 19.5% must be returned for adjustment. Even when instruments are not sent back to the factory, up to one fourth require adjustment in the office to solve comfort and performance problems.

Advertising and Referral relationships

Advertising, referrals from ENT's, referrals from customers and repeat customers are the main sources of business for dispensers. For HIS dispensers, about 13% of their

budget is spent on advertising, and they receive 40% of customers this way. Other important sources are repeat customers, accounting for 31% of business, and customer referrals, accounting for 21% of business.

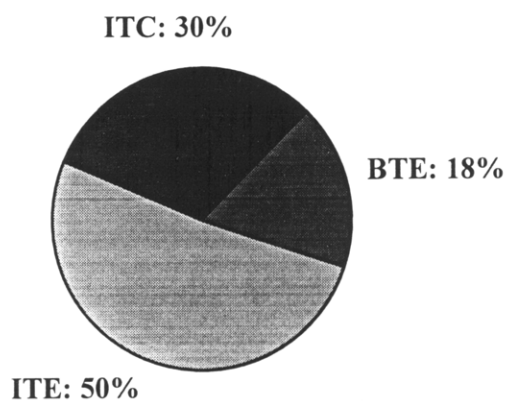
Audiologists in clinical practice (DAC), on the other hand, spend only 5% of their budget on advertising, and receive just 5% of customers this way. Referrals from ENT's represent a much more important source of sales, 41%, and 15% of sales come from customer referrals.

Audiologists in private practice (DAP) are somewhere in between. 20% of sales come from customer referrals, 18% from advertising, 29% from ENT referrals, and 18% from repeat customers.

Image Problem

The image of hearing aid dispensers among the public is not high, and this is a constant subject of discussion in industry journals. People working in the industry have commented that patients approach dispensers with distrust, sometimes imagining dispensers as thieves or charlatans. Negative word of mouth is a large problem for dispensers; there has been a conscientious effort among dispensers to improve customer satisfaction, but a few bad dispensers as well as the high expectations of customers has still left some people unhappy. Current problems with the FDA are not helping matters. One thing which can help dispensers is formation of strong referral relationships with doctors; if a doctor recommends a dispenser, that patient will often have a more positive attitude when approaching a purchase.

FIGURE 2.1: HEARING AID MARKET SHARE BY PRODUCT TYPE ³⁴



³⁴Cranmer-Briskey, Karen, "Hearing Instrument Dispensing- 1991", Hearing Instruments, Volume 42, no. 6, 1991, pg 9.

Section 3- Comparisons with Optical Industry

In this section the optical industry is described in order to provide additional insight into how the hearing industry may develop. Through the following observations it is possible to see how various medical, market and regulatory factors can influence an emerging and expanding medical product industry.

A variety of factors contribute to the richness of comparisons between these two industries, most notably the purpose of the device and the market structure. Both eyeglasses and hearing aids attempt to improve the quality of human sensing of the environment, and this leads to similarities in the implementation of the products. The industries also are similar in product distribution, customer demographics, regulation and challenges faced by manufacturers. Hearing aids and eyeglasses are frequently compared in the public media, and this might actually cause the industries to have an effect on each other; a typical comparison was seen in early 1993 when FDA commissioner David Kessler began his criticisms of the hearing industry: Kessler said “Getting the right hearing aid is probably more complicated than getting the right eyeglass prescription.”³⁵

It will be shown in this section how one could consider the optical industry to be a more developed version of the hearing industry; the optical industry offers a similar product, but dispensing occurs at a lower comparable price, with greater convenience, and to a much larger portion of the total market. To the extent that the products and markets are alike, the current structure of the optical industry might suggest something about the future of the hearing industry.

³⁵ Vick, Karl, “Senate Panel Hears Hearing Aid Scams”, St. Petersburg Times, Sep. 16, 1993, pg 1A.

This chapter will begin with a section describing the optical industry, including market data, customer demographics, types of eye care professionals, and competing technologies. The second section will describe more dynamic issues in the optical industry, including industry growth over the last 30 years, new growth of the contact lens market, and current actions by manufacturers. The final section of this chapter will summarize some significant ways in which the two industries are similar and different. These observations will contribute to discussions in section four about the opportunity for an inexpensive, quickly customized hearing aid.

