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Session 86 PD New Trends in Supplemental Benefits: Vision and Hearing

Track: Health

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Summary: New technologies have created alternative treatments to improve vision and hearing. What are these technologies and their cost? Can these procedures be insured? What is the cost impact if covered? Attendees learn available alternatives to corrective lenses for vision and hearing aids, how supplemental benefits can be expanded to cover these alternatives and whether your company should consider adding these benefits

MR. FLOYD RAY MARTIN: I'm with the Tillinghast business of Towers-Perrin. We have two distinguished speakers that are going to give us an overview of the latest technologies in both vision and hearing. After I finish a short presentation on where dental and vision insurance is today, we have Matt Wickham, O.D. He's the executive director of TLC Laser Eye Center in my hometown of St. Louis, and he will be speaking, obviously, on the vision area. Charles I. Berlin, Ph.D., who is from New Orleans here, is the Kenneth and Frances Barnes Bullington Professor of Hearing Science and clinical professor of otolaryngology, head and neck surgery at Louisiana State University (LSU) Health Science Center here in town. He is going to talk to us about new developments in hearing restoration.

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I'd like to talk a little about the vision market, what vision insurance plans look like today and average rates for those types of coverages. Then I'll talk about the hearing market, hearing plans and hearing insurance rates. I'll touch a little on the future, and then we'll let our speakers have the podium.

I did a little research on what the vision insurance market looks like today. I looked at stand-alone vision plans as opposed to plans that have been bundled with either dental or medical or other benefits. I also compared vision plans to dental plans. According to the statistical abstract of the United States, 32 percent of the workers have a dental plan and 19 percent have a vision plan. Of the white-collar workers, 37 percent have dental and 21 percent have vision, which is a little higher than the average. For blue-collar workers, 33 percent have dental and 20 percent have vision. What I found very interesting is that the union plans are much higher. Union plans have pushed for both vision and hearing benefits, so 51 percent of union employees have dental coverage and 37 percent of the population that has vision coverage. When we look at groups over 500, 96 percent of those have dental coverage and 54 percent have vision coverage.

Then I looked at which plans are financed by employers and which are financed by employees. Again, my numbers are from the statistical abstract. You may wonder if these numbers agree with what you may have seen in the industry, for example, the NABP report. Of the dental plans, 17 percent are totally paid by employees, and for vision plans, 38 percent are totally paid by employees. So twice as many of the vision plans' premiums are paid by employees as opposed to the employer.

I recently saw an article released by Aflac on a vision study that they performed. This is available to the public. Of the general population, 63 percent spent money on vision care in the last year. In the last two years, 75 percent of the public had an eye exam. That's pretty high. However, 40 percent postponed treatment because of the cost for vision services. Fifty-nine percent said that they had dental insurance, which is different from what we saw from the national abstract, which was only in the high 30s. Something in the 50 to 60 percent range is probably more likely for dental. Only 49 percent of the public said that they had vision insurance, and I was surprised that that would show up even that high. They may be thinking of a discount-card-type vision coverage. Twenty-five percent of the public said that they were covered for LASIK surgery, and I was surprised that that number was also that high. Sixty-six percent of the population said they would trade one vacation day for vision coverage. I got this information from National Insurance, in the daily summary that tells you about current things going on in the industry, so you might want to look that up to get more information. Their survey population was around 1,500 people.

What do vision plans look like today? Typically they cover exams, frames, various lenses (depending upon the type of restoration someone needs) and contacts. Contacts are almost universally covered by vision plans today; if you went back

maybe 10 years ago, they were covered less frequently. There's usually a scheduled benefit for each of these types of services as opposed to actual charges or usual/customary-type prices. There are also discount plans that allow you to pay for an exam for a certain amount, pick out certain frames at a discount and get your lenses, again, at a discounted fee, somewhere between 20 and 25 percent off the off-the-shelf cost. I would call that a discount access plan; it gives you access to discounted fees.

What do these visions plans cost? Rough numbers nationally are somewhere around \$5.00 per month for a single and maybe \$12.50 per month for a family. That allows payments of about \$25 for an exam, \$50 for frames and around \$25 to \$45 for lenses, depending on the complexity of the lenses.

In the hearing market, I wasn't able to find as much information on what percentage of the population is actually covered by a stand-alone hearing benefit. I used to do work for General Motors, and I remember that a big item they had was a hearing benefit. A few of the major unions may still continue to have a standalone hearing benefit. Otherwise they may have a lifetime maximum or an annual maximum benefit under their medical plan. There are a few states that have mandated certain hearing coverage for smaller groups. They cover different areas, from just covering minors to just covering hearing aids. I was surprised that Kentucky actually covers cochlear implants as a mandatory benefit. These are usually included with the medical coverage.

Those hearing plans that are out there usually have a fixed-fee schedule for exams, a certain amount they would allow for hearing aids (that amount might be enough to cover low-range hearing aids as opposed to more progressive and more advanced ones) and a maximum amount that could be paid out. What would rates be for that type of a simple hearing plan? I'm estimating that the rates for those might be \$0.60 a month for a single and \$1.50 a month for family.

Part of the reason we have put this presentation together is that technologies have changed quite a bit in the last 10 years for both vision and hearing. There are new procedures that will have a long-term physical correction as opposed to a short-term temporary correction that may have to change periodically from time to time. With most new technologies, there's a related expense. We want to know if there are enough trade-offs to be able to cover these expenses and if we're going to be saving in the long run. We want to know the best solution for the insured individual. Should we be giving our insured population more choices instead of forcing them all into one type of solution for hearing and vision?

DR. MATT WICKHAM: I have a couple of comments on the portion on vision. If you can find the 25 percent that have LASIK coverage, will you send them our way? I haven't found any out there that have it. Also, there is one reason that people may say that they have vision insurance when they actually don't. It's very common in primary care optometry that if a patient comes in without vision

insurance and if you can find a red eye, an itchy eye or eyes that are irritated at all, it goes to a medical coding. The patient may perceive that he or she has vision insurance when, in fact, it's the optometrist using the patient's medical insurance.

