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December 6, 2015

The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President:

I am writing to support PCAST's Recommendation to open up the market for innovative hearing technologies. However, I believe it doesn't go far enough. It is just a start. The 'Recommendation' should be updated to:

- Include accurate hearing loss population numbers.
- Require generic names for hearing aid features with a rating system.

I. **The numbers are not fully accurate and do not account for the full hearing loss marketplace**.

Hearing loss is a national problem that affects everyone in this country whether directly or indirectly. The letter's first section severely underestimates the population affected by hearing loss. '10% of the population or 48 million people[1] have some form of hearing loss' versus the '30 million (Footnote #2) and 30% over age 65[2] have some form of hearing loss' versus the 25% used. (Footnote #1)

PCAST solely looked at the hearing loss market through an older adult lens despite 70% or the vast majority of the hearing loss market being younger than 65.[3] The letter implies that hearing loss is solely an older adult issue. The letter

[1]"Basic Facts About Hearing Loss | Hearing Loss Association of America." HLAA Updates. 2015. Accessed November 28, 2015. http://www.hearingloss.org/content/basic-facts-about-hearing-loss.

[2]Ibid.

[3]Ibid.

mischaracterizes the population and how hearing loss impacts the needs of people with hearing loss. One in five teens has some form of hearing loss.[4] Lack of access to quality hearing aids is critical if we are going to change how children with hearing loss grow up, are educated and enter the job market.

On a personal note, my daughter who is 21 has a hearing loss. She continuously worries that she will not be able to afford hearing aids, despite the fact she is starting at an entry level job in a corporate company and she doesn't have student loans. Lack of access to hearing aids is a huge hurdle to obtain an education. A lack of education impacts future employment.

Hearing loss, while prevalent in older adults, is not just an older adult issue.[5] Omitting children, teens and younger adults from the discussion reinforces the incorrect perception that hearing loss solely affects older adults. Failure to include children and younger adults can then have a ripple effect in legislation and benefits not being available for children and younger adults.

This is not the first time a government or quasi-government agency failed to fully understand hearing loss. A recent CDC study[6] "forgot" hearing loss[7]. The CDC apparently wanted to collect data using phones. Many people with hearing loss cannot use phones. The CDC, rather than change how the data was collected, decided to eliminate hearing loss as a disability. Failing to include hearing loss prevented another opportunity to accurately count people with hearing loss. The agency's response was essentially a "My bad" when confronted with the omission. The data was not footnoted nor was the omission mentioned.

The numbers used are severely underestimated. Data collection for people with hearing loss is tricky. It requires people with hearing loss to self-identify they have a hearing loss. But many people with hearing loss deny they have a hearing loss even when it is a well known. President Clinton for years denied having a hearing loss. Former Mayor Bloomberg to this day, upon information and belief, still does not wear hearing aids. Raise the issue to him and his response is "I cannot hear you." It is unlikely that either of these two people would respond to a surveyor that they are "hearing impaired."

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[4]Shargorodsky, Josef, Sharon Curhan, Gary Curhan, and Roland Eavey. "Change in Prevalence of Hearing Loss in US Adolescents." The Journal of the American Medical Association 304, no. 7 (2010): 772-78. Accessed November 27, 2015. doi:10.1001.

[5]Lintz, Janice. "Who Are The Role Models Since Helen Keller?" Https://janiceslintz.files.wordpress.com/2015/06/fwa-2015-jun-jul-pg79.pdf. July 1, 2015. Accessed November 28, 2015. https://janiceslintz.files.wordpress.com/2015/06/fwa-2015-jun-jul-pg79.pdf.

[6]"CDC: 53 Million Adults in the US Live with a Disability." Centers for Disease Control and Prevention. July 30, 2015. Accessed November 28, 2015. http://www.cdc.gov/media/releases/2015/p0730-us-disability.html.

[7]Lintz, Janice. "Hearing Loss, the Forgotten Disability." The Huffington Post. July 30, 2015. Accessed November 28, 2015. http://www.huffingtonpost.com/janice-s-lintz/hearing-loss-the-forgotte_b_7896184.html.

To understand the complexity of the issue, one only has to look anecdotally at a random multi-generational family gathering. An older adult might deny having a hearing loss. Yet, that same person is likely to be unengaged and perhaps smiling and/or nodding during conversations despite not hearing the conversation. They might also shout and/or turn up the volume on their television or phone to an uncomfortable level for people who can hear. My own mother falls into this category. She will emphatically tell everyone that she can hear. Yet, my siblings and I all agree that she cannot hear. We all know people who fit into this scenario. But if a person who thinks they don't have a hearing loss is asked if they have a hearing loss by a surveyor, they will respond that they do not have a hearing loss. This person is thus not counted in the hearing loss population despite having a hearing loss. As a result, the number of people with hearing loss and the severity of the problem is gravely underestimated. This issue is more critical and urgent then even PCAST realizes.

Minimal data for people with hearing loss is unavailable. The government fails to collect data as noted above by the CDC's failure to include hearing loss in its recent survey. In the United States, Hearing Loss Association of America (HLAA) is the only major hearing loss organization to advocate for people who are hard of hearing. HLAA, advocates primarily for older adults. Hard as it is to believe, there is not a single organization in the US that advocates effectively for children with hearing loss. HLAA struggles financially and cannot afford to collect data. Thus, the only data collected is by self-serving industry organizations since HLAA cannot afford to collect it, there is no organization serving the needs of children with hearing loss and the government just omits people with hearing loss that is too inconvenient to collect. This seems incredulous but it is accurate.

The Hearing Industry Association (HIA) which upon information and belief, is the hearing aid manufacturer's lobbying organization falsely states in its letter that when hearing aids are covered that hearing aid usage does not increase. It in fact does. Goldman Sachs' 2011 European Hearing Aid Report Exhibit 4 shows "Countries with more generous public reimbursement systems tend to see higher hearing aid penetration."(Exhibit A) This chart was prepared internally by Goldman Sachs, who has no reason to not accurately measure the market, unlike an organization that is, upon information and belief, heavily funded by the 6 hearing aid manufacturers. HIA's statement also defies common sense.

II. The Market for hearing aids is also characterized by lack of transparency.

This section is fully accurate but omits a critical part of the issue: the lack of transparency. Even if the market places shifts as the PCAST hopes it does, the consumer has no idea what they are purchasing unless there is greater transparency. The letter mentions the issue but seems to think the Consumer Electronics Association (CEA) will be able to fill the gap. The following is an

article that is pending publication in *Huffington Post* that illuminates the need for generic names for features.

It's easier to compare computer brands than hearing aids. Hearing aid manufacturers use trademarked proprietary names for important features which makes it impossible to compare them. Contrasting components is virtually impossible without generic names. Hearing aid buyers and parents of children with hearing loss are thus dependent on the audiologist or hearing aid dispenser to provide information, which may present a conflict of interest because the audiologist/hearing aid dispenser:

1. Represents a limited number of manufacturers and may not have knowledge of all hearing aids on the market.

Audiologists/hearing aid dispensers are presumed to know all the aids on the market, but the reality is that that they only dispense a few brands. The hearing aid mix they offer is based on such concerns as percentage of earnings, incentive pricing, delivery schedule, quality, and customer support. Some of these concerns, such as percentage of earnings, are not in the best interest of the consumer.

2. May receive bonuses/equipment based on the volume of hearing aids sold.

Many hearing aid companies provide free equipment or incentives or perks to audiologists/hearing aid dispensers based on their sales volume. This marketing program is now frowned on in the pharmaceutical business and should be eliminated in the hearing aid business as well.