Optical Industry Background

Definition of the market

The optical industry, or vision care market, is broadly defined to include prescription glasses, contact lenses, sunglasses and reading glasses and are available from many retail outlets. The simplest products, inexpensive reading glasses and sunglasses, are found in pharmacies and local markets. More sophisticated prescription glasses are found in small optical shops, large retail optical chains, and most recently in optical shops located within mass merchandise stores. Contact lenses, a growing segment of the optical industry, can be found in the same retail outlets. Total sales of these products was estimated to be \$11.5 billion in 1993.³⁶

Technologies defined

Prescription glasses hold the largest market share in the industry, and their lenses are available in two forms: glass or polycarbonate plastic. Polycarbonate is lighter weight than glass and can be ground into thinner sections, thus providing advantages over traditional lenses. Since their introduction, plastic lenses have gained 80% of the lens

³⁶ Dallas Business Journal, "Pearle Eyes Explosive Growth", Dallas Business Journal, May 22, 1992, pg 1.

market. Glass lenses, on the other hand, offer better scratch resistance than plastic and also come in photochromic versions. Either lens can be ground to match the vision correction needed for the patient, and either can have bifocal or continuous focus features.

Contact lenses have an advantage in cosmetic appearance, and are sold in two main categories-- disposable and non-disposable. Non-disposable lenses, include soft lenses and rigid gas-permeable lenses, must be removed each night and cleaned properly. Disposable lenses are available in several styles, including regular disposable (for up to two weeks use), planned replacement (for one to three months use), and extended wear (for up to six months use), and may be worn continuously without cleaning. Contacts have disadvantages of higher cost, the expense and bother of cleaning solutions, and an increased risk of serious eye disease. This type of infection, called ulcerative keratitis, is 14 times higher than normal among people who use disposable contact lenses.³⁷

Eye care professionals:

There are three types of eye care professionals: ophthalmologists, optometrists, and opticians. These are explained below.

Ophthalmologists: Doctors of Medicine (M.D.) who are concerned with the structure, function and diseases of the eye. They are trained to perform surgery, diagnose and treat eye diseases, perform eye examinations, write prescriptions for eyeglasses and contact lenses, and fit contact lenses.

Optometrists: Doctors of Optometry (O.D.) who are trained to diagnose and treat eye diseases, perform eye examinations, prescribe eyeglasses and contact lenses and fit contact lenses.

³⁷ Consumer Reports magazine, "Contacts vs. Glasses", Consumer Reports, August 1993, pg 503.

Opticians: Opticians are trained to fill the eyewear prescriptions of the above two and fit or adjust the eyeglasses.

Among the three groups there is a range of involvement in the dispensing process.

Ophthalmologists do not normally sell eyeglasses, although they may be associated with an eyeglass shop; usually a patient obtains only an eyeglass prescription during a visit to an ophthalmologist. Optometrists commonly work with or own an optical shop and do both eye exams and dispensing. Opticians have the least amount of training of the three groups and are most often found at retail chain optical shops. Due to the convenience and low inventory costs of holding contact lenses, all three groups compete in the sale of contact lenses.

Market data

The vision care market is highly competitive, providing low prices which have benefited the consumer. The average price paid for glasses in 1991 was \$132.53, down 1% from 1990.³⁸ Contact lenses are priced a bit higher: soft contact lenses cost \$175 to \$275 per pair for the original fitting. Rigid gas-permeable lenses cost about \$25 more. Extended-wear lenses cost \$225 to \$375 a pair, and disposables cost \$450 to \$600 for a year's supply³⁹. Optical retail chains account for 33% to 40% of the total optical industry sales. Pearle Inc. and Lens Crafters are the two largest optical retail chains, with a larger market share than the next 18 chains combined.⁴⁰

Demographics

³⁸Morgan, Babette, "Visions of Profits... Discount Stores Enter Market for Eye Care", St. Louis Post-Dispatch, Aug. 3 1992, pg 1.

³⁹ Consumer Reports magazine, "Contacts vs. Glasses", Consumer Reports, August 1993, pg 503.

⁴⁰Dallas Business Journal, "Pearle Eyes Explosive Growth", Dallas Business Journal, May 22, 1992, pg 1.

In 1991, the US prescription glasses market served more than 85 million people, and according to Bausch and Lomb the contact lens market in the US was 20-22 million people.⁴¹ During the late 1980's the market size increased at a rate of 5-8% per year, a similar figure to the hearing aid market, and this is expected to continue through the year 2000 due to the aging baby boom generation. For people 45 years and older, 90% need corrective eyewear; by the end of the decade this group will include 96 million people.⁴² Despite growth of the older age segments, vision companies are also looking toward the youth for significant market growth. Modern lenses are soft, comfortable, and require little or no cleaning because they are disposable; these are qualities which appeal most to young, active customers.