I'm from TLC-St. Louis. TLC is the world's largest provider of refractive surgery. We do about 10,000 procedures each and every month across the country. What is LASIK? Has anybody in here had LASIK before? There are some indicating that they have had it. What do you think the national penetration is for LASIK surgery? Between 5 and 6 percent of the people that are eligible for a refractive surgery have actually had it. It's the most commonly performed refractive surgery in the United States. Cataract surgery is a form of refractive surgery. In cataract surgery, you take the lens out from within the eye and put in a new lens. In doing that, you can change the power within so that if a patient has a prescription, when you remove the diseased lens, you can put in a new one with a new prescription.

LASIK is now more common than cataract surgery. It's certainly less invasive and has fewer complications. About 1 million procedures are performed in the United States per year. It has leveled off. In 1998, 1999 and 2000, it was growing exponentially. We had a proliferation of discount centers. With that came some horror stories about the LASIK procedure. We saw a lot of Canadian companies come into the United States and go bankrupt. So now it has leveled back off, and we expect to do 1.4 million in the United States this year. That's up maybe 100,000 or 200,000 from a year ago.

Chart 1 shows the LASIK procedure. The outer clear portion of the eye is the cornea. The cornea is about 0.5 millimeters thick, about the thickness of a credit card. We can create a flap within that cornea, about a third of that thickness. Once we have that flap created, the laser comes and does the shaping. There's a misconception out there that the laser does all the work. The laser only does what the surgical staff has programmed it to do. If you put in good numbers, you get a good surgery. If you select good candidates, you get a good outcome. If you have good technology along the way, you have a good outcome. A lot goes into programming those numbers and making sure that we get a good outcome. Once we've done the shaping that we need to do, we replace that flap.

<u>Chart 1</u> How It Works



The skin of the eye, called the epithelium, is the fastest healing tissue in the body. Literally more than 95 percent of patients are driving the next day after this procedure. I was raised on a farm and was always taught that if it's too good to be true, don't believe it. This LASIK, for the most part, is fantastic. The following day, they're driving. As far as time off work, if we do the actual LASIK procedure, you're only off that day. You take Valium the day of the procedure, which is typically in a surgical facility. You have some plastic shields over your eyes that you wear overnight, and you sleep in those for five nights just as protection. But most people can go back to work the next day. In most surgical centers, Friday is the popular day because everybody wants to recover over the weekend, but if you're not exposed to contamination or to trauma in your workplace, then you really don't have a valid excuse not to be at work the next day.

There are potential complications. No surgery is risk-free. So much depends on the surgical center and the surgeon that you're using. We've done about 15,000 LASIK procedures in the last five years. We have had maybe 1 in 1,000 where, while we're creating that flap that you saw on Chart 1, we'll have a flap complication. You can lose suction during a procedure. That still is not a time-off-work type of event. It's unsettling to everybody in the center and to the patient, but you put the flap back in position, you put a contact lens over it and typically in three to five days it's healed. The patient didn't get the surgery or the correction or the outcome that he or she wanted, but you can go back in two or three months, if the patient has the nerve to do it again, and perform the procedure. Luckily at our facility we have a wonderful surgeon, Dr. Stephen Wexler. It's only about 1 in 3,000 or 1 in 4,000 that has a flap complication.

Another complication is that you can get inflammation after a procedure. It's still not an issue where you'd have to miss work. It's a microscopic inflammation that we have to see underneath the microscope. The view between three and five days is very critical and so if you find it, it's very treatable. You just put the patient on oral steroids or topical steroids very aggressively. It's not a sight-threatening issue unless it goes untreated and undetected.

You might hear some talk about dryness. There are no long-term studies that show that LASIK permanently dries the eyes, but there's no question that for the first 30 to 60 days, the average person produces less tears than they would without the LASIK procedure. It's not usually significant enough that it causes the patient any downtime, but we put every patient on lubricating drops or artificial tears, just like you'd use lotion on our skin or lip balm on your lips. If you live in a very dry area, say Denver or Arizona, you may have a little more dry eye complication, but, again, it would be very rare that you'd need any time off work.

Night vision is a complication you have all probably heard about. The most common laser out there is the VISX Star laser. It has had four software upgrades (S2, S3 and S4), and each upgrade dealt with the night vision. We used to have a very narrow treatment zone. The theory was that as the pupil got larger and smaller,

you'd cross that transition zone, and so you might have some night vision glare. They made it an 8 millimeter zone now, which is wider than the pupil typically gets, and so we rarely have those issues.

The next advancement was to make a blend zone. In the past, the laser would come in, and where we did the surgery was a perpendicular treatment zone. If you had a high prescription, there would be a very strong barrier where you had done the transition. Now they have a blend zone. Last but not least, there is wavefront, or custom, technology. If you look at the FDA studies, you're 10 times more likely to have improved night vision than you are to have night vision that's made worse. When it's worse, people let you know about it, but the statistics will tell you that it's 10 times more likely to have improved night vision.

I want to be sure that I talk about enhancements. The national average is about 10 percent, where you eliminated almost all of the prescription on the patient, but you left a little. This laser was originally designed to engrave microchips. IBM invented this laser having no idea what it would do for vision correction. If you engrave a silicon microchip 50 microns, it's going to be 50 microns every single time. But people's corneas have different properties and so while it's almost always the same, the composition of your eyes makes a difference. Sometimes you're going to get exactly 50, sometimes you're going to get a little less and sometimes you're going to get a little more. The more a surgical center does to control its environment (the temperature, the humidity, an air filtration system), the more consistent and less variable the outcomes will be. But occasionally we have to do an enhancement, usually three to six months later. The patient may need some glasses or contacts in the meantime, so while we can't say it's 100 percent success on the first procedure.