3. Has a financial incentive to maximize the likelihood of making a sale.

Audiologists/hearing aid dispensers make a substantial profit when they sell hearing aids. Critical information that may obstruct the sale, such as the pros and cons of various features, may not be disclosed. The hearing aid manufacturers also heavily fund, either directly or indirectly through advertising, many of the hearing loss organizations, which can interfere with their advocacy on this issue as well.

Consumers can only educate themselves with information that is easily attainable and understandable, but there is no incentive for manufacturers or vendors to provide it unless they are required to do so. The FDA can bring greater transparency and accountability to the dispensing of hearing aids by developing a rating system for the various hearing aid features based on international ANSI standards and by standardizing the naming of these features. The availability of this information will enable consumers to become better informed and more satisfied with their purchase.

Standardizing terminology for hearing aid features will also help consumers to evaluate personal sound amplification products (PSAPs) which are not hearing

aids and thus not regulated by the FDA. PSAPs are flooding the market, and consumers have no idea how effective these devices are for people with hearing loss—they only know that PSAPs are more affordable. If generic names for hearing aid features were used, then consumers could compare PSAPs to hearing aids and see what they are or are not receiving.

As Sy Syms said, “An educated consumer is our best customer.”

Portions of this article previously appeared in a Petition to the FDA.

It is insincere for HIA to state that an audiologist would know which hearing aid works best since even they are unable to compare one hearing aid to another since the information doesn’t exist. (See article above.)

The CEA is an industry lobby group funded by membership companies. Having sat on the Federal Communications Commission’s (FCC) Consumer Advisory Committee under Chairman Martin for two terms, the CEA is unlikely to do their part without regulation. The changes made by the CEA primarily occurred in my opinion when mandated by the FCC including adding a captioning chip to televisions. CEA did not do this voluntarily but was mandated by the FCC. The same was true for adding an easy to find close captioning button on television remote controls. The FCC does not have this oversight on hearing aids. There will be no regulatory authority to ensure CEA acts in the best interest of people with hearing loss.

Another illustration of this issue was with another membership organization, The Wireless Association (CTIA). Hearing aid compatibility for cell phones required knowing the radio frequency immunity numbers or Hearing Aid Compatible (HAC) numbers for cell phones as well as for hearing aids. The FCC required the cell phone manufacturers to provide HAC ratings. Only the FDA could require the hearing aid manufacturers to provide its HAC ratings. The FCC did not have oversight over hearing aid companies. While the FCC was willing to require the cell phone companies to provide the ratings, the FDA was unwilling to do so the same for hearing aid companies. Having one rating without the other was meaningless and infuriating.

Even with the information being required, some of the cell phone companies grudgingly provided the information in tiny print that was hard to find, failed to properly train their employees and refused to provide a sufficient numbers of attractive and popular models with appropriate ratings.[8] So, the issue became one of form over function. The information was available but good luck finding it.

The FDA meanwhile refused to mandate hearing aid manufacturers to provide HAC ratings. This made it impossible to purchase a cell phone for our daughter. At the time, no one at the FCC would contact the appropriate person at the FDA to set-up a meeting between the FCC and FDA Chairmen to resolve this issue. I

[8] The FCC is finally now addressing the product array issue.

was repeatedly told, only a Chairman could contact a Chairman. It became an issue of protocol.

The problem was inane and infuriating to me. But, as a mother, I could call anyone since government protocol did not apply to me… So, I did.[9] I literally called the FDA Chairman almost every single day until a voluntary rating system was adopted.

The voluntary hearing aid rating availability meant our daughter could finally purchase a cell phone after we purchased new hearing aids. To close the remaining gaps that the cell phone manufacturers refused to provide, CTIA as a voluntary membership organization could not mandate but merrily suggest and the FCC refused to address, I published the article, “How to Buy a Cell Phone when You Have a Hearing Loss” . The article was initially published by the State of New Jersey[10] and republished by Alexander Graham Bell Association’s Volta Voices[11] and Better Hearing Institute. The article embarrassed the various cell phone companies to disclose the information needed by people with hearing loss.

This information would not have moved forward without this article that was heavily vetted off-the-record by people from cell phone manufacturers, FCC, CTIA and CEA who could not publicly speak on the record but assisted me behind the scenes. It was simply ridiculous. I was literally the only person in the country who could publish this information because of various regulations, protocols, company policies and lack of common sense.

I learned through this process and working with other membership organizations such as NEA and ANA[12] that certain large companies have tremendous clout and place unwieldy pressure on membership organizations. The membership organizations cannot mandate anything but can only recommend action. Placing people with hearing loss, who have no market force, dependent on these organizations is untenable. Success is only accomplished by people like me who have dedicated their life to work for free to achieve success for people with hearing loss. This is inappropriate and burdensome. I am frankly, tired of working for free to do everyone’s job.

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[9]Lintz, Janice. "How an Ordinary Person Can Change the World, Well at Least Start the Process..." The Huffington Post. July 13, 2015. Accessed November 28, 2015. http://www.huffingtonpost.com/janice-s-lintz/how-an-ordinary-person-ca_b_7756394.html.

[10]Schacter, Janice. "How To Buy A Cell Phone When You Have A Hearing Loss." Monthly Communicator. September 1, 2008. Accessed November 28, 2015. http://www.state.nj.us/humanservices/ddhh/newsletters/communicator/archive/2008MCs/MCSep08.pdf.

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[12]Schacter, Janice. "The Benefits of Closed Captioning Commercials." December 1, 2010. Accessed November 28, 2015. https://janiceslintz.files.wordpress.com/2015/03/ana_closedcaption_whitepaper-f.pdf.

People with hearing loss have no market force as evidenced by the lack of significant change with hearing aids. People with hearing loss cannot be dependent on membership organizations or the generosity of people to receive the information that they so sorely need. Another example, is my 2009 petition before the FDA on these issues has gone unanswered. (Ex B) The hearing aid market needs a radical overhaul, clear regulation and oversight. The hearing aid industry and audiologist stranglehold must be broken.

III. **HIA's Report is Self-Serving**

HIA's report is self-serving to protect the organization's funders which are upon information and belief, hearing aid manufacturers. The report discussed hearing aid alternatives. Other than a cochlear implant which would be prescribed by an otolaryngologist, there aren't alternatives. The after-market accessories are just that, after market add-ons that audiologists peddle to consumers similar to gum at the supermarket checkout stand. Most of the products do not work and are relinquished to sitting in the drawer. The one product that is routinely not recommended is the telecoil. The feature adds only $50 to the sale of a hearing aid but tends to require a lengthy discussion. So, audiologists omit the discussion even when required by law in four states: Arizona, Florida, New York and Rhode Island. [13] (Exhibit C)

HIA's discussion of complex algorithms is insincere. Audiologists are not mathematicians. The hearing aid manufacturers have developed software to calculate the formulas. The audiogram numbers are inputed into the software to determine the hearing aid program. The hearing aids are adjusted based on consumer input after testing the aids. This statement is just utter nonsense.

Summary

I fully support PCAST's recommendation but the numbers need to be updated to include accurate numbers as well as the 70% of the population that has some form of hearing loss including but not limited to adults and children under the age of 65. Omitting these numbers reinforces the stereotype that only older adults have hearing loss. This is insulting to people like my daughter and the millions of children and adults with hearing loss.

Greater transparency of features whether they are hearing aids or PSAPs is needed. Consumers need to understand how the features serve their needs whether they are purchasing an PSAP or a hearing aid.

Best,

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[13]Schacter Lintz, Janice. "What Is a T-Coil & How Do You Use It?" Monthly Communicator. April 1, 2013. Accessed November 28, 2015. http://www.nj.gov/humanservices/ddhh/newsletters/communicator/current/mc_apr13.pdf.

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Thomas Wheeler, FCC Chairman (Email address omitted.)

