

Public Written Comments

Submitted to PCAST

November 18, 2015 to January 5, 2016

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From: "Jennifer Brooks" [REDACTED]
 Subject: Letter from the President of the American Academy of Audiology, Larry Eng AuD
 Date: Thu, November 19, 2015 1:48 pm
 To: [REDACTED]

Attached letter sent on behalf of the President of the American Academy of Audiology, Larry Eng AuD.

Jennifer Brooks
 Executive Assistant
 American Academy of Audiology
 [REDACTED] 20

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November 15, 2015

Mr. Barack Obama, President of the United States
and
President's Council of Advisors on Science and Technology
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mr. President and Members of the Council:

The American Academy of Audiology (Academy) appreciates the opportunity to respond and provide input to the recent report of the President's Council of Advisors on Science and Technology (PCAST), focusing on the accessibility and affordability of hearing care for the millions of Americans with untreated hearing loss. We acknowledge and agree that there is a significant need to improve access and reduce the cost of hearing care for older adults. Both the PCAST report and the concurrent work of the Institute of Medicine's Committee on the Accessibility and Affordability of Hearing Care in Adults are welcomed reviews of the current state of hearing health care in America.

Unlike vision and corrective lenses, there is no treatment that "corrects" the types of hearing losses described in the body of the PCAST report. In fact, the treatment of hearing loss most often focuses on the functional changes associated with the loss. In this regard, treatment for hearing loss may be as simple as counseling, or extend to the provision of sensory aids such as cochlear implants or hearing aids, or may require some degree of therapeutic intervention. While vision loss and hearing loss can both be classified as sensory impairments, they cannot be related in terms of evaluation, treatment, impact, or outcomes.

Within the body of the PCAST report is the note that the average price of a hearing aid in 2014 is \$2,363 per unit (page 1), but that the Veteran's Administration (VA) can purchase hearing aids for approximately \$400 per unit. It is true that the VA, due to its volume buying power, can command a lower price for the device than the private sector. This also explains why retailers such as Costco can command lower costs. The private sector, particularly individual practices, does not receive the same level of discounts from the manufacturers that volume buyers command. Immediately then, the price to the patient is higher in the private sector simply due to the cost of goods.

In the private sector, the charge for the device and the charge for the *services* are often bundled together. This is not unlike the charges for a surgery where the cost for follow-up services, the "global" period, is bundled into the charge for the surgery by the physician. Similarly for hearing aid products, the global period includes all services, but generally extends for a year or more. The private sector, unlike the VA, must factor in the cost of the service associated with the dispensing of the devices, including the communication evaluation, selection, fitting, verification, and validation of the devices, the accessories (such as batteries and ear molds), and the follow-up services. Thus it is unfair to compare the wholesale cost of a hearing aid at the VA with the cost of dispensing a device in the private sector. Nonetheless, we do believe this bundling of charges for the device and the services has contributed to the public perception that the cost of a hearing aid is high.

Response to Specific Recommendations

Recommendation 1. *FDA should designate as a distinct category (“basic” hearing aids) non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss and adopt distinct rules for such devices.*

(a) FDA should approve this class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser. FDA should also approve for OTC sale, both in stores and on-line, tests appropriate to the self-fitting and adjustment of these OTC devices by the end user. Such hearing treatments and tests meet the FDA requirements for OTC products, which are that consumers should be able to self-diagnose, self-treat, and self-monitor the condition.

(b) FDA should exempt this class of hearing aids from QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer- electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids.

Response

In several places in the report, PCAST relates hearing aids to consumer electronics. The audiology community has never considered a hearing aid to be a consumer electronic device. In fact, its regulation by the FDA as a “Class I medical device” clearly differentiates the hearing aid from other consumer electronic devices such as televisions, smart phones or tablets. Thus, our perspective is that the creation of a class of hearing aid as an over-the-counter consumer electronic would further confuse the consumer. We would recommend that should this category of device be created, that it not be labeled as a hearing aid. Conversely, the consumer should be able to differentiate an over-the-counter device from the devices available to treat more complex or substantial hearing losses.

We also recommend that the FTC should require that all OTC devices be sold with an open platform format that will allow any audiologist to view, adjust, repair, or modify the parameters as needed by the patient. Currently, software used to program or adjust hearing aids is proprietary to the manufacturer and, as noted in the PCAST report, places restrictions on the number of hearing aid brands available at any one location. To assure that additional barriers of having to identify local audiologists who may or may not have access to proprietary software associated with an OTC device, an open platform would allow greater access to professional care when needed.