FROM THE FLOOR: Do you do one or two eyes at a time?

DR. WICKHAM: The patient always has the option to do one eye at a time, but we typically do both at the same time.

Let's run through the differences between LASIK and alternative refractive procedures. LASEK is a form of LASIK where if the cornea is too thin, you have to go in and do the procedure right on the front surface. Rather than create that flap, which takes up some of the structural integrity, you do it right on the front surface. PRK is another form like that. Those two take a good one to three weeks for a person to see clearly, and you can only do one eye at a time. Because you're left very blurred for a week or so, you don't want to leave both eyes blurred at the same time. You get complete healing in the first eye, go back and do the second eye. Those patients do experience a bit of an awkward time while one eye has been done and one eye has not. As you're working up what's covered and what's not, just know that LASEK and PRK make up about 10 to 15 percent of the total refractive procedures that we do.

We do lens implants for those who have very high prescriptions that aren't eligible for LASIK. We can actually do contact lens implants internally in the eye. They just got FDA approval, so those will be a small segment of the marketplace. It's a slightly more invasive procedure. Radial keratotomy was the procedure preceding LASIK, where we took a hand-held surgical diamond-bladed knife and made incisions in the cornea. That, in a sense, would flatten it, and that would cause a near-sighted patient to be less near-sighted. Anyone practicing with radial keratotomy now isn't doing the standard of care. Conductive keratoplasty is a new technique that treats people who have trouble with up-close vision. It's not a cure for the bifocals or for presbyopia. They will take two good-seeing-distance eyes, and they'll make one eye clear for near. You can do that with LASIK or with a contact lens, but the national campaign of conductive keratoplasty has been "We cure presbyopia," this focusing problem. They really don't, because to cure it would mean you could do both—you could see far away and you could see up close. They actually just take one eye and make it clear for up close, so it's called monovision. Some people wear contact lenses that produce the same effect.

Let's talk about some results. In the 2004 U.S. Navy study geared mostly toward LASIK, the U.S. Navy had an 86 percent 20/20 rate with traditional LASIK. These are fantastic results. When custom (or wavefront) came along, they got up to 97 percent 20/20. These are very controlled patients and parameters, which is why it's a little higher than the 95 percent that we talked about earlier for a good surgical center.

We talked about that FDA statistic. While night vision has always received a lot of press for the people who have trouble with it, the FDA will tell you you're 10 times more likely to see better at night than you are to see worse, with the exceptions being those people who need that enhancement that we talked about earlier. Uncorrected error is the biggest problem for having some nighttime difficulty, so you go in and touch up the unresolved error, which is the enhancement procedure.

Let's discuss LASIK expectations. As you look at these plans and consider whether you would use them or not, not every patient is a candidate. We turn down probably 10 to 15 percent of the people who come in wanting LASIK because they have an underlying corneal disease, they have a systemic disease (the two big systemic contraindications are lupus and rheumatoid arthritis) or they're pregnant or nursing. As far as postoperative glasses or contacts, LASIK does not cure presbyopia (loss of focusing ability). While it does treat distance vision issues for all time with a few exceptions (TLC has a lifetime commitment), you get one 1 of 2,500 or 3,000 that may drift a little over the years. We have that lifetime commitment as a safety net, but in good conscience I can tell patients that generally this is going to be a lifetime treatment for them. However, it doesn't cure that loss of the focusing ability, so a 30-year-old who has LASIK, just like any other normally sighted distance person who doesn't need glasses, will eventually need reading glasses. True, they're usually the drugstore reading glasses, so it is a less

expensive alternative once you've had this done, but reading glasses will still be necessary.

Some people are under the impression that contact lenses are contraindicated after you've had LASIK. That's not true, either. If you could wear contacts before LASIK, there should be no reason why you couldn't wear contacts after LASIK. Really, there's no reason that you should need contacts after LASIK, but some people will put in a contact lens for near, like we talked about with the conductive keratoplasty, and have their LASIK eye for distance.

Let's define the pricing of LASIK. It is a zoo out there. In St. Louis you will see an ad in the funny papers for \$299 an eye, with an asterisk next to it. It really is in the funny papers; the company is LASIK Vision Institute. The highest-priced private surgeon in town is \$2,600 an eye. If you want wavefront, which has the better results, or if you have hyperopia (farsightedness instead of nearsightedness), it goes up to \$6,200. So you've got a range of \$299 to \$3,100 per eye. I don't know how you can make sense of that. You have flat pricing, which is what we do in St. Louis, but we're the only TLC center that does flat pricing.

We think it's a bad discussion to have with patients when you start saying, "Well, your prescription is this high, so it's going to be this much," or "You want the wavefront or the custom so it's going to be this much." The reality in the marketplace is that it's a bait-and-switch, as far as I'm concerned. They will bring you in for the \$299 an eye or the \$799 or the \$999, but when you get there, they'll say, "Oh, you have astigmatism. That's going to be this much," or "Oh, you're highly nearsighted." There is a broad spectrum of pricing out there. If we could all get on a flat price, it would sure be nice. So you have the Center's philosophy, and you have the discount model, which, again, runs the gamut from \$299 an eye to, say, \$999 an eye, but there's always an asterisk next to it. You'll never see it without an asterisk. They're always going to get you in and find a way to charge more per patient. Then there's the upscale, private model. We call it a "boutique" in our industry. That's the high-priced center in town, where you get a bottle of wine after your procedure (that's probably not a free bottle of wine), they pamper you all the way through it and you're seeing the elite surgeon. If they can keep the numbers up, why see more patients when you can charge more and work less? TLC and LASIK Plus are in the middle. They're not as high as the high-priced, but they're also not the bargain-basement discount pricing that you see.