Medical path

Patients obtain glasses or contact lenses by first visiting an ophthalmologist or optometrist for an eye exam. The patient does not have to visit a trained M.D.. If the eye exam is performed by an ophthalmologist, the patient then takes the prescription to an optical shop to be filled. If the eye exam is performed by an optometrist, the patient can either have the prescription filled at that location or take it to a retail chain store. The dispenser (optician) supplies lenses or contact lenses which match the prescription supplied by the specialist.

Competing technologies

There are several competing medical technologies which improve vision, the most important being radial keratotomy and eximer laser treatment.

⁴¹Grone, Jack, "Seeing Into the Future: Biggest Developments in Eye Care Coming in the Contact Lens Field", St. Louis Business Journal, July 8, 1991, pg 1B.

⁴²Morgan, Babette, "Visions of Profits... Discount Stores Enter Market for Eye Care", St. Louis Post-Dispatch, Aug. 3 1992, pg 1.

Radial Keratotamy, by far the most common procedure for improving vision, is a surgical procedure which reduces the severity of a patient's myopia. It is accomplished by making four to eight incisions with a scalpel, cutting through 95% of the corneal substance, thus causing the cornea to flatten. The procedure can be done in a doctor's office, and over 1.5 million people have chosen radial keratotamy.⁴³ The procedure has some problems, most notably because the it is not totally predictable and the wounds may be unstable, causing variations in vision. Also, the patient must still wear glasses despite the dramatic improvement in vision quality, and the scars on the cornea may make night vision difficult.

A similar treatment is under FDA trials, but it uses energy bursts from an excimer laser instead of cuts from a scalpel to change the shape of the cornea. The procedure can be used to cure nearsightedness, farsightedness and astigmatism by reshaping the cornea with the nanosecond laser pulses. The technique has the potential of creating or restoring 20/20 vision without producing scars. The FDA testing involves 48 machines made by three manufacturers and is being tested on volunteers nationwide; approval may come as early as 1994. The treatment currently costs \$3000 per eye, but may drop to \$500 to \$1000 per eye in the future. This high price is due in part to the cost of the laser itself, between \$250,000 and \$500,000, as well as annual maintenance costs of \$30,000 to \$50,000 per year.⁴⁴ VISX, Inc., one of the manufacturers of the lasers, was given permission in 1991 to expand export activities to Canada, Italy, Saudi Arabia, France, Venezuela, and Korea.⁴⁵ The procedure has the disadvantage that in some cases it leaves

⁴³Signor, Roger, "Surgery May Cure Myopia", St. Louis Post-Dispatch, June 12, 1993, pg 3A.

⁴⁴Benmour, Eric, "Excimer Laser May Improve Bad Eyesight", Business First-Louisville, July 29, 1991, pg 1.

⁴⁵"VISX Incorporated received FDA Permission to Expand Export Activities of its Twenty/Twenty Excimer Laser System",Business Wire, Aug. 13, 1991.

a light fog over the entire cornea, but the history of this is unclear and medical trials are seeking to learn more about the problem.

Dynamics and Trends

Change in competition

The optical industry has changed over the last twenty five years as a result of evolving technology, regulations and marketing methods. Before these changes, the industry was characterized by small, independently owned and operated optical shops. Prices were much higher than today for both eyeglasses and early contact lenses.

The first major industry change happened in the mid 1970's, when the FTC changed regulations which restricted advertising by professionals; this change affected professionals in many industries, including doctors, lawyers, pharmacists and eye professionals. The rules had originally been set up to protect individuals from unscrupulous practitioners, but by the 1970's consumers and some professionals were arguing that the rules only reduced competition. Limitations on advertising, for example, meant that an optician who wished to advertise in the yellow pages faced limitations on the size of the ad, could not include his or her own photograph, and was forbidden from using slogans such as "lowest price in town". Reformers argued that a wide range of prices existed in the market, but consumers were not able to locate the cheaper ones because of advertising restrictions. With less restrictions on advertising, they argued, competition would force the highest prices to fall. In the end, courts around the country decided that the First Amendment guaranteed consumers the right to know information about goods and services available in a market. The FTC enforced this interpretation, thereby changing the rules of both states and professional organizations.

Around this same time, the FTC made another important decision affecting the optical industry: it decided that eye professionals must give a copy of an optical

prescription to any patient who requested it. This meant that patients could take their prescription from the doctor or optometrist and have it filled at a lower priced store. The change further increased the competitive nature of the optical market.