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Ex A

Goldman Sachs

Europe: Healthcare: Medical Devices

Equity Research

Hearing aids: Staying on sidelines following AAA

US private market likely to accelerate; mix seems to be improving

Conversations with audiologists and managements at the American Academy of Audiology (AAA) meeting suggest that the US private hearing aid market is likely to accelerate in 2011 driven by modestly higher volumes and improving mix as patients trade up to higher-end devices. Specifically, we estimate that in 2010, ASP's in the US private market were –1%, driven primarily by mix, suggesting that patients remained unwilling to trade up to the higher-end devices among continued economic uncertainty. However, with consumer confidence in the US improving, we expect mix – and hence ASP's – to improve going forward.

Industry in midst of a cycle; no major product introductions at AAA

We saw no major product introductions at this year's AAA as most manufacturers rolled out new platforms in 2010. Consequently, most focused on highlighting their recent platforms and niche product offerings (such as accessories or invisible HAs).

Invisibility in focus: We see Lyric as disadvantaged

We have seen continued focus on "invisible" hearing aids at this year's AAA, with Siemens and Sonic (now part of WDH) both introducing a micro-CIC. Although we do not see this market as sizeable – given that only 30%-40% of patients meet the criteria for a mini-CIC (i.e. appropriately-sized and shaped ear canal), – we believe that the concept of invisibility could drive incremental demand from patients who are otherwise unwilling to wear a hearing aid given the associated stigma. We view the micro-CICs as better positioned vs. Sonova's Lyric; we believe that 1) patients will prefer a removable solution, and 2) price-wise, mini-CICs are more affordable.

Sonova: Staying on sidelines; some weakness in FY12 likely

Following AAA we revise our FY12-14 Sonova estimates downward 13% to 15% – we now forecast only modest share gains in FY12 as we believe that Sonova will struggle to capture incremental market share given initial problems with the Spice platform. Our revised 12-month price target of SFr88 (from SFr95) implies 3% upside potential and we retain our Neutral.

We maintain our Neutral on William Demant – we believe that the recent re-rating (+20% in four weeks) reflects near-term upside potential from any disruptions at Sonova; our revised 12-month price target is DKr480. We make minor adjustments to our estimates and price target for Amplifon.

OVERVIEW OF RATINGS AND PRICE TARGETS

		Price target		
Company	Rating	Ccy	New	Old
Amplifon	Neutral	€	4.5	4.4
Sonova	Neutral	SFr	88	95
William Demant	Neutral	DKr	480	455

Note – all price targets have 12-month horizons.
Source: Goldman Sachs Research estimates.

COVERAGE VIEW: NEUTRAL

UPCOMING EVENTS

Amplifon 1Q11 results – April 29, 2011

William Demant 1Q11 results – May 12, 2011

Sonova FY11 results – May 24, 2011

EUHA Congress – October 19-21, 2011

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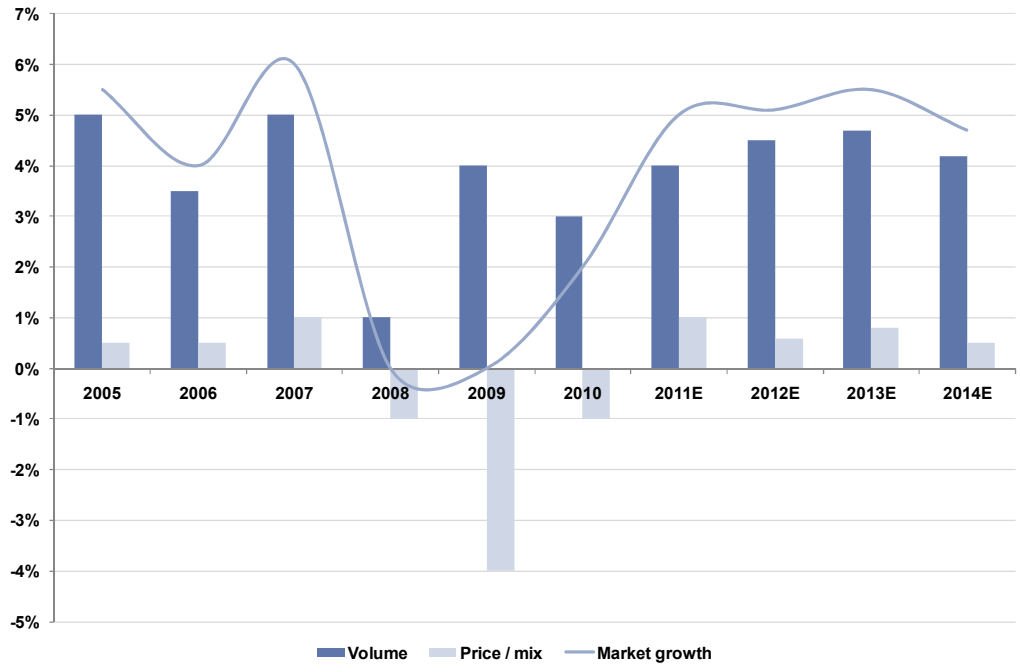
Hearing aids: Staying on sidelines following AAA

We attended the American Academy of Audiology (AAA) meeting last week to get an update on volume trends, recent product introductions, and market dynamics within the hearing aid market. Our key takeaways from AAA are as follows:

Pricing stable in our view; 2010 ASP weakness driven primarily by mix

Our conversations with managements and audiologists suggest that in general, pricing has remained stable in 2010/11 with most manufacturers maintaining like-for-like pricing discipline. Most managements we spoke to believe that the modest ASP weakness seen in 2010 – we estimate ASP's in the US were down roughly 1% based on our conversations at AAA – was driven by continued unfavorable mix as some patients continued to trade down to lower-priced devices. Given increasing consumer confidence levels in the US – consumer confidence in the US rose in February to its highest level since 2008 – we would expect mix to improve in 2011; **in general , we continue to believe that manufacturers will be able to obtain positive innovation-driven mix in the medium-term.**

Exhibit 1: We expect positive ASP's going forward
Global hearing aid market growth: Price/mix vs. volume



Source: Company data, Goldman Sachs Research estimates.

No major reimbursement changes on the horizon; outlook in UK still unclear

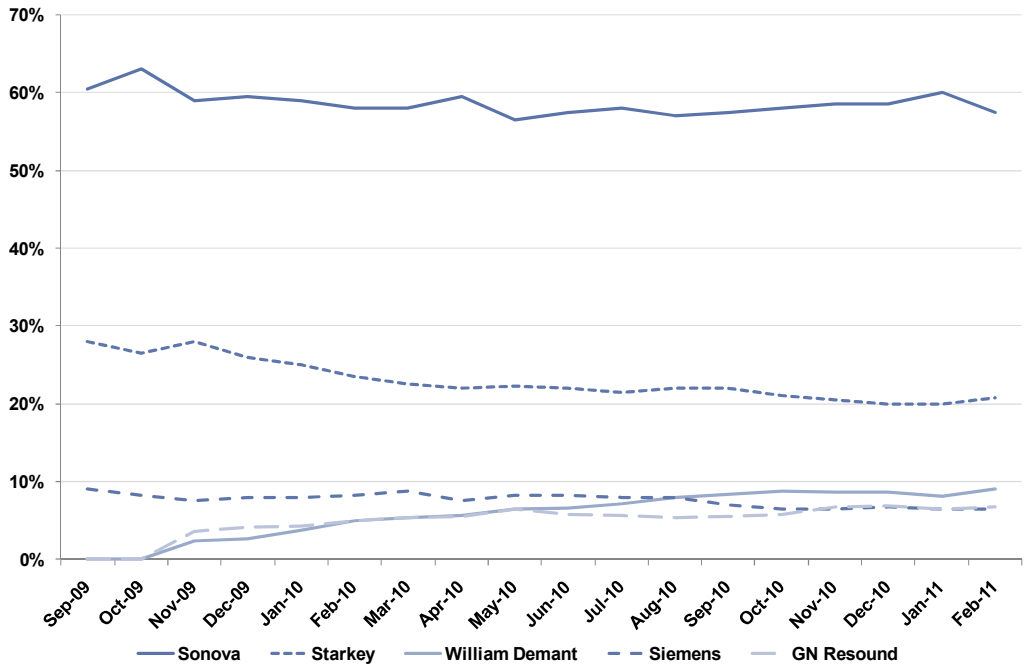
We continue to view meaningful changes to reimbursement of hearing aids in Europe – excluding the UK – as fairly unlikely given that spending on hearing aids accounts, on average, for less than 1% of total healthcare budgets. We also expect continued volatility in the Swiss market as the government's recent decision to reduce reimbursement from SFr1,500 per hearing aid to SFr1,000 per hearing aid as of July 1, 2011, is likely to front-load some purchases into 2Q/3Q (from 4Q); on average, Switzerland accounts for less than 4% of Sonova's and William Demant's revenues.