The direct-to-consumer model means that you advertise directly to the patient. The patient comes to your center and has the pre-operative care, the surgery and the post-operative care all within one entity. In the optometric, or co-management, model, you start with your primary care provider. You get the initial valuation, and you probably have an option to go to two or three different surgical centers. The patient goes there for surgery and then back to his or her optometrist for post-operative care. There's some sort of fee attached to both the surgery and to the pre- and the post-operative care. A lot of patients are more comfortable with the

recommendation of their local doctor and like them to be involved in the process. In a lot of the other models, whether it's discount or private, I think people feel like a piece of meat sometimes. It's just "get them in and get them out." There's a nice security in using the optometrist as a player or teammate with you in doing this procedure.

There are national providers. TLC is the largest, with about 70 centers across the country. Our model is co-management. It doesn't mean that we do 100 percent comanagement (co-management meaning that you partner with the local optometrist). We do about 50 percent co-management at our center in St. Louis. It allows the people from rural Missouri and rural Illinois to see their local eye doctors. If it's an hour-and-a-half drive to St. Louis, nobody wants to make five drives for a 15-minute routine post-operative visit to make sure they're doing okay. The rural areas have a higher penetration of that co-management model. TLC also has 900 independent surgeons across the country. I'm from a town of about 15,000 on the other side of the state of Missouri. There is not a TLC Laser Center there, but there is a LASIK surgeon, a laser and technicians, and TLC assists them with that procedure. You'd never know that it was a TLC procedure. We have 70 centers, but we do LASIK in conjunction with 900 affiliate surgeons across the country. LASIK Plus has been the up-and-comer in the market. Their stock has almost doubled in the last year. They are a high-end discount model, if you will. They've got about 45 centers across the country. They do the tiered pricing, but it's done with a little more class than the LASIK Vision Institute, where it's clearly a bait-and-switch tactic and volume-driven.

We have several different options. In terms of coverage, I wish it were 25 percent. If you can get it to 25 percent, we'd be really happy at TLC. The only plans out there typically are discount plans. Maybe we'll partner with an A.G. Edwards or a Boeing in St. Louis and say, "Hey, if you give us exposure to your employees, we'll provide them with a discount." You see that, but very few medical insurances are latching on with us and actually providing a discounted plan.

Funded plans are primarily with the unions. Many of the unions in St. Louis will fund maybe \$1,000 per eye. The patients may have to forfeit their vision benefits for several years, but in doing so, they get not only a discount from the Center for participating in the plan, but they also have the company fund a portion of it. It gets to be a reasonable rate for those employees, and they're very appreciative of it.

Has anybody heard of TruVision or Amerisight? TruVision is affiliated with Blue Cross/Blue Shield. They serve as an intermediary. They market to the patients, have a call center and typically deal exclusively with one surgeon provider in the metropolitan areas. The patient pays a "finder's" fee to TruVision (I think it's \$100 per eye), and then the surgical center gives TruVision patients and TruVision employees a discounted price on the surgery. It's a significant discount. Amerisight, out of Chicago, has done the exact same thing. Their model is identical to the

TruVision model. In our center, we're the exclusive provider for TruVision in St. Louis. We see a lot of Blue Cross/Blue Shield Missouri and Blue Cross/Blue Shield Illinois. They are typically smaller businesses that are providing benefits for 25 or 50 employees, and they typically don't know that they have this benefit. When they get to the center, they find out that they do and that it cuts the price for them by about 30 to 35 percent. Amerisight is going after the funded plans and trying to combine with them. TruVision has been affiliated with Blue Cross/Blue Shield. Maybe they've done more than just Blue Cross/Blue Shield, but that's all I'm aware of.

You are probably aware that this is covered under flexible spending accounts or cafeteria plans. Employers like when employees take advantage of LASIK. It's such a high-dollar item on their cafeteria plan that you will often find that, while not endorsing the procedure or endorsing any certain facility, they will accommodate it being covered on a flexible spending account.

IntraLase is one of the new technologies out there. We talked about the creation of the corneal flap. When you come in to have your LASIK procedure, we'll say, "We gently create a flap." The truth is that it's an oscillating blade that goes through the cornea that creates that flap. IntraLase is a new laser technique. About 10 to 15 percent of the procedures are now using IntraLase. A laser actually goes in and creates that flap. If you have a surgeon who is not great with the keratome that creates that flap, this is going to be a nice option for you. They haven't come out in controlled studies and shown that IntraLase is better than the keratome. We're more comfortable with it, doctors love having toys and we don't like to use terms like "oscillating blades." But it's a \$300,000 investment, you have a per-use fee and there's no question that if the industry goes to IntraLase, it will increase the cost of the procedure by probably another \$400 to \$500 an eye.

Every market is different. In San Antonio, they've got an IntraLase on every corner. In St. Louis, no one has one yet. We're all looking at each other, waiting for the other to blink and say who is going to get the IntraLase. We're just not convinced clinically that it's worth the investment, especially with the number of patients that it may push toward discount centers because we've elevated our price by another \$1,000 by having this new technology.

I alluded to phakic IOLs a little bit earlier. Those are implantable contact lenses. There was a lot of buzz for the last three or four years that those who aren't eligible for LASIK will be able to have the phakic IOLs, but they come with their own snafus. They're going to be very expensive, because they have to be done in a sterile setting. LASIK is a surface procedure. It doesn't have to be in a sterile environment. While we do everything we can to keep it sterile, it's not regulated like an internal surgery, such as a cataract surgery. Phakic IOLs will be an internal surgery, so it will have to be in an internal sterile environment, and you're going to have to use an ambulatory surgery center (ASC) or a hospital surgical center.