These changes made possible the proliferation of low price chain stores. The stores were staffed with lower wage opticians and had strong buying power, thus giving the chains a cost advantage in the marketplace. Many professionals feared the increased competition and argued that quality and service would suffer, but the industry transition took place anyway. Price competition became common in the industry.

Growth of the contact lens

The first contact lenses had appeared on the market in the 1960's, but it was not until the innovation of soft contact lenses in the 1970's that the product became popular. In 1971 the FDA gave approval for Bausch and Lomb to sell soft contact lenses, produced under license from a Czech process, which had an advantage over hard contacts that they did not collect dirt, did not pop out of the eye, and were more comfortable. Bausch and Lomb had a monopoly for the next three years, allowing the company to charge high prices and earn large profits. By 1977, however, five more company's products had been approved by the FDA and 15 others were awaiting approval, and this caused prices to drop. In the early 1970's the price for an eye examination plus a pair of soft contact lenses was \$400, but by 1979 the price had fallen to \$120 at some retailers.⁴⁶ Wholesale prices for a pair of soft lenses fell from \$90 to as low as \$37.⁴⁷

Sales growth of contact lenses growth followed the changes occurring in the optical market. In the area of price competition, the most aggressive price cuts occurred at the new retail chains. Customers who filled their prescription at the chain store instead

⁴⁶ "Deregulation: Soft Contact Lenses", *The Economist*, May 12, 1979, pg 88.

⁴⁷ "Deregulation: Soft Contact Lenses", *The Economist*, May 12, 1979, pg 88.

of the optical shop could save up to \$100 on lenses and a lens care kit. In the area of marketing, there was a change in marketing focus during this period away from doctors and toward the general public. Bausch and Lomb created this new approach, and with it the company hoped to increase sales volume and profits despite the new competition. Bausch and Lomb and the retail chains were “natural allies”; Bausch and Lomb’s profit was the same whether the consumer paid \$300 at an optical shop or \$150 at a retail chain, but at \$150 per pair Bausch and Lomb could sell many more lenses.⁴⁸ Owners of the smaller shops were aware of how loyalties might be changing in the market: Dr. G. Peter Halberg, president of the contact Lens Association of Ophthalmologists noted at the time “I wonder whether Bausch and Lomb’s more aggressive marketing policy eventually aims to circumvent the professionals in the contact lens field.”⁴⁹

The contact lens market provided the largest growth area for the vision care industry, growing at a 23-30% rate from the late seventies into the early eighties.⁵⁰ In 1969 there were 2 million people wearing contact lenses, by 1977 there were 6.5 million people wearing contact lenses, and just two years later that number was between 10 and 15 million people. By 1991 the number of people using contact lenses had grown to 22 million people.⁵¹

Modern changes

Complaints by ophthalmologists and optometrists about retail stores continues today, especially in the area of advertising. Professionals claim that the retail store’s “buy 1, get 1 free” ads are rarely what they seem: the second pair is often a discontinued

⁴⁸ Berman, Phyllis, “Shifting Channels”, Forbes, May 1, 1977, pg 27.

⁴⁹ Berman, Phyllis, “Shifting Channels”, Forbes, May 1, 1977, pg 27.

⁵⁰ “Lens Boom Ahead”, Chemical Week, Nov. 16, 1977, pg 31.

⁵¹ Grone, Jack, “Seeing Into the Future: Biggest Developments in Eye Care Coming in the Contact Lens Field”, St. Louis Business Journal, July 8, 1991, pg 1B.

frame, and the offer may include expensive options which are not free. The professionals also claim the chain stores push expensive options onto consumers and have poor customer service. In addition, they claim that the fitting staff is poorly trained, and that in combination with trying to hurry the prescription within one hour results in warped lenses and frames.⁵²

The newest change to optical distribution involves merchandisers such as Walmart, Kmart, Pace and Sam's, and the situation is reminiscent of the 1970's. These companies envision large profits in optical sales, and have the advantages of a wide network of stores with a large customer base, strong buying power, and low overhead. They see existing optical stores which mark up as much as 2-3 times, and they believe that they could sell for less. Walmart opened 200 optical centers in 1992 as a test of the concept, and it plans to expand to 1700 stores nationwide. By comparison, the largest optical retailer, Pearle Vision, has only 900 stores in the United States.

Arguments over quality and service have continued along with these changes in the distribution path. The president of Pearle, Bob Stetson, believes that the industry's image will decline with the entrance of the superstores. "When you're selling eyewear next to tires and panty hose, something's lost."⁵³ Within these sentiments, however, must exist a larger worry over the threat posed by the mass merchandisers; their entry can change the industry structure within a few short years.