The American Academy of Audiology also recommends to the FDA that any OTC device be labeled with the recommendation that it is in the best interest of the patient to seek a comprehensive audiological evaluation prior to obtaining any device for the treatment of hearing loss. The labeling should also include a listing of the red-flag conditions that might signal the presence of ear disease. We recommend the labeling includes the fact that these products are intended to address hearing loss in adults with typical, age-related, mild-to-moderate sensorineural hearing loss. We strongly recommend that the labeling include warnings that these products should not be used by children.

We are concerned about the use of online hearing tests and the current potential for such procedures to under- or overestimate the degree of hearing loss. Consumers would be best served by having a comprehensive audiologic evaluation, at least at the onset of their communication difficulties and to rule out ear disease. Due to these factors, we believe that it would be inappropriate to refer to any online or in-store test as a “hearing evaluation” or a “diagnostic” procedure. Comprehensive audiologic testing results in a determination of the type, degree, possible etiology of hearing loss, and a determination of the impact of the hearing loss, and requires, at a

minimum, a battery of procedures conducted in controlled environments. We would support, however, online tests that provide *screening* procedures of sufficient degree to determine that a hearing loss falls inside or outside the mild-moderate hearing loss category.

Recommendation 2. FDA should withdraw its draft guidance of November 7, 2013, on Personal Sound Amplification Products (PSAPs). PSAPs should be broadly defined as devices for discretionary consumer use that are intended to augment, improve, or extend the sense of hearing in individuals. PSAP manufacturers should continue to be able to make truthful claims about their use in normal settings. FDA should not require language in PSAP labeling or advertising that excludes their use by individuals with age-related hearing loss no worse than mild to moderate.

Response

Similar to our comments in Recommendation 1 earlier, PSAPs should be labeled with indications, uses, and warnings. In addition, we recommend that the FDA require labeling that indicates these devices are not specifically designed for the treatment of hearing loss. We recommend that PSAPs include a recommendation that consumers seek a comprehensive audiologic evaluation from an audiologist or physician prior to purchasing the device, particularly if they intend to use the device “off-label,” for treatment of hearing loss. We also recommend that the devices be labeled with warnings regarding the red-flag conditions. We strongly recommend that the devices include warnings that they should not be used for children.

Recommendation 3. Analogously to its “Eyeglass Rule,” FTC should require audiologists and hearing-aid dispensers who perform standard diagnostic hearing tests and hearing aid fittings to provide the customer with a copy of their audiogram and the programmable audio profile for a hearing aid at no additional cost and in a form that can be used by other dispensers and by hearing aid vendors. Also analogously, the availability of a hearing test and fitting must not be conditioned on any agreement to purchase goods or additional services from the provider of the test.

Recommendation 4. Similarly in effect to its “Contact Lens Rule,” FTC should define a process by which patients may authorize hearing-aid vendors (in-state or out-of-state) to obtain a copy of their hearing test results and programmable audio profile from any audiologist or hearing-aid dispenser who performs such a test, and it should require that the testers furnish such results at no additional cost. While FTC has the authority to issue new regulations of this sort, action can be accelerated and strengthened by legislative direction. We urge the Administration to work with Congress to initiate bipartisan legislation that would instruct FTC to issue a rule for hearing aids and PSAPs similar to the eyeglass and contact lens rules.

Response

The American Academy of Audiology supports these recommendations as they are essentially consistent with current requirements of the Health Insurance Accountability and Portability Act (HIPAA) of 1996. HIPAA ensures that all patients have access to their medical records, including their audiogram and plan of care. The audiology community routinely provides this information to all patients currently. We do note, however, that the comments for allowing access to “...programmable audio profile...” suggests that there is a common methodology for reporting such information. Currently there is no such common methodology across practices or manufacturers of devices.

Additional Recommendations

The American Academy of Audiology supports the concepts of greater access and lowered costs for patients with hearing loss. The recommendations put forth in this report are noted to provide a few simple actions on the

part of federal government that could enhance the pace of innovation and rapidly decrease costs. The report also notes the complexity of this issue. As such, the American Academy of Audiology offers these additional recommendations that can be undertaken by the federal government to improve access to hearing care and to reduce the costs to the consumer.

Recommendation #1: Reclassify hearing loss as a chronic health condition.

The American Academy of Audiology recommends that the Centers for Disease Control and other appropriate federal agencies be directed to consider and classify hearing loss as a major public health condition and as a chronic medical condition. The expanding population of adults older than age 65, coupled with longer lives, will result in an expansion of the number of persons with hearing loss in the decades to come.