We view the UK as most at risk as far as reimbursement is concerned though given low ASP's within the NHS, shifting away from the NHS would be a positive for the industry in our view (WDH is the largest NHS supplier). At the beginning of 2011, the NHS reduced the number of hearing aids it purchased from 800,000 units to 650,000; consistent with history, we would expect an increase in NHS waiting lists to drive modestly stronger growth in the private market in 2011.

Sonova's VA share stable despite recent entrants; Starkey has seen the largest share losses in 2010

Despite the entry of William Demant and GN ReSound into the Veterans Affairs (VA), Sonova's market share has remained stable at approximately 55%; Starkey has seen the biggest losses in the VA driven by the company's limited BTE offering.

Exhibit 2: Sonova's share in VA has remained stable despite recent entry of William Demant and GN ReSound
Monthly share in VA



Source: Company data, Goldman Sachs Research estimates.

Competitive environment has intensified

We believe that the competitive environment within the hearing aid market has intensified in the last 12 months as the smaller manufacturers have closed some of the technological gaps versus Sonova and William Demant. Specifically, apart from GN ReSound, all major manufacturers now offer devices with binaural processing capabilities, which improve patients' spatial sound perception as well as increase understanding of speech in noise; these are often highlighted by patients as areas they are most dissatisfied with as far as hearing aids are concerned.

Exhibit 3: Most competitors now offer features comparable to Sonova and William Demant
Overview of recently launched high-end product

Manufacturer	Product / platform	Ear-to-ear connectivity	Directional algorithms	Spatial recognition	Indicated hearing loss	Launch date
Oticon	**Agil / Rise 2**	**Yes**	Yes	Yes	Mild to profound	March 2010
Phonak	**Ambra / Spice**	**Yes**	Yes	Yes	Mild to profound	November 2010
Siemens	**Pure / BestSound**	**Yes**	Yes	Yes	Mild to severe	March 2010
Widex	**Clear440 Fusion / Clear-ISP**	**Yes**	Yes	Yes	Mild to profound	March 2011
Starkey	**Wi Series**	**Yes**	Yes	Yes	Mild to severe	April 2011
GN ReSound	**Alera / Range**	**No**	Yes	No	Mild to profound	September 2010

Source: Company data.

Amplifon recently signed a supply agreement with Starkey in its Sonus network (Starkey was not a supplier to Amplifon previously), as, according to our discussions with Amplifon management, the company now finds the Starkey product offering much more competitive – relative to the bigger players – than in the past.

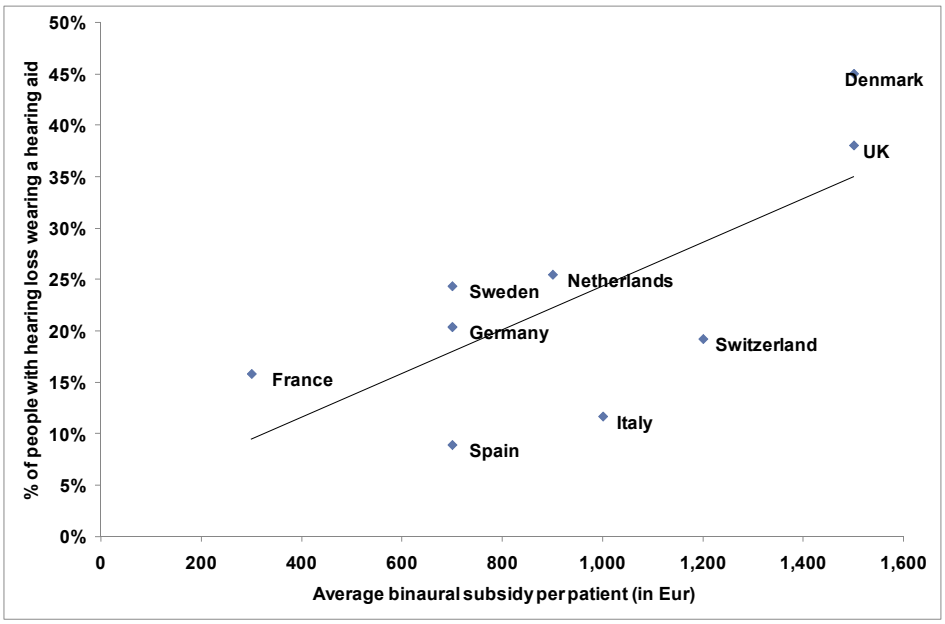
Notable products at AAA 2011: Starkey's AMP could drive penetration higher

We saw no major product introductions at this year's AAA as most manufacturers introduced or rolled out new platforms in 2010. Consequently, most manufacturers focused on highlighting their recent platforms and some niche product offerings, such as accessories or invisible HAs.

The most notable product at this year's AAA was Starkey's AMP in our view; the AMP is an instant-fit in-the-canal hearing aid targeted at the mild-to-moderate hearing loss patient who has not worn a hearing aid previously. Unlike other micro-CIC solutions, however, the product will retail at a much lower price point of US$750 per ear (vs. other micro-CIC's at US$3,000-4,000 per ear). Consequently, we view the AMP as potentially the most inventive device in the industry; this is not from a technological perspective however, but rather as we believe the product could go some way towards addressing the two main concerns non-wearers of hearing aids have – affordability and stigma.

We believe price is among the most significant barriers to hearing aid penetration; countries with more generous hearing aid reimbursement schemes tend to see higher hearing aid penetration than those that offer limited or no reimbursement (and hence place a higher economic burden on the patient). As such, we believe price is an important factor in purchasing a hearing aid and view a reasonably-priced, esthetic, and technologically-advanced solution as crucial to driving penetration levels higher.

Exhibit 4: Countries with more generous public reimbursement systems tend to see higher hearing aid penetration
% of people with hearing loss wearing a hearing system vs. GDP/capita (2009)



Source: Company data, Goldman Sachs Research estimates.

Invisibility in focus: Micro-CIC's superior to extended wear

We have seen growing focus on "invisible" hearing aids, with Siemens and Sonic (now part of WDH) both introducing micro-CIC products at this year's AAA; in total, we count four truly "invisible" products on the market today: the SoundLens (Starkey), iMini (Siemens), Groove (William Demant), and the Lyric (Sonova). Although we do not see this market as sizeable – given that only 30%-40% of mild to moderate-loss patients meet the criteria for a deep-in-the-ear device (i.e. appropriately-sized and shaped ear canal) – we believe that the concept of invisibility could, on the margin, drive incremental demand from patients who are otherwise unwilling to wear a hearing aid given the associated stigma.