You all know what the market is for presbyopia, the loss of focusing ability. Literally 100 percent of the marketplace is going to need treatment for presbyopia. Even two months ago, if you would have asked me if there was any hope that after age 45 you wouldn't need the reading glasses, I would have told you not to count on it. But we've been working with our TLC centers in Canada, which have much looser restrictions, and they've done 38 patients up there (76 eyes). Everyone has been happy with the presbyopic treatment, to the point that the clinical director is going to have it done herself. It's pretty convincing that maybe in five to seven years we'll have a presbyopic treatment out there with the laser.

FROM THE FLOOR: I have a question related to that. If presbyopia is secondary to stiffness of the eyeball and the muscles accommodating, does the treatment change the muscles, or does it change something in the lens?

DR. WICKHAM: The way contact lenses for presbyopia work right now is that they have concentric rings. You have a distance, a near, a distance, a near, a distance and a near. The brain does a phenomenal job at saying, "I'll look at the distance image" or "I'll look at the near." We're able to use the laser to make those same concentric ablations. The brain picks up the image that it wants to see, the distance one or the near. We're not doing anything to the lens, which is what we've been trying to do for 30 years.

FROM THE FLOOR: How many procedures has your center done?

DR. WICKHAM: We've done about 15,000 in the last five years.

FROM THE FLOOR: Why would it be \$500 per eye for a \$300,000 machine?

DR. WICKHAM: Because there's a per-use fee. There is a recurring fee called a "cone fee" that you have to change each time. I wonder if it's really needed, though. That's how the company continues to get residuals afterward. Just like the initial procedure, there's a laser royalty fee that we have to continue paying even though we've purchased the laser.

FROM THE FLOOR: Is there a difference in the rate of infection?

DR. WICKHAM: I don't know if there have been any studies done yet, but you have to realize that it's a new sterile blade for every procedure that we use, so you're still exposing the interface one way or another, and that's the most likely place you can get an infection. We've done 30,000 procedures in our facility and 15,000 with our current surgeon, and we've never had an infection. I can't say infection is nonexistent, but somebody is not doing something right if you see recurring infections in a facility.

DR. CHARLES I. BERLIN: I am an audiologist and hearing scientist at LSU Medical Center. I brought with me a device I'm going to show you that will allow me at the

front of the room and a person way in the back to be able to communicate. The basis of that device is what the Secret Service uses now to protect various important statesmen.

Is there anybody here who has an agenda vis-à-vis hearing loss? I'd like to know why you came and what it is that appeals to you about hearing loss. Anybody with hearing loss-impaired members in their family?

FROM THE FLOOR: My mother has hearing problems and wears hearing aids that sometimes work and sometimes don't.

DR. BERLIN: I'm going to show you why hearing aids sometimes work and sometimes don't. I'm going to talk about some recent discoveries we've made about what happens in the inner ear. I'm going to take you into the inner ear, let you learn how it works and then explain where it breaks down and where hearing aids will help and where they won't. Knowing that in advance will help you decide if your mother will benefit from them or if you should not waste your money.

Anybody have some other experiences with hearing loss? If not, then you don't know you've had them then, because I'll show you that a fairly large proportion of the country has a problem. As we age, our hearing gets worse, but it's not age that's the cause of the hearing loss. There are four basic causes of hearing loss in this country. One of them is noise exposure, such as rock and roll, loud bands and boom cars. Secondly, free radicals, or oxidative stress, is a cause not only of vision loss but of hearing loss. I'm going to show you that antioxidant therapies are now being introduced in the armed services to prevent and manage noise-induced hearing loss and also to prevent tinnitus (ringing in the ears). About one-third of the people in this room have ringing in their ears, but they tend to ignore it. Of people who hunt, the left ear of most right-handed shooters is poorer than the right ear, and it has ringing in the ear. I'll talk to you at some length about that.

The third most common cause of hearing loss is intravenous antibiotics of the type called aminoglycosides, like kanamycin and vancomycin. The fourth most common cause of hearing loss is genetic causes. We have now discovered 128 different genes that cause hearing loss. Whether or not you might want to be involved in genetically screening a patient for hearing loss and either accepting or rejecting the risk of a hearing aid is something we can talk about as I go through the various causes of hearing loss.

The incidences of hearing loss by age group, as you can well predict, is much greater in people over 55 than under 55. However, we now have universal hearing screening in this state and in many states around the country, so that the identification of hearing loss at birth becomes mandatory. I'm going to show you how and why that's very important and how that's going to change the insurance and management landscape in the future, because the incidence of manageable hearing loss is going to go up dramatically as a result of early discovery and early

management. I'll show you why management versus identification are very important issues. You can identify someone as being hearing-impaired, but there are two types of hearing loss that will respond to hearing aids and one type that will not. I'm going to take you through what it's like to have a hearing loss, show you what it sounds like and then show you why this one type, which has only recently been discovered and put in the literature, does not respond to hearing aids.

By the time you get to be my age, which is a little over 72, you do not have a chance of having normal hearing unless you protected your ears through your lifetime. I make a living here in New Orleans as a professional musician, but I wear earplugs on every job I play and I don't play rock-and-roll jobs at all. Two million people with hearing loss are under the age of 18. This is the third leading chronic disability following arthritis and hypertension. About 15 percent of college graduates have a level of hearing loss equal to or greater than their parents because of their noise and loud music exposure. Let me tell you how to know when you're in a dangerous noise. There are three signs. You can know this yourself; you don't have to carry around a sound level meter. First of all, it will make you shout over the noise. Second of all, it will leave you with a dullness in your ears. Third, it will leave you with a fullness in your ears and maybe a ringing.

Anyway, 60 percent of hearing loss is genetic. About one in four people are carriers of one of 128 genes we've discovered for hearing loss. Three of these genes were discovered here in my laboratory and at LSU, and they involve a horrible disease indigenous to Louisiana called Usher syndrome. Usher syndrome involves people being born deaf and men going blind in the middle of their teenage years. Knowing that these people have Usher is very important because we then will not urge them to use sign language and raise them in sign language, because when they go blind, they'll be lost except for tactile communication. This is a horrible disease, and identifying it early is very important. Fortunately, we have the genetic test for that.