The U.S. Department of Health and Human Services (HHS) defines chronic illnesses as conditions “that last a year or more and require ongoing medical attention and/or limit the activities of daily living.” As the most common forms of hearing loss in adulthood are persistent, permanent, and progressive and impose functional limitations, hearing loss meets the HHS definitions of a chronic health condition. Defining slowly progressive hearing loss in the adult population as a chronic medical condition will allow Medicare and other third-party payers the latitude to provide reimbursement for services related to the condition, including treatment services, even if the devices are not covered.

Recommendation #2: Require insurance coverage for hearing care services.

The PCAST report identified the lack of insurance coverage for hearing care services as one of the barriers to hearing care. As was indicated in the report, Medicare does not provide coverage for hearing aids, nor does it provide coverage for the services associated with obtaining amplification devices. As such, the full cost for the devices and the services are borne by the patient. Directing Medicare and other payers to reimburse for the services associated with the provision of hearing aids would allow greater access to the devices, even if the cost of the devices was borne by the patient.

The American Academy of Audiology also recommends the following regulatory changes at the Centers for Medicare and Medicaid Services, specifically with regards to Medicare:

- Inclusion of an acoustic hearing screening and subsequent audiologic evaluation if the patient fails the initial screening, in the Welcome to Medicare examination.
- Elimination of the Medicare requirement that requires audiologists, to ensure Medicare coverage, receives a physician order prior to testing medically necessary audiologic and vestibular evaluations.
- Inclusion of coverage for routine audiologic evaluations on a periodic basis (every two-to-four years), to monitor hearing status.

Recommendation #3: Eliminate FDA medical evaluation requirement.

The American Academy of Audiology recommends that the FDA be directed to eliminate the requirement for the medical clearance/waiver for adults (anyone 18 years of age or older). This requirement has been inconsistently implemented and poorly enforced to date. There is no evidence that the medical evaluation requirement has led to improved hearing care, as most patients tend to waive the requirement. In fact, this requirement increases costs by requiring a medical evaluation and decreases access by requiring multiple visits to multiple providers. If over-the-counter options become available,

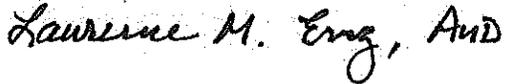
this requirement becomes moot and it would put an additional burden on the licensed provider that would not exist in the retail arenas; thus, creating additional access issues when the patient seeks care from a licensed provider.

Summary

The American Academy of Audiology supports the concept that providers offer patients access to every treatment or amplification option available, whether it is a hearing aid, personal sound amplification product, assistive listening device, FM system, or rehabilitation program. In this regard, we recognize the importance of the work of PCAST to raise awareness of hearing loss as a public health concern and to assist in aligning federal agencies with the goal of improving access and lowering costs. The American Academy of Audiology supports the PCAST recommendations to encourage greater competition and innovation within the hearing health-care environment. To date, the designations and labeling requirements assigned to different technologies has led to confusion in the dispensing community, and thus in the public as well. While we support many of the recommendations of the PCAST, we also believe that additional recommendations from the federal government would enable greater access and reduce the cost to the consumer of the services.

Please do not hesitate to call on us should you have any questions or concerns about our response or recommendations. We stand ready to work with the President's Council of Advisors on Science and Technology to improve access and reduce the cost of hearing care to the more than 30 million Americans with hearing loss.

Sincerely,

A handwritten signature in black ink that reads "Lawrence M. Eng, AuD". The signature is written in a cursive style.

Larry Eng, AuD, Board Certified in Audiology
President
American Academy of Audiology

1/5/2016

Endorsement of October 2015 PCAST recommendations on hearing devices.

From: "Dean R. G. Anderson" <[REDACTED]>
Subject: Endorsement of October 2015 PCAST recommendations on hearing devices.
Date: Fri, November 27, 2015 3:09 pm
To: [REDACTED]

Dear President Obama and PCAST Advisers;

As a research scientist in the field of psychoacoustics, I fully endorse the October 2015 PCAST recommendations for hearing devices. I will applaud their implementation!

Best regards,

Dean R. G. Anderson
President
Pixation Corp.