In contact lenses, the most recent trend has been toward disposable (or planned-replacement) contact lenses. These products avoid the hassle of cleaning solutions because the lenses are replaced when they become dirty. Disposable lenses are also

⁵² Wascoe, Dan, "Eyewear Price Promotions Attract Increasing Scrutiny", Star Tribune, April 12, 1992, pg 4D.

⁵³ Dallas Business Journal, "Pearle Eyes Explosive Growth", Dallas Business Journal, May 22, 1992, pg 1.

easier to manufacture. The leader in this area is Johnson and Johnson's Vistakon division, which shipped 29.2 million units in 1990; sales in 1991 were \$235 million, with over half that being in the U.S. disposable contact lens market.⁵⁴ The company is innovating by going to a just in time delivery system, with a goal of reducing inventory costs at distributors and customers. The company has a three day shipping commitment to retailers. Bausch and Lomb has also entered the replaceable contact lens area and is second to Vistakon. Bausch and Lomb experienced growth in overall contact lens sales, due mostly to disposable lenses. In 1993 the company hired 300 new workers in the contact lens division, a 20% increase in employment.⁵⁵

Actions by manufacturers:

This section outlines three recent actions in the optical industry which may have relevance in the changing hearing industry.

Vistakon distribution

Vistakon corporation has responded to pressure from optometrists and ophthalmologists concerning the quality of eye care in the contact lens area. The company has decided to sell its contact lenses only through stores with authorized eye care professionals, with the goal of preventing health risks to its customers. In cases where the product is sold without "a licensed practitioner personally fitting contact lenses on the premises... Vistakon reserves the right to terminate any relationship, including the sale of the product." Stores without licensed professionals claim that the real reason for this move is that optometrists and ophthalmologists have complained about losing business to retail stores.

⁵⁴ South Florida Business Journal, "Contact Lens Battle Heats Up", South Florida Business Journal, May 18, 1992, pg 3.

⁵⁵ Le Beau, Christina, "Bausch and Lomb to Hire 300 Contact-Lens Workers", Rochester Business Journal, June 11, 1993.

The surprising aspect of this report is that the largest disposable contact lens manufacturer would suddenly become concerned with the small shops. Perhaps the change reflects the lower wholesale cost of contact lenses and J&J's move toward a just in time delivery system; it is now easier for small shops to afford and maintain a supply of the lenses. In reverse of earlier trends, the small shop now represents an opportunity for sales growth of disposable lenses. Hearing aid companies seeking to market an inexpensive product will have to make similar decisions over distribution emphasis.

Bausch and Lomb price discrimination

Bausch and Lomb was observed engaging in an interesting kind of price discrimination, and the situation shows a problem in the sale of disposable devices. The company manufactures one type of disposable contact lens and sells it under three separate brand names: Optima, Medalist, and SeeQuence 2. The products vary only in their packaging and labeling. Optima is advertised as lasting a year and sells for \$23 per lens wholesale; Medalist is advertised as lasting two months and costs \$16 for two pair; and SeeQuence 2 is advertised as lasting one week and costs \$15 for six lenses.⁵⁶ The company defends this approach saying that it rewards customers who replace their lenses more often; the company also says that it will not distribute contacts to any dispenser who explains the pricing policy to patients and sell them the cheapest lenses. The FDA has found nothing illegal in what Bausch and Lomb is doing. Sellers of an inexpensive hearing aid will also have to deal with price discrimination questions, especially given the strong buydown characteristics reported by Kochkin.

Pearl Strategy

⁵⁶Summer, Constance, "D.A. Questions FDA Approval of Lens Labels", Los Angeles Times, Sept. 4, 1993, pg B1.

Pearle Incorporated is moving to face the challenge of mass merchandisers entering into optical distribution. The company plans to add 1000 new franchises to its existing network of 1100 stores (of these, 900 are in the U.S., and 500 are franchises). With this effort it hopes to increase sales from \$750 million in 1991 to \$1.5 billion by 1996.⁵⁷ It has made internal management changes also, cutting management layers from nine down to three, and attempting to bring management closer to the customer. Whether Pearle reaches this goal of opening 1000 new stores may depend on the profitability of its existing shops in the face of the new competition. In the hearing industry, companies with existing distribution systems will face similar challenges if new entrants change the market structure.