Exhibit 5: Overview of "invisible" hearing aid products

Manufacturer	Sonova	Starkey	Siemens	William Demant
Product name	**Lyric**	**SoundLens**	**iMini**	**Groove**
Product form	IIC	IIC	Micro CIC	Micro CIC
Technology	Analog	Digital	Digital	Digital
Disposable	Yes	No	No	No
Removable	**Only by audiologist**	**Yes**	**Yes**	**Yes**
Price per ear (3-year equivalent; in US$)	**5,400**	**3,000 - 4,000**	**3,000 - 4,000**	**3,000 - 4,000**
Launch date	2009 (US), mid-2010 (Europe)	March 2010	March 2011	March 2011

Source: Company data, Goldman Sachs Research.

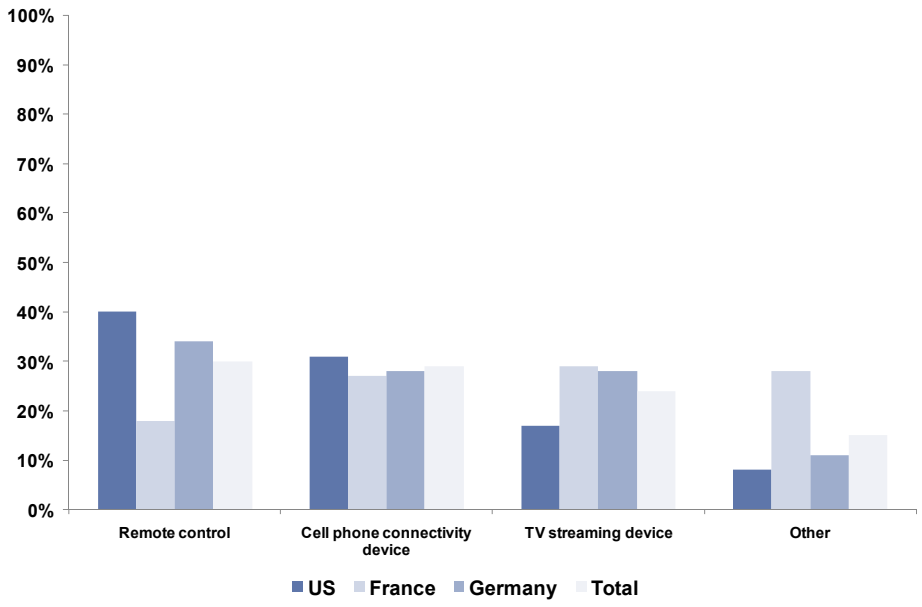
The micro-CICs are likely to gain much more traction than Sonova's Lyric in our view, as we believe that audiologists and patients will prefer a removable solution given it is more flexible. The Lyric can only be removed and replaced by an audiologist when the battery dies (approximately every 60-90 days), meaning that patients might have to wear a non-functioning hearing aid for number of days, especially if this happens over the weekend or while travelling. In addition, the micro-CIC's are more affordable – a year-long subscription to the Lyric costs US$1,800 per ear vs. a micro-CIC, including a 3-year service contract, costing approximately US$3,000-4,000 per ear.

Consequently, we are reducing our Lyric forecasts 10% to 55% on average; we now expect Lyric to achieve revenues of SFr94 mn by FY2014, which is below the company's long-term guidance of SFr200-SFr300 mn.

Accessory competition heating up; GN offering no longer unique in our view

In general, we believe accessories are tertiary to consumer's product choice and hence not important drivers of hearing aid purchases; we highlight that 1) accessories are included in only 30% of all hearing aid purchases (with the most common accessory being a wireless remote), and 2) only 15%-20% of all hearing aid users regularly use their TV or phone accessories.

Exhibit 6: Accessories do not drive product choice, in our view
Proportion of patients who purchase an accessory



Source: Company data.

Historically, TV streaming suffered from significant latency problems (delays ranged from 70-130 milliseconds), meaning that patients experienced a highly noticeable echo when watching TV. GN ReSound was the first company to significantly improve TV streaming when it launched the Alera in 2010; with the Alera, the audio feed is delayed by 18 milliseconds (vs. 70-130 milliseconds with competitor products), which is hardly noticeable to a human ear. We have previously viewed this as one of the unique selling points of the Alera, and hence believed it could drive some modest share gains for GN ReSound among patients who are more technology-focused (i.e. younger and/or more active patients). **However, following competitors' product introductions at this year's AAA, we no**

longer view GN's accessory offering as unique since both William Demant and Starkey now offer TV streamers with similar latency (i.e. 15-18 milliseconds).

Separately, as latency problems disappear, we would expect a growing proportion of patients to purchase accessories and use them more actively; while this will be a modest positive for revenue growth, accessories have a lower operating margin than devices, and hence will be, on the margin, modestly dilutive to operating margins.

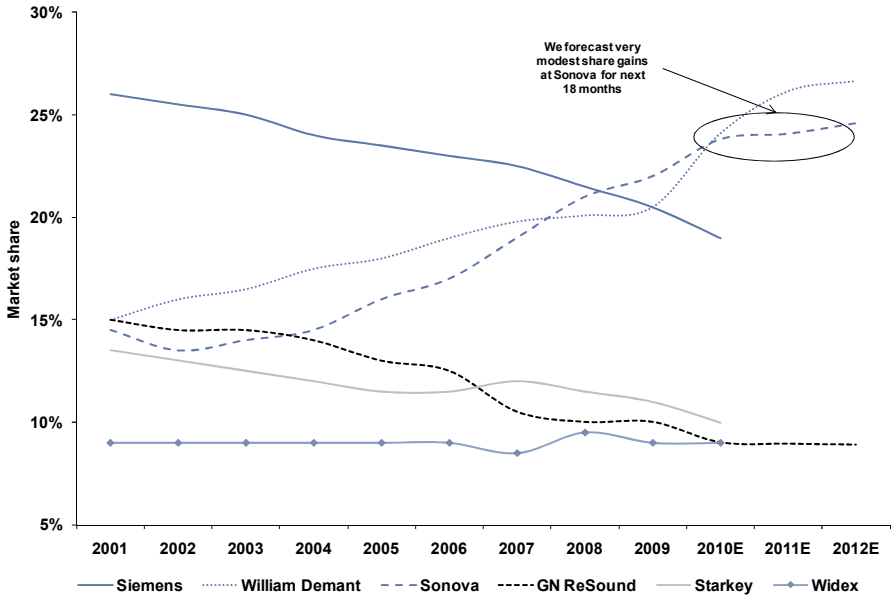
Sonova: Visibility limited; regaining momentum will be difficult; retain Neutral

Following AAA we revise our FY12-14 Sonova estimates downward – we now forecast only modest share gains in FY12 as we believe that Sonova will struggle to re-capture audiologists who have experienced problems fitting the Ambra in the initial product rollout stage. Our 12-month price target of SFr88 implies 3% upside potential and we retain our Neutral rating.

We forecast only modest share gains for Sonova in FY2012

We do not expect the Spice platform to drive significant share gains in the next 12-18 months; we forecast FY2012 organic hearing instruments growth rate of 5%. We base our forecasts on the belief that audiologists who have had problems with the initial fittings of the platform will likely use the platform less frequently going forward as they have access to alternative products with similar features and likely an easier fitting experience (such as the Agil).