1/5/2016

International Hearing Society Comments on PCAST Hearing Technology Report

From: "Alissa Parady" <[REDACTED]>
Subject: International Hearing Society Comments on PCAST Hearing Technology Report
Date: Wed, December 2, 2015 1:25 pm
To: [REDACTED]

To whom it may concern,

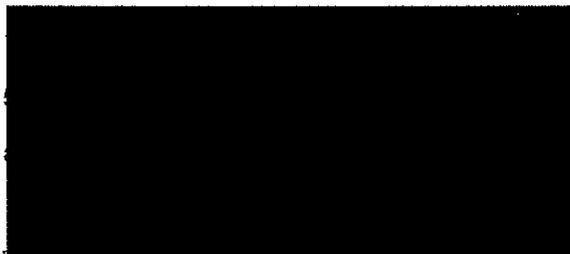
We would appreciate the distribution and consideration of the attached letter to PCAST regarding its report on hearing technologies.

Thank you.

Alissa Parady

Director of Government Affairs

International Hearing Society



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IHS Comments to PCAST re Hearing Aid Technology Report and Recommendations-FINAL.pdf
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Type: application/pdf
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December 2, 2015

President's Council of Advisors on Science and Technology
Executive Office of the President
Sent via email: [REDACTED]

Re: October 2015 PCAST Recommendations on Hearing Technology

Members of the Council:

I am writing on behalf of International Hearing Society (IHS) to express our strong concerns and opposition to the recommendations released by the President's Council of Advisors on Science and Technology (PCAST) in October 2015 regarding hearing technology. While we respect the goal of the PCAST, finding ways to expand the use of technology to improve hearing health access for Americans with hearing loss, IHS believes the PCAST's narrow focus and the resultant recommendations could in fact create unnecessary divisions between all stakeholders who are committed to finding meaningful solutions that both maintain patient safety and promote access to care.

During a meeting of the Institute of Medicine's (IOM) Committee on Accessible and Affordable Hearing Care for Adults on November 13, 2015, PCAST working group chairwoman Dr. Chris Cassel cited PCAST's focus as two major issues: 1) the role of technology and how it can help advance a variety of topics and challenges, and 2) potential changes using administrative actions. This focus is evident in your four recommendations that seek to modify or create new policy using the Food and Drug Administration (FDA) and Federal Trade Commission (FTC). Unfortunately, by looking at just one sliver of the hearing healthcare and delivery pie, the report and recommendations oversimplify the conditions and rationales behind the large number of hearing impaired people who haven't yet adopted hearing aids, and disregard the value of the imperative existing processes for obtaining care, and could ultimately create unanticipated negative consequences for both patients and the hearing aid delivery system at large.

Both the existence of hearing loss and the hearing-impaired consumer's path are complex in nature; not only does it involve the technology itself, but also the significant amount of psychology involved as the consumer grapples with their personal identification and perception of hearing loss, as well as the broader societal perceptions. It also requires proper identification and support by a qualified hearing healthcare professional, which may include an otolaryngologist (ENT physician), audiologist, or hearing aid specialist. If a consumer does not pass through these steps at the appropriate time, such as obtaining proper selection, fit and function of their hearing aids, they can easily revert to their initial stage of frustration and denial. It can be years before they opt to enter back into the hearing health system again, if at all. That being said, complexity does not equal difficulty. Once a consumer is ready to obtain care, qualified providers are readily available and are trained to guide them through the process of adopting and adapting to the use of hearing aids and learning strategies to reach success.

IHS understands that your report and recommendations target older adults with age-related hearing loss. The perceived goals of your recommendations – to create an over-the-counter (OTC) hearing aid classification, to allow a non-regulated third-party organizations to establish standards for OTC hearing aid

sales, to loosen truth in advertising restrictions on personal sound amplifiers (PSAP), and to allow for people to more easily purchase hearing aids over the internet with limited or no professional care – would likely create the exact opposite effect of that PCAST is intending. Instead, the relaxation of basic hearing healthcare requirements could create an atmosphere of confusion and mistrust, and promote unethical behaviors by unlicensed/unregulated hearing aid and PSAP providers targeting our vulnerable older population. IHS is aware of no evidence to support the efficacy or safety of these recommendations, nor the existence of evidence that they would positively impact responsible accessibility, cost, or the use of hearing aids in a meaningful way. Hearing aids and PSAPs are already being sold on the internet and through mail order sales and are delivered at a wide range of unsupported cost points, making them both seemingly accessible and affordable. Despite this present day reality, utilization rates still remain low. The primary challenges of hearing-impaired citizens is perception and awareness, to which these recommendations would have little impact.