Of the 12 million people in this country who have hearing aids, only 6 million actually wear them enough. When they don't work, it's almost always because they haven't been fitted properly and/or even though there's a hearing loss, the type of loss isn't amenable to a hearing aid.

The importance of early identification can't be stressed enough. It has been shown that if you can identify a deaf child before the age of six months and introduce either hearing aids or some other language to him or her, by six years of age, the child can function in normal schools. What happens if you can't do that? The longer you wait to teach a first language to deaf children, the more you risk their future academic performance and potential earning ability. I've been involved in a number of suits for wrongful deafness. The cost of deafness to a child in terms of his or her income is a staggering amount of money, and I've worked with actuaries to try and estimate that. It comes to \$7 million to \$9 million of lost earning potential, cost of hearing aids, cost of special devices and so on. I'm not sure that the \$9 million was

a fair number, because it involved punitive dollars as well, but those things are being done.

Let me explain what happens when you don't raise somebody to be a hearing/speaking person. If you read the language of a very intelligent person who was born deaf and raised in sign language, you would probably not hire this person. The person is seriously handicapped by learning sign language as his or her first language. There's nothing wrong with sign language; it's an elegant language. But it's not English on the hands, it's French and a French grammar on the hands, without any of the sounds of English and signs of English. What audiologists, physicians and insurers can do is to facilitate early identification to prevent these types of language disruptions and discriminate between two types of hearing loss: conductive and sensory-neural loss, or outer hair cell loss, and inner hair cell loss. I'm going to explain how different they are, because the management under both these conditions is quite different.

A high-frequency hearing loss is an outer hair cell hearing loss. It's very clear that you're not deaf. So your mother hears, but she doesn't understand. Her complaint is not that she doesn't hear, but that you don't speak clearly.

An inner hair cell hearing loss is a condition that has only recently been reported. If someone has an inner hair cell hearing loss and the sound is incomprehensible, telling that person to get a hearing aid and make it louder is not going to work. Our group was responsible in part for the discovery of this particular problem. Let me describe what goes on in the ear when this happens. There are three bones in the ear. They move in response to sound, and they bring sound into the inner ear. If you look at the ear from the top, there are normal nerve fibers and hair cells when you have a normal ear. When the ear is damaged due to noise or due to drugs, the normal nerve fibers and hair cells are gone. An audiogram of the damaged ear shows loss of high frequencies. If zero is normal, then these things go down. You see numbers like 20, 30, 40 and 60. Those are not percentage numbers. If you end up dealing with hearing loss in percentage, you're missing the point. Those numbers are logarithmic numbers. Ten, 20 30 and 40 is the same as 10, 100 1000 and 10,000. So a 60-decibel hearing loss is 1 million times worse than normal, not 60 percent worse. That is a very important concept.

We are now able to do some remarkable things, including objectively measure the auditory function of a newborn baby. This has not been universally possible until quite recently, with the advent of portable computers. First, we study the inner ear in my laboratory (and others like it). The ear goes around in a spiral. That spiral has a shelf, and on this shelf are hair cells. It's not the hearing loss or the audiogram that determines management, but the kind of hair cell damage you have and the consequences of the hair cell damage. When the ear moves, the hair cells on the shelf move up and down.

There are two types of hair cells: outer hair cells and inner hair cells. The inner hair cells are the real weapon of the inner ear. They drive and fire the nerve fibers. The outer hair cells have an entirely unusual phenomenon attached to them (I'll explain what that is in a moment). When the ear moves, the hair cells move up and down and the nerves fire. The type of hearing loss I talked about earlier with regard to your mother comes when these outer hair cells are damaged. The type that sounds incomprehensible comes when the inner hair cells are damaged. You need to be able to split this organ in half, test the outer hair cells and compare them to the inner hair cells. The outer hair cells can be tested with two tests. One is otoacoustic emissions, and the other is cochlear microphonics. The exact procedures are secondary to what they show you. The inner hair cells can be tested by four separate tests: electrocochleography, auditory brain stem response and middle ear muscle reflex. If you have damage to the inner hair cells, hearing aids will not help you.

Your mom may have a combination. She may have started out with outer hair cell loss and then may have gotten inner hair cell loss. With that bit of information, let me explain two other things. The inner hair cell is the only cell in the body that spontaneously discharges. It's probably the source of ringing in your ears that a lot of you get when you're around loud noises or when you're trying to go to sleep at night. The ringing comes from a spontaneous discharge of electrical fields related to the reactive oxygen species in your ear. To keep a healthy ear, you must keep your antioxidant levels very high. That means vegetables, vitamins and minerals. A little later, I will show you that commercially available vitamins and minerals are not the way to go because they are not verifiable, and I'll discuss what can be done about that.

When you move the hair in one direction, it synchronizes the nerve fiber firing; when you move it in the other, it turns it off. What an experienced or knowledgeable audiologist does when he or she tests patients is test things in opposite polarities. That's a technical problem with which we have to deal, and I'll show you more about it as we get closer to the end.

The three dimensions of sound are frequency, intensity and time. I'm going to add two things to this bit of information. We speak the way we hear. You can meet someone who talks like he or she was born in Brooklyn or the Bronx or New Jersey, but you know, if you live in Louisiana, that the person could be born right here in New Orleans and live in a section of town called the Irish Channel, where the people have never been out of the south, but they talk exactly like they're from the Bronx. The reason they do is that they grew up listening to Irish, Italian and Spanish influx, and their English has been filtered through that.

Let me show you how critical your hearing and speech is to the way you perceive things. Would this side of the room do an exercise with me? I want you to count out loud from one to 10. At the number five, put your fingers in your ears. When you do that, you will make your own voice very loud, and you will instinctively talk

softer. The reason that happens is that you speak the way you hear. If you all have this noise going on, you try to talk over it. If you block the noise out, your voice sounds louder to you, and you talk softer.