Parallels and Differences

By observing the parallels and differences between the optical and hearing industries, one can imagine or predict how the hearing industry might change as a result of cost, quality, and convenience improvements. The two industries have similarities, such as the goal of the device and the consumer nature of the product, which might suggest that hearing aids will follow similar development path. But strong differences exist also, such as the complexity of the fitting challenge and the regulatory framework of the industry, which may hold back improvements in service and consumer prices. The goal of this comparison is to discern which lessons from the optical industry might be relevant to the hearing industry, and which lessons will not apply.

Ability to Measure

The most important difference between the examples of hearing and sight may be the ease with which one can measure and then correct for the disability. In the case of

⁵⁷Dallas Business Journal, "Pearle Eyes Explosive Growth", Dallas Business Journal, May 22, 1992, pg 1.

sight, the loss can be easily measured using a set of corrective lenses; when the person can see details most clearly, the proper lens has been identified. Fitting a pair of glasses simply requires grinding the correct lens shape and placing them in a set of frames. With hearing, the ability of a subject to report information is more variable, leading to variation in the quality of the initial testing process. Once an audiogram has been produced, it is still unclear what might be the best fit for a hearing aid. Usually tuning of the device electronics is required, as well as adjustment of the physical form to control feedback and own-voice sound.

In vision care it has proved reasonable to have a technician perform the dispensing of glasses or contacts once the necessary prescription is identified. In hearing, no two patient conditions will be identical, so a hearing aid may never be fitted as quickly or as easily as a pair of glasses; testing and fitting may always require the presence of a skilled practitioner. Eliminating the time spent tuning the hearing aid to the patient's loss, or reducing the skill level of the dispenser, would directly harm the success of the fitting.

Current Position in Development Path

Comparisons between the development of each industry can be valuable. The optical industry has gone through several major phases of development, beginning with the small, individually owned stores of the 1960's and early 1970's, later switching toward retail chain stores, and most recently the toward mass merchandisers. If one imagined the hearing industry in this same structure, it might appear to be fairly young in its development. Similarities include the success that Miracle Ear and Starkey are having with national advertising, and also the retail expansion of Miracle Ear through franchise shops, Sears hearing centers, and the Australian optical shops. An important difference is

that in the hearing industry, retail chains do not compete based on price; instead they advertise the small size which their brand offers and (until recently) the quality of sound amplification. Whether the hearing industry will follow the optical industry depends on additional factors such as regulation, actions by industry groups, and manufacturers success at producing products which address customer needs.

Regulation: Licensing of Dispensers

Regulation faced by the two industries, particularly the certification of dispensers, is a strong effect on the evolution of the markets. As recently as 1991 only 21 states had adopted standards for the training of opticians.⁵⁸ This is surprising in light of the great changes which took place in that industry over the last thirty years; ophthalmologists and optometrists must not have been able to demand strict training standards of retail dispensers. In hearing aids, every state except one has training standards for dispensers, and current action in many states focuses on tightening those standards. These regulations evolved as a way for the hearing industry to raise quality standards of its own dispensing system, and hopefully improve the public's perception of hearing aid dispensers; they were not necessarily aimed at the type of retail dispensers who have appeared in the optical industry. Training requirements such as these help prevent the hearing industry from closely following the development pattern of the optical industry, because they raise the employee education requirements and therefore the overhead of retail chain stores.

Strength of Existing Groups to Shape Industry

The ability of groups within an industry to shape the markets is another important factor. In the optical industry there are examples of both success and failure of groups to

⁵⁸Helms, Sherry, "Critics Still Seeing Red About Mass Marketing of Eye Care", Houston Business Journal, June 17, 1991, pg 16.

influence the market. When the retail chains first appeared, the ophthalmologists and optometrists warned that quality would suffer and that consumers would be worse off, but this had little effect in stopping the changes. Professional's concerns about quality did not outweigh the opposing concerns advocating competition and the freedom to advertise, and therefore did not shape the industry. There was, on the other hand, the example of Vistakon deciding to distribute contact lenses only to those groups who used certified dispensers to fit them, in effect supporting the position of professionals and placing an extra burden on retail chains. This move is influential because of the strength Vistakon has in the market. In the hearing market industry groups have shown the ability to require more stringent training, a move which affects the current and future market structure. For a company planning to offer an inexpensive, quickly customized hearing aid, the influence which dispensers or audiologists might have over that product introduction should be a large concern. Product quality is important, but just as important is the reaction from these retailers. Where the product is sold, and whether it competes against existing retailers, could decide whether the industry accepts or rejects the product.