Exhibit 7: We forecast very modest share gains for Sonova in FY12 and FY13
Market share development 2001-2012E



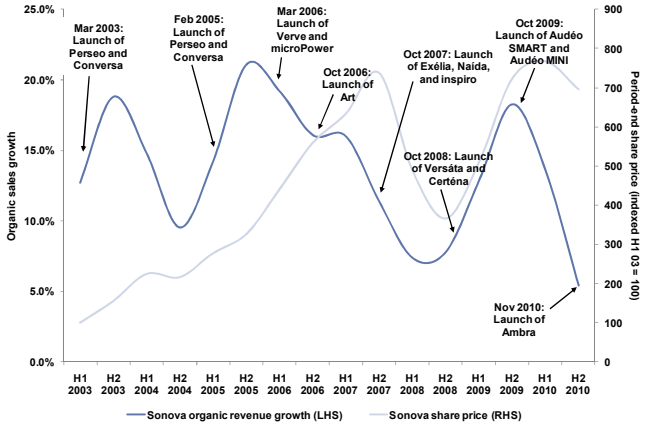
Source: Company data, Goldman Sachs Research estimates.

In general, return business is directly correlated to patients' fitting experience, i.e. the fewer sessions a fitting requires, the more likely the patient is to return to the audiologist for subsequent hearing aid purchases. Therefore, audiologists tend to prefer products which are easy to fit and seldom returned by the patient. As such, we believe that audiologists whose first experience with the Spice platform was difficult will be hesitant to fit the new Phonak product range extensively going forward.

Product cycles the most important driver of growth in the hearing aid market

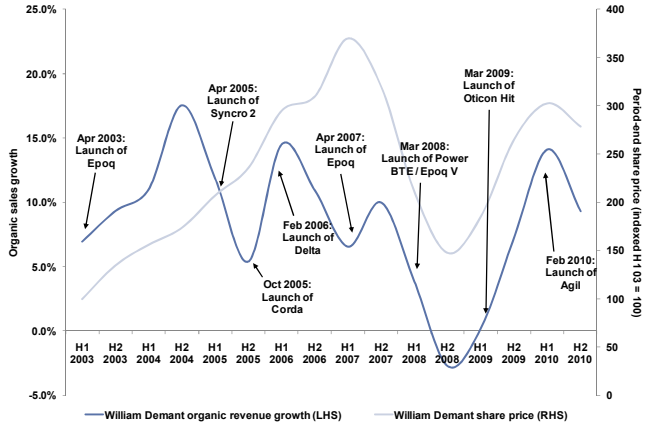
We view successful product launches as the most important driver of revenue, and hence earnings growth and subsequent share price performance within the hearing aid market.

Exhibit 8: Product cycles are a key driver of organic revenue growth and share price performance: Sonova
Sonova organic revenue growth (LHS) vs. share price performance (RHS, indexed to 1H2003)



Source: Company data, Goldman Sachs Research estimates, Datastream.

Exhibit 9: Product cycles are a key driver of organic revenue growth and share price performance: William Demant
William Demant organic revenue growth (LHS) vs. share price performance (RHS, indexed to 1H2003)



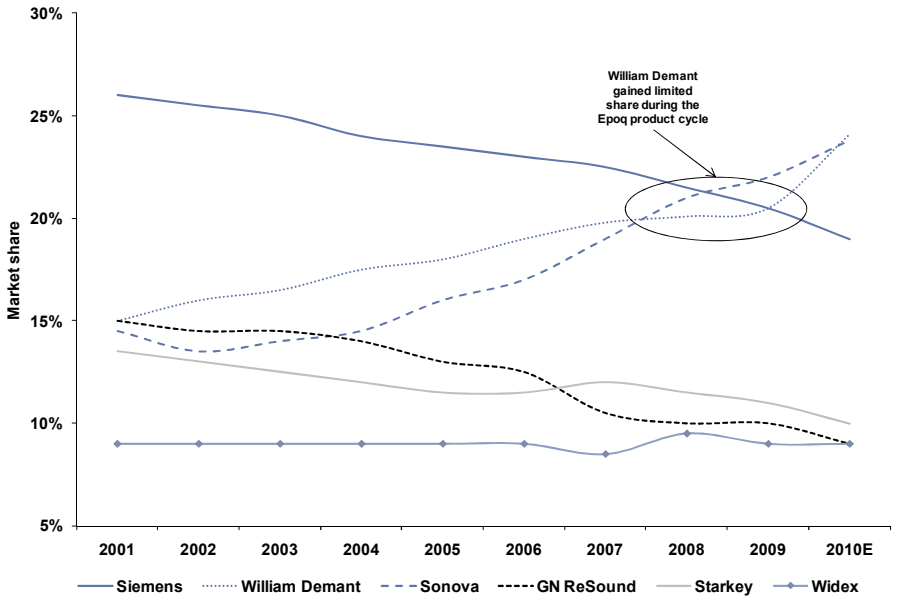
Source: Company data, Goldman Sachs Research estimates, Datastream.

Unsuccessful product launches tend to impact growth for a full cycle

We believe that unsuccessful high-end product launches impact product uptake – and hence growth trajectories – for a full product cycle (i.e. 18-24 months); we highlight the unsuccessful launch of Epoq at William Demant in late 2007, which impaired the company's growth trajectory for approximately two years.

Following the success of Oticon Delta (which was launched in March 2006), William Demant experienced above-market organic growth in its wholesale hearing aid division of +12.7% in FY06 and +8.1% in FY07. However, at FY2007 results the company noted that its core 2007 premium product launch – Oticon Epoq (introduced in late May 2007) – was performing below internal expectations due to a delayed and poorly executed product launch. The poor uptake of the Epoq depressed sales growth at William Demant for almost two full years and William Demant saw only very limited market share gains during this period. We believe that Sonova was the key beneficiary of poor growth at William Demant during this period given the company's broad product offering.

Exhibit 10: William Demant did not gain share during the launch of the Rise 1 platform
Market share development, 2001-2010E



Source: Company data, Goldman Sachs Research estimates.

SPICE not entirely similar – lack of form factors drove some Epoq weakness in our view

While we believe that Epoq provides some insight into what could happen to a company's market position following an unsuccessful product launch, the issues Sonova has experienced with the Spice platform are not entirely similar to William Demant's issues with the Rise I platform. Most importantly, we believe that the uptake of Epoq was depressed not only due to technical problems with the platform (such as improperly working algorithms), but also due to the fact that William Demant did not introduce all form factors at the time of the initial product rollout in 2007. This, in our view, adversely affected the uptake of Epoq in the first 6-9 months (similar to what we have seen with GN ReSound's Alera to-date).

Advanced Bionics: We forecast November re-launch in US

We continue to expect Advanced Bionics to return to the US market no later than November 2011. At AAA, Sonova announced that it has now completed manufacturing validation (as required by the FDA) and that it plans to submit all of the required documentation to the FDA for review in coming weeks. Prior to the recall, US accounted for approximately 30% of AB revenues. We estimate that an incremental 6-month delay to AB re-launch in the US (i.e. beyond November 2011) would reduce our FY2012 EPS 4%-6%.

We reduce our FY12-14 EPS 12% to 15%

Following AAA we reduce our Sonova EPS estimates 12% to 15%; our detailed estimates can be found below. We highlight that in the absence of meaningful share gains in FY12/13, we see limited operational leverage within Sonova's hearing instruments business, especially given that we expect the continued SFr strength to negatively affect EBIT margins by approximately 100-120 bp in FY2012.

Exhibit 11: Sonova: We reduce our estimates 13% to 15%

	New			Old			% change		
SFr mn	FY11E	FY12E	FY13E	FY11E	FY12E	FY13E	FY11E	FY12E	FY13E
Revenues	**1,603**	**1,649**	**1,824**	1,607	1,734	1,963	-0.2%	-4.9%	-7.1%
Organic growth	*6.4%*	*6.0%*	*8.4%*	*6.7%*	*11.5%*	*10.4%*			
EBITDA	**372**	**385**	**462**	372	437	538	-0.2%	-12.0%	-14.1%
Margin	*23.2%*	*23.3%*	*25.3%*	*23.2%*	*25.2%*	*27.4%*			
Net Income	**264**	**277**	**341**	264	318	401	-0.2%	-13.1%	-14.9%

Source: Goldman Sachs Research estimates.