You can apply this to everyday life when you talk on the telephone. When most people talk in a noisy room, they cover one ear. Don't do that. Cover the mouthpiece. The next time you talk on the phone, blow into it and you'll hear your own breath in your ear. That tells you that the phone company knows what I'm about to show you, which is that your speech and hearing are linked together. They let you hear yourself as you talk and hear all the background noise. When you're in a noisy room, what you want to do to hear better is to cover the mouthpiece so that the noise in the room doesn't get into your ear. Then open it up to talk and cover it again to listen. Try it the next time you're in a noisy room. Cover the mouthpiece when you want to hear better, and open it up when you want to talk.

You speak the way you hear. The three dimensions are frequency, intensity and time. I need a volunteer. I want you to hold these earphones close to your ears. I'm going to interfere with the time at which our volunteer, Toby, hears himself. He'll talk quite normally until he gets his feedback delayed. Toby, say the alphabet as fast as you can. [Toby says the alphabet quickly and clearly.] Do it again. [Toby says the alphabet haltingly when his feedback is delayed.] Tell everybody what's happening in your ear.

TOBY: It's not quite an echo, but it's a delay.

DR. BERLIN: Almost anybody who went through this would demonstrate the same thing. If you don't hear yourself right, you can't talk right. That makes sense. All I did was interfere with your time, the point at which you heard yourself.

There is an everyday application of that, by the way. If you watch a musician on stage, he or she will need a feedback speaker so that he or she can hear. If musicians take the sound from the stage and bounce it off the walls, they can't perform, because the echo of their own performances interferes with them.

Here's the take-home message: You speak the way you hear. If you don't hear well as a child, there's a high likelihood that you won't speak properly. If you don't hear the language around you, then you won't develop language, not just speech. If you listen to babies babble, they say, "ba-ba, ba-ba, da-da," if they are raised in English-speaking families. But if the family speaks French or Italian or Spanish, listen to the baby babble. The baby will babble "ba-ba, ba-ba, da-da," but with the accent on the second or third syllable because that's the language they hear. This is very powerful if you make recordings of Arabic babies. Only Arabic has the sound "nda" in it. It's unique to Arabic. So Arabic babies start to babble "nda-nda" as young as three months of age. They're listening to the people around them, and they're mimicking. If you have children of your own, you'll watch this and watch how they do this.

I want to tell you what the outer hair cell does. The outer hair cell moves in response to sound. It's that motion that makes these otoacoustic emissions, but the outer hair cell is also an amplifier. Its major job is to make faint sounds drive the inner hair cell. In the absence of outer hair cells, you have a hearing loss, but you can certainly be helped by hearing aids. In the absence of inner hair cells, however, you don't have a chance. Your only hope is a cochlear implant.

We know this is the case because this kind of hearing problem that I described to you desynchronizes the muscles of the ear. When the implant is put in place, the muscle moves. This is the middle ear muscle reflex being driven by a device called a cochlear implant. A cochlear implant currently costs about \$45,000 to \$50,000, including rehabilitation and the device.

Let me tell you how wonderful it is by telling you about a patient of mine. She was quite deaf, and hearing aids did not help her because she had an inner hair cell hearing loss due to a genetic anomaly. Two-and-a half years after I began working with her, she was implanted. Here is a conversation with her:

"Lexy, how old are you?" "Seven." "Really. Do you go to school?" "Yes." "Where do you go to school?" "Amber Valley." "Amber Valley." "Where's Daddy today?" "At work." "At work." "Do you know where he's working?" "Yes, office." "In his office. Is he in the airplane today?" "No." "Where is the airplane?" "At the airport." "At the airport, okay." "Who came with you today?" "My grandma." "Grandma, okay. Are you ready for Christmas?" "Yes." "Okay."

She's now in a normal school, needs no help at all and can carry on telephone conversations. I will tell you that her cochlear implant was denied, by me, because I didn't understand her problem. I told her mother that it wouldn't work. So her mother just went ahead and had the child implanted. She taught me a heck of a lesson; she's one of my great teachers.

The actions you can take for hearing loss are for the two types of hearing loss that involve the middle ear and the outer hair cells. The aids are now marketed at \$800 to \$6,000 per pair. The Class A hearing aid, regardless of the price the person sells them for, costs the person who buys it \$80. The Class D hearing aid, somewhat more expensive, costs \$100. The wide dynamic range compression (WDRC) costs about \$280, and the high-end digital aid costs about \$1,100. The costs to the patient vary, depending on the ethics and the training of the person who dispenses the hearing aid. They work best if they're coupled with real-ear measurements.

When patients have inner hair cell disorder, we watch and wait, because 7 percent of them get better. If not, we use visual languages, like cued speech and sign language.

There are some benefit plans, but not many. HearUSA, formerly HEARx, has a \$500 benefit. They will sell that to the insurance company, and the insurance company

will use that benefit as an incentive to join their plan, but the hearing aids then will cost \$500 more at the other end. There are other group buying plans, but there are many ways to approach it. Depending upon your state, there are hearing aid dealers versus audiologists.

FROM THE FLOOR: How do cochlear implants work?

DR. BERLIN: They correct severe deafness, or the inner hair cell type of deafness. They slide in under the nerve, and they are body-worn computers that are now miniaturized to fit behind the ear. They stimulate the nerve with the sounds of speech so that you can hear and carry on conversations. However, you can't take them and use them on a deaf person who has signed all his or her life. That person's brain isn't organized for that. You've got to do that in very young people.

FROM THE FLOOR: A very high-profile person, Rush Limbaugh, had profound deafness that came on in, it seemed, over the course of just a couple of months.