To this point, as we consider how hearing technology is delivered around the world and how the United States can adjust its model to increase access, often we evaluate the European model. However, IHS would like to draw your attention also to the findings from a study done in Japan about adoption and satisfaction rates. According to JapanTrak, a study conducted in 2012 by the Japanese Hearing Instrument Manufacturers Association (JHIMA) and European Hearing Instrument Manufacturers Association (EHIMA), despite hearing instruments being more widely available and costing between \$460 and \$3700¹ and public assistance available based on the severity of one's hearing loss, hearing aid adoption rates are at just 14.1% and satisfaction rates are at an alarming 36%. At the time, only 57% of hearing aids were purchased through professionals – audiologists and hearing aid specialists – which could explain the low satisfaction ratings. These poor satisfaction rates, which create a negative perception of hearing aids, combined with a low percentage of recommendations for hearing aids by general practitioners and otolaryngologists no doubt contribute to the low hearing aid adoption rates.² The lesson we can take away from this situation is that professional involvement is important and necessary, and greater understanding and acceptance of the benefits of hearing aids by the physician population would help drive adoption and satisfaction.

IHS asks that you please consider the following comments on your recommendations:

Recommendation 1. PCAST recommends FDA designate a distinct and uniquely regulated over-the-counter (OTC) classification of hearing aids intended to address bilateral age-related hearing loss (presbycusis) for those with mild to moderate hearing loss, for which no professional consultation is necessary and for which consumers would self-identify, self-treat, and self-monitor their condition. **IHS opposes this recommendation.**

IHS has significant concerns with this recommendation. First of all, it would be impossible to restrict the sale of such devices to this limited population for this intended use. It would put in the hands of the consumer the responsibility of making medical determinations at their own risk. Second, it would eliminate the necessary professional evaluation, examination of the ear, determination of need, recommendation of appropriate devices, and follow up and counseling services that contribute to successful patient outcomes. Third, it would completely upend the existing state regulatory structure that defines who can competently test, fit, and dispense hearing aids.

¹ <http://www.hear-it.org/hearing-loss-japan>, retrieved 11/20/2015.

² Audio infos n° , "EuroTrak 2012: the new countries," February 2013.

The creation of this unique class of hearing aids would impact not only this targeted population, but also loosen important regulatory safeguards for the hearing loss population at large. This could have negative consequences for the millions of people, of all ages, who would attempt to self-diagnose and self-treat a perceived hearing loss, potentially at the expense of their health and wallets. Would an individual without the requisite knowledge and personal home use of the proper instrumentation know when they have an audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz, for example, or be able to visibly inspect their own ear and identify signs of a cholesteatoma, acoustic neuroma, or an ear infection? The answer is no. And in fact, the symptom of hearing loss associated with these pathologies may be gradual, leading them to believe they are experiencing age-related hearing loss. However, the consequence of missing these signs could be significant. Further, a study in the Journal of American Medicine Association (“JAMA”) indicated that while most hearing loss in the elderly is sensorineural and due to presbycusis, up to 30% of these patients may have cerumen impaction and chronic otitis media that can be treated by the primary care physician.³ As a result, individuals with hearing loss may be purchasing hearing aids unnecessarily or in doing so, delay necessary medical care.

The FDA has repeatedly reaffirmed its position that hearing aids are medical devices and that it is in the user’s best health interests to seek medical evaluation. Understanding that there may be limited access to licensed physicians, and either mobility or personal and religious beliefs that prevent an individual from seeing a physician, they instituted the option for a waiver. While the exact number of people who use the waiver is unknown, the intrinsic value of the FDA rule is that the requirement for a medical evaluation is triggered by observation of the eight FDA “red flags” (21 CFR 801.420). This model has worked well since its establishment in 1977. The red flags are appropriate devices for non-medical licensed providers – audiologists and hearing aid specialists – to determine if physician referral/intervention is necessary and/or if the person experiencing hearing loss is an appropriate candidate for a hearing aid. This “red flag” screening, which must be conducted by an appropriately trained and licensed hearing healthcare provider, must be maintained for all hearing aids in order to ensure consumers are referred and when appropriate receive help.

In 1986 the State of Colorado determined that the regulation of audiologists and hearing aid specialists was no longer needed because of a lack of complaints by consumers. The result of unregulated hearing aid sales spoke for itself. Within months unscrupulous, untrained and incapable people flocked to the state. These were people who could not get licensed previously or had their licenses revoked either in Colorado or in other states, or who were trying to make a quick dollar. They would open storefronts or operate out of their vehicles, but when a client needed them, they would often disappear. Or they would hold seminars promising phenomenal results, taking money from those in need, and not deliver on their promises. People with hearing loss, including the elderly, were hurt in these transactions both financially and psychologically, and the recovery once