William Demant most likely to benefit from problems at Sonova

We believe that William Demant will be the biggest beneficiary of problems at Sonova as the company has, in our view, the strongest product offering and the broadest product portfolio from among the other large hearing aid manufacturers.

Consequently, we raise our revenue growth expectations for William Demant from 7.5% to 11.2% in FY2011 (in local currencies and excluding acquisitions); we raise our EPS 4% to 7% between FY2011 and FY2013. We continue to view the Otix acquisition as meaningfully dilutive to margins in 2011, meaning that we see limited opportunities for margin expansion until FY2012.

Exhibit 12: William Demant: We increase our estimates 4% to 7%

	New			Old			% change		
DKr mn	FY11E	FY12E	FY13E	FY11E	FY12E	FY13E	FY11E	FY12E	FY13E
Revenues	**8,071**	**8,762**	**9,851**	7,911	8,732	9,470	2.0%	0.3%	4.0%
Organic growth	*11.2%*	*6.6%*	*10.4%*	*7.5%*	*8.4%*	*6.5%*			
EBITDA	**1,979**	**2,306**	**2,711**	1,892	2,237	2,540	4.6%	3.1%	6.7%
Margin	*24.5%*	*26.3%*	*27.5%*	*23.9%*	*25.6%*	*26.8%*			
Net Income	**1,228**	**1,467**	**1,756**	1,167	1,415	1,635	5.3%	3.6%	7.4%

Source: Goldman Sachs Research estimates.

We have also modestly revised our estimates for Amplifon to reflect recent FX moves.

Exhibit 13: Amplifon: We have modestly revised our estimates

	New			Old			% change		
€ mn	FY11E	FY12E	FY13E	FY11E	FY12E	FY13E	FY11E	FY12E	FY13E
Revenues	**857**	**932**	**1,019**	867	940	1,028	-1.1%	-0.9%	-0.9%
Organic growth	*5.1%*	*6.9%*	*6.6%*	*7.0%*	*6.5%*	*6.5%*			
EBITDA	**149**	**176**	**201**	153	180	205	-2.9%	-2.0%	-1.9%
Margin	*17.4%*	*18.9%*	*19.8%*	*17.7%*	*19.1%*	*20.0%*			
Net Income	**56**	**72**	**87**	56	73	89	-0.5%	-1.5%	-1.6%

Source: Goldman Sachs Research estimates.

Summary of ratings, price targets, and risks

Exhibit 14: Summary of ratings, price targets, and risks

Stock	Rating	New target price	Old target price	Potential upside / downside	Methodology	Risks to target price
Amplifon	Neutral	€ 4.5	€ 4.4	13%	EV/EBITDA	Meaningfully worsening macro-economic environment, failure to successfully incorporate NHC acquisition, failure to execute on store conversion program.
Sonova	Neutral	SFr 88.0	SFr 95.0	3%	Director's Cut	Higher- or lower-than-expected share gains, failure to re-launch the HiRes 90k by November 2011, better cost control, and SFr strength.
William Demant	Neutral	DKr 480	DKr 455	3%	Director's Cut	Significant market share losses, better-than-expected improvement in margins, failure to successfully integrate the Otix acquisition, and favorable US$/DKr moves.

Source: Goldman Sachs Research estimates, Datastream.

Reg AC

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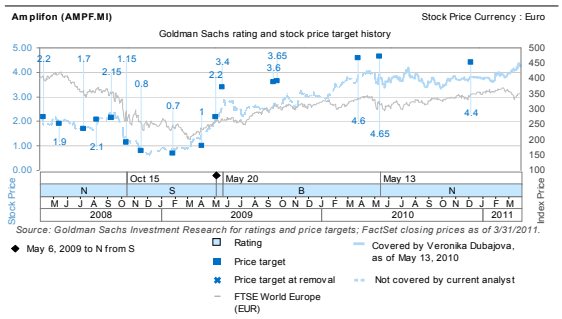

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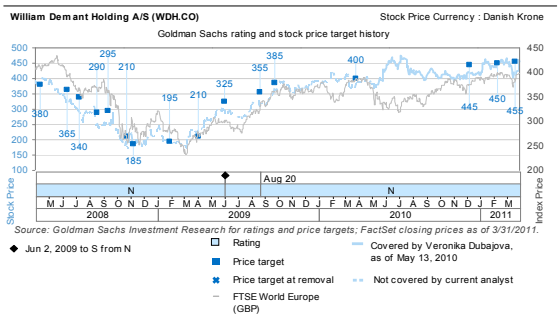

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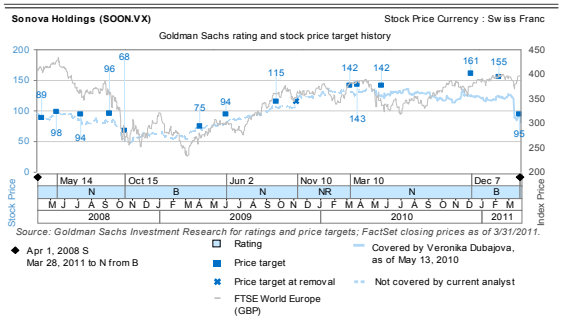

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5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852

Re: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

Issue: How can consumers compare hearing aid features so they can be informed consumers?

Discussion:

Hearing aids offer a number of features but it is difficult for consumers, audiologists and hearing aid dispensers to compare brands. Manufacturers do not use common names for features and many manufacturers trademark the names they use. Comparing features is virtually impossible without consistent names.

Users and parents of children with hearing loss are dependent on the audiologist or hearing aid dispenser to provide information, which may present a conflict of interest because the audiologist/hearing aid dispenser:

1- Does not represent all manufacturers nor have knowledge of all hearing aids on the market.

Audiologists/hearing aid dispensers are presumed to know all the aids on the market but the reality is that that they only dispense a few brands. The hearing aid mix they offer is based on such concerns such as but not limited to percentage of earnings, incentive pricing, delivery schedule, quality, and customer support. Some of these concerns, such as percentage of earnings, are not in the best interest of the consumer.

2- May receive bonuses/equipment based on the volume of hearing aids sold.

Many hearing aid companies provide free equipment or incentives or perks to audiologists/hearing aid dispensers based on their sales volume. This marketing program is now frowned on in the pharmaceutical business and should be

eliminated in the hearing aid business as well.

3- Has a financial incentive to maximize the likelihood of making a sale. Audiologists/hearing aid dispensers make a substantial profit when they sell hearing aids. Critical information that may obstruct or delay the sale such as the pros and cons of various features may not be disclosed.

The hearing aid manufacturers also heavily fund many of the hearing loss organizations, which can interfere with their advocacy on this issue as well. The FDA can bring greater transparency and accountability to the dispensing of hearing aids by developing a rating system for the various hearing aid features and standardizing the naming of these features.

Conclusion:

Regulation of hearing aid features is critical to enable consumers to be educated consumers and not dependent exclusively on the audiologist/hearing aid dispenser. Consumers can only educate themselves with information that is easily obtainable. This information is currently not available. There is no incentive by the manufacturers or vendors to provide this information. Therefore, the FDA should ensure that the information is made available so that consumers can become better informed and more satisfied with their purchase.

Sincerely,

Janice L. Schacter

Ex C

Proposed Amended Telecoil Legislation

Issue:

How do we ensure that hearing aid dispensers inform their patients about the benefits of having a telecoil (also known as T-coil or T-switch) technology in their hearing aids?