Ability to Reach Customers

Public perception of each product illustrates an important difference between the two industries. Such perception determines the acceptance of the products into daily life in a way which companies cannot control through their individual marketing efforts. Because of the way eyeglasses are perceived, the industry has achieved nearly 100% market penetration. Testing of vision is done in the public school system at a very young age, either with eye exams or through observations by school teachers. Eye glasses for people with vision problems are considered a necessity, and charitable organizations often provide glasses to the poor. Given the current low cost of glasses, it is rare that a person in this country who needs glasses does not have them.

Hearing aids, on the other hand, are not widely perceived as necessary. Doctors receive little or no training in medical school about treatments for hearing loss. As a result, general and family practitioners rarely recommend hearing aids for their patients who might benefit from them. In other parts of society, such as public schools, people are just now becoming aware of the benefits of hearing aids. The Americans with Disabilities Act (ADA), for example, is beginning to change the way that public schools work with the hearing impaired. It is possible that government actions like the ADA and industry-wide advertising campaigns may change the way people feel about hearing aids, but it is doubtful that an improved hearing aid image could approach that of eyeglasses.

Hearing and Optical Industry Segments

A similarity between the two industries concerns the existence of various market segments. In the optical industry, the advent of contact lenses let people avoid the discomfort of heavy glass lenses and the stigma of wearing them, but contact lenses were not for everyone. For some the contacts are uncomfortable, for others the cleaning is too much trouble, and for still others the worry of infection is too great; these problems have meant just a 20% overall market share for contact lenses. Even within the traditional eyeglass market, tradeoffs between polycarbonate and glass mean that neither is completely dominant.

The market for hearing aids is similar: there will always be a need for the different styles. One reason is dexterity, which prevents some older people from manipulating small objects; these people need ITE or BTE hearing aids. Another is the tradeoff in sound quality versus size. Still another reason is the need for extra features, such as telecoils. Full consideration of the customer needs and preferences is important when

calculating how new technology might change the industry, and no matter how good a new product, market share will be difficult to earn.

Chapter 4- Opportunity for a Inexpensive, Quickly Fitted Hearing Aid

Over-The-Counter Dream

It is tempting to imagine the future of hearing aids as one where a patient walks into a pharmacy, listens to a series of recordings on a pair of headphones, selects the one that sounds best, then buys a hearing aid off the shelf. There are so many examples in modern culture where technical innovations make lives easier and more convenient, so why shouldn't it happen here. Small, inexpensive and high quality commercial products, like the portable CD player and hand held television, make an over-the-counter (OTC) hearing aid seem simple.

The vision of the OTC hearing aid incorporates many "wouldn't it be great if..." scenarios-- mostly from the manufacturer's and consumer's points of view. The product and marketing features would be reminiscent of the optical industry in convenience and cost. The product would be mass produced inexpensively and sold to the customer at a low price. The product would be so revolutionary that it would capture most of the market.

It would be the design of the hearing aid would make all of this possible. The physical shape would fit any ear with minimum effort, possibly with snap on sleeves or a "one size fits all" shape. The electronic content would work for anyone after only a minor adjustment of preferences, and the product would be easy to use. Perhaps the best feature of this idealized OTC hearing aid is that it would require no personal fitting to the ear or hearing loss by a professional; the product would be do it yourself and therefore inexpensive and quick to obtain.

Limits to OTC Concept

There are many reasons why it is not possible to create this idealized OTC hearing aid, and the background has been introduced in the preceding chapters. First of all, fitting the hearing aid is not easy and it never will be. From the acoustic point of view, each person's loss is unique in type, severity, and breadth across frequencies. From a physical point of view, each person's ear canal is a different length and diameter, and has different curves. These problems make it difficult to have a one size fits all device.

Another element of the vision, that of selling through competitive retail chains such as Pearle Vision, seems unlikely. A retail chain of hearing aid stores would benefit from national advertising, but would not have economies of scale like Pearle. Each retail shop would require a trained professional, meaning that the chain store's costs would be nearly the same as the small independent shop.

Final price could not match the vision of the OTC device either. Current prices include the cost of the device, two fitting appointments at the dispenser, and several follow up visits; it is doubtful that all of these could be reduced to the point where the device was extremely inexpensive. Finally the OTC device won't take over the whole market. Some patients need large BTE's or ITE's because of dexterity issues. Some need specialized circuits because of specific hearing losses. Some will desire a circuit with the highest sound quality.