DR. BERLIN: Yes. The unfortunate rumor was that it came on because of his misuse of Vicodyn and street drugs. That's not true. I am no fan of Rush Limbaugh, but he went deaf because of a very common problem called autoimmune disease. His inner ear literally had a fight with its own cells. It ate the cells up and destroyed his inner ear but not his nerve fibers, just the hair cells. An implant was the right thing to do, and one of my colleagues at the House and Ear Institute did it.

FROM THE FLOOR: Are these types of hearing losses always bilateral?

DR. BERLIN: No. Actually, this inner ear hearing loss can be unilateral. Anything can happen, and that mother's opinion of my advice applies every place. Just about any combination of things can happen. We have patients who lose one ear, one eye, use of their arm and the use of their leg from certain kinds of neurologic diseases.

FROM THE FLOOR: What round of tests is there for newborns for hearing?

DR. BERLIN: The tests that identify deafness in newborns are otoacoustic emissions, which test the outer hair cell, and auditory brainstem response (ABR or BER), which tests the inner hair cells. Neither one of them by themselves is 100 percent accurate. It's only the combination that is the right thing to do. The outer hair cell test, the otoacoustic emissions, will miss about 10 to 12 percent of the patients who have this inner hair cell disease. The auditory brainstem response will pick them all out, but then if they follow up with the otoacoustic emissions, they'll mislabel children as being normal when they're deaf. Neither test is 100 percent accurate for screening, but they should be reimbursed so that you can get them both at the right time.

There's an inherent insurance problem here. What happens is that neurologists have their EEG technicians do ABR or BER screening at birth. They look at the

waves, make an interpretation and declare the child deaf or hearing. But it's not their field. To manage the child, the child then has to go to an audiologist and have some of the same tests reviewed. But the audiologist won't get reimbursed for that, and there you have an insurance dilemma that we're trying to resolve. The test has already been done. The problem is that the test hasn't been done correctly to discriminate the inner hair cell from the outer hair cell type of hearing loss.

FROM THE FLOOR: What about cochlear implant surgery?

DR. BERLIN: In our area, yes, but you have to fight for them. I have not had a patient who got his or her implant funded on the first request until the past two years. Now they're much more common.

FROM THE FLOOR: How do you know what it sounds like to the hearing-impaired?

DR. BERLIN: That's a wonderful question. First of all, we have many people who only have one bad ear, so we ask them to adjust their good ear to sound like the bad ear. Then we have procedures called psychophysical judgments, where we ask the patients to make certain judgments. We test their hearing ability. Say, for example, that I knock on the table two times. Most people would hear the two knocks, but some of these patients with inner hair cell disease would hear just one knock. They can't hear when things come rapidly; they can't hear the sequence. Then you take that psychophysical performance, and you superimpose it on computer-generated speech. Then when it comes out, that's what you get. It's certainly simulation, but then some people have it only in one ear.

FROM THE FLOOR: Didn't you start off by saying there were three types of deafness, including conductive?

DR. BERLIN: Yes. Conductive means your ears are blocked. Then there are the outer hair cell loss and the inner hair cell loss. Of course, remember that combinations are always possible. When we have three effects, you can have six combinations.

FROM THE FLOOR: Do the hairs ever regenerate to some degree?

DR. BERLIN: Until very recently, the only species that regenerated hairs were in cold-blooded animals: birds, snakes, lizards and so forth. However, we have recently successfully regenerated hair cells in mammals, in guinea pigs. There's a gene, called the Math1 or Atoh1 gene, which has now been injected in guinea pig ears, that regrows outer hair cells. The hair cells are functional, not entirely, but partially. Now we're trying to make sure that the nerve fibers regrow. How long it's going to take to get that into humans is unclear, because when you put something like that into a human, you're putting in a gene vector that will help cells grow independently. When you have rapid growth without apoptosis (without death),

then you have cancer. Do you want to run the risk of cancer elsewhere in the body to regrow hair cells? That question is going to take a long time to resolve.

FROM THE FLOOR: Is transplant not possible?

DR. BERLIN: As far as transplants versus implants is concerned, the middle ear can be transplanted. The cochlea, so far as we know, cannot be transplanted. As soon as it's taken out of the body, it dies. In addition, it has 30,000 nerve fibers coming out of it that have to be soldered onto 8,000 inner hair cells, about four to five nerve fibers per hair cell. Right now I don't see that as the future.

FROM THE FLOOR: What is the success rate of the implants?

DR. BERLIN: It depends upon your selection criteria. If the selection criteria are solid, the success rate is very high, over 90 percent. If your selection criteria are slipshod, it can be horrible. I'll give examples. Say, for example, a mother brings me a 45-year-old young man who was raised in deaf culture to be signing deaf, and he has no concept of speech and language. She says, "I have cancer. I'm going to die. I've been taking care of my son all his life. What's going to happen to him after I die? He won't be able to survive. Please implant him and make him talk." That's a tragedy. I wouldn't do that. I would do a newborn. Absolutely. We have done them as young as a year of age. In Europe, they do them down to six months old. The younger, the better.

FROM THE FLOOR: What about the antioxidants from vitamins?

DR. BERLIN: What I said was store-bought vitamins that are made food-grade are not as good as vitamins made by U.S. pharmaceutical (USP) means. If you have a Physicians' Desk Reference (PDR), look in that. You will see that there are very few, if any, vitamins and minerals in the PDR, Those that are there are made USP. They're made like a drug; that is, their purity, their solubility and their potency are all guaranteed and perfect.

FROM THE FLOOR: What causes a conductive hearing loss?

DR. BERLIN: That's the most common type of hearing loss in children: fluid in the ears, wax in the ears and infections in the ears. It's the same as having your ears blocked up. That's when they put the tubes in. If you go right to tubes without being sure that there's fluid in the ear, you've certainly helped the surgeon buy a yacht. It's not always appropriate. In fact, there's some disagreement in the field between pediatricians and otolaryngologists as to when and whether to use tubes.