Background:

Hearing aids with a telecoil receive sound directly via magnetic induction when conversing on a hearing aid compatible phone. These include all landline phones and select cell phones, using an induction loop system or when there is an inductive coupler within the device such as in phones, audio guides or sound enhancement devices. The telecoil setting maximizes the customized output of the person's own hearing aid. The benefit is that telecoil users do not need additional equipment such as a receiver. Additional information can be found at www.hearingloop.org.

New York State already has legislation that requires hearing aid dispensers to "instruct new users of hearing aids on basic information about how to use the aid. This training should include, at a minimum, the following: (viii) use of the telecoil-switch." [1] Two other states have similar legislation, Arizona [2] and Florida, [3] but

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[1] Section 192.18* Consumers.

(a) Complaints. A consumer may register a complaint with any office of the department in person, in writing or by telephone.
(b) Printed educational information. Printed educational materials should include:
(1) Procedures by which a consumer may file a complaint.
(2) General information about the general use of hearing aids and the advantages and disadvantages of monaural and binaural hearing aid use, including: information of the value of hearing aid use for a prospective purchaser; consumer protection piece - what to be aware of in sales pitches and "hard sell" techniques, such as "giveaways" and sales pitches that minimize the need for medical and audiological exams; basic "how to" use a hearing aid for a new consumer; and information about the advantages of purchasing and using the telecoil switch (t- switch).
(3) General information on assistive listening devices (ALDs), including a basic overview of the types of ALDs currently available and how ALDs may be used with hearing aids.
(4) A statement regarding the availability of support groups for people who are deaf and hard of hearing.
(c) Training of consumers.
(1) The dispenser shall instruct new users of hearing aids on basic information about how to use the aid. This training should include, at a minimum, the following:
(i) basic care and use of the hearing aid;
(ii) communication strategies to adjust to a new hearing aid;
(iii) information on support groups;
(iv) storage of the hearing aid when not being used;
(v) protection of the hearing aid from perspiration and moisture;

(vi) Installation of a battery;
(vii) frequency of necessity to purchase batteries;
(viii) use of the telecoil-switch;
(ix) telephone usage;
(x) reasonable longevity of the hearing aid;
(xi) information about purchasing insurance to cover loss or damage;
(xii) review of 45-day return policy; and
(xiii) review of complaint policy.
(2) Such training may be offered in a group setting provided provisions are made to allow all participants to hear the presentation (e.g., provide ALDs compatible with their hearing aids) and/or to provide written materials, and shall be offered to all new purchasers of hearing aids and those who need to review the hearing aid orientation materials.

[2] *SENATE BILL 1348*

AN ACT

AMENDING SECTION 36-1909, ARIZONA REVISED STATUTES; RELATING TO HEARING AID
DISPENSERS.

Section 1. Section 36-1909, Arizona Revised Statutes, is amended to read:

36-1909. Bill of sale; requirements

A. A hearing aid dispenser or dispensing audiologist shall deliver a bill of sale to each person supplied with a hearing aid by the hearing aid dispenser or the dispensing audiologist or at that person's order or direction.

B. A bill of sale shall contain the hearing aid dispenser's or the dispensing audiologist's signature and shall show the address of that person's regular place of practice and the number of that person's license, a description of the make and model of the hearing aid and the amount charged. The bill of sale shall also state the serial number and the condition of the hearing aid as to whether it is new, used or rebuilt.

C. A BILL OF SALE SHALL CONTAIN LANGUAGE THAT VERIFIES THAT THE CLIENT HAS BEEN INFORMED ABOUT AUDIO SWITCH TECHNOLOGY, INCLUDING BENEFITS SUCH AS INCREASED ACCESS TO TELEPHONES AND ASSISTIVE LISTENING DEVICES. IF THE HEARING DEVICE PURCHASED BY THE CLIENT HAS AUDIO SWITCH TECHNOLOGY, THE CLIENT SHALL BE INFORMED OF THE PROPER USE OF THE TECHNOLOGY. THE CLIENT SHALL BE INFORMED THAT AN AUDIO SWITCH IS ALSO REFERRED TO AS A TELECOIL, T-COIL OR T-SWITCH.

only Arizona requires the “bill of sale shall contain language that verifies that the client has been informed about the telecoil, including benefits such as increased access to telephones, assistive listening devices, its proper use and that the switch is also referred to as a telecoil, T-coil or T-switch.”

Arizona’s requirement that the bill of sale have language indicating that the purchaser was told about the telecoil and the phone program ensures that the consumer was advised and provides “teeth” for enforcement. The current New York State law provides no “safety net” to ensure compliance.

On a personal level, our family was never advised of the telecoil by any hearing aid dispenser who sold her a hearing aid in 14 years. Some reasons given by hearing aid dispensers for not advising adult clients about the telecoil are that the clients will think they are being charged extra for unnecessary options, they tend not to use the features, and their fingers may not be sufficiently, nimble to maneuver the tiny switch. (Interestingly, they are able to manage the tiny batteries.) Another issue dispensers have mentioned is that purchasers may find the array of options too confusing and leave without completing the sale. The hearing aid dispenser has a conflict of interest in not wanting to provide information that he/she thinks might jeopardize a sale.

For children, hearing aid dispensers have expressed concern that the child may inadvertently switch the aid to the T-setting and not hear. Today’s children, however, are very technologically savvy, so this does not seem like a realistic issue. Children who receive benefit from their hearing aids will want to hear as well as possible and will quickly adjust to the settings.

D. A BILL OF SALE SHALL CONTAIN LANGUAGE THAT INFORMS THE CLIENT ABOUT THE ARIZONA TELECOMMUNICATIONS EQUIPMENT DISTRIBUTION PROGRAM ESTABLISHED BY
SECTION 36-1947 THAT PROVIDES ASSISTIVE TELECOMMUNICATIONS DEVICES TO RESIDENTS OF THIS STATE WHO HAVE HEARING LOSS.

APPROVED BY THE GOVERNOR APRIL 16, 2007.

FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 16, 2007.

[3] FSS 484.0501 (5) (b)
At the time of the initial examination for fitting and sale of a hearing aid, the attending hearing aid specialist must notify the prospective purchaser or client of the benefits of telecoil, "t" coil, or "t" switch technology, including increased access to telephones and noninvasive access to assistive listening systems required under the Americans with Disabilities Act of 1990.

Enacted October 1, 1994

Legislation should require that the telecoil be demonstrated so consumers understand what they are purchasing or decline knowledgeably if they choose not to have telecoils in their hearing aids. It is interesting to note that all new cochlear implant devices now have a telecoil. An induction loop should be installed in every hearing aid dispenser's office to demonstrate the potential benefits of the telecoil for that purpose, in addition to having the client test it with a phone.

In Arizona, the Department of Health Services and the Office of Special Licensing that oversees and licenses dispensing audiologists and hearing aid dispensers also surveys dispensers, investigates complaints, and will work with the Attorney General's office for enforcement and penalties when a violation is found. See http://www.azdhs.gov/als/slp/index.htm.

Arizona supported hearing aid dispensers by developing a telecoil brochure (attached) and providing it free to healthcare professionals who can place their own branding on it and hand it out to consumers. The brochure was created by a task force of hard of hearing consumers from around the state, and the New York State Interagency Council for People who are Deaf, Deaf-Blind or Hard of Hearing could produce a similar document.

Summary:

New York State legislation should be amended to follow Arizona's model, which requires that hearing aid bills of sale include language indicating that purchasers were advised of the telecoil option and tested it. Hearing aid dispensers should also be required to demonstrate the T-coil switch by installing an induction loop in their office/store. The Interagency Council for People who are Deaf, Deaf-Blind or Hard of Hearing should develop brochures that provide information on the benefits of the T-coil. Hearing aid dispensers should distribute the brochures.

Written by Janice Schacter, chair Hearing Access Program.