Opportunity Which Does Exist

The opportunity which does exist in the hearing industry reflects the fact that a hearing aid can move closer toward the OTC product, even though not all the way there. From the section on customer dissatisfaction we know that hearing aids do not sell because of vanity, cost and sound quality, but we also know that each of these can be addressed using recent technology. By using a skilled design and currently available components it is possible to approach the goal of an inexpensive, high sound quality,

quickly fit CIC hearing aid, a product which is currently not available in the market. By addressing each of the major customer dissatisfactions, it is possible for this product to have a dramatic impact on the market.

The CIC hearing aids currently sold address customer needs in terms of size, but they leave other issues unaddressed. The Philips XP has been criticized for its sound quality, which is said to be a variation on a linear Class A circuit. In addition, fitting the XP to the ear canal is difficult, leading to a low success rate on fitting attempts and therefore long delays in product delivery. To its credit, the XP does use a remote, which adds to the convenience. Another CIC available in the market, made by General Hearing Instruments, makes use of high quality K-AMP sound processing, but again is specially fit, leading to long delivery times. Both these products are quite expensive.

An important aspect of the hearing aid proposed in this paper is the physical design and form. As will be described in detail in further work by Greg Lambrecht, the proposed housing is one which can be inflated with gel or liquid inside the ear canal, allowing the dispenser to achieve a comfortable fit during one sitting. This easily customizable form is the closest that one can come to the “one size fits all” ideal. It may still take several attempts to get the fit just right, but if a fitting is not comfortable, the dispenser can just take off the sheath of the first attempt and try again. The significant aspect is the change to customization at the point of sale. Several patents exist in this area, among the strongest being held by Siemens AG, but no use is being made of these patents in the current market and further design opportunities exist.

Another important aspect of the hearing aid is the choice of electronics. The hearing aid would most likely use one of the high quality LDFR circuits available in the market, and it must be programmable. With the programmability the device can be more quickly and reliably customized based on customer feedback at the time of fitting. With

an LDFR circuit, the hearing aid will contain the sound processing quality necessary to meet customer's expectations. Other circuit types could also be used, such as a less sophisticated FFR circuit combined with a programmer and several feature settings, but this would be larger and of lesser sound quality than the LDFR circuit.

The physical form and sophisticated electronics easily meet the customer needs of size and sound quality, but together they meet another customer need: convenience. The physical and electronic fitting would still be performed by a professional, but at least it could happen in one session. If all went well the patient can have his or her hearing aid the same day, instead of several weeks later.

Another improvement is in price, which would not be as low as the idealized OTC aid, but could be much lower than the current price of \$717. Several points of savings are found. Customization at the point of sale means that all devices are the same at the manufacturing step, thus providing efficiency and lowering costs. Elimination of the need for a custom ear mold removes an expensive step in the process. Reducing the dispensing visits from two to one saves valuable time for the dispenser. As we will described on further work, it may be possible to lower price to one third of present amounts.

Sales volume can be quite large (though not the entire market, as we learned from the optical and hearing market backgrounds), because this product would be ideal for the group of under 65 year old, moderate hearing loss patients. As was seen in the customer needs section, this group was primarily concerned with vanity, and this product's CIC size, combined with cost and high sound quality, meets these requirements. The hearing aid could be sold across all distribution channels because the units would be inexpensive and easy to stock, similar to the Vistakon product in Chapter 3. Audiologists could offer the product as effectively as the retail chains.

FDA regulations represent one of the largest hurdles in this new product introduction. As long as a manufacturer of this product used conservative judgment in advertising, the FDA would not slow the marketing of the product, but repercussions of the current FDA/Hearing problems might make basic product approval more difficult. Still, there are examples of recent FDA approvals of 510K applications in the hearing field, suggesting that it is not impossible to introduce a new product in the current regulatory climate.

Another challenge for manufacturers is the lack of patent protection. Almost all parts of the design can be bought in the open market, providing the benefits of quick development time and market introduction, but also giving the drawback that other companies can follow. Physical fit is one of the few aspects that can be patented, but there are numerous approaches to this and several patents are already granted. The most likely developer of this product may be a group with preexisting distribution channels, who can make strong use of first mover advantage. As was seen in the examples of Starkey and Miracle Ear, marketing skill is critical for earning and holding market position. As a result of weak patent protection, delays in market introduction because of FDA regulations could have a large impact on a company's success.

In summary, an opportunity exists for a product which seeks to combine many technologies which are currently available, such as programmability, LDFR circuits, and a new design for the physical form. These create a product which can be sold in a new way, reducing costs and increasing convenience, which can satisfy customer needs in a way unlike any hearing product sold in the past. Further work by Lambrecht will suggest product designs and likely methods for marketing and distribution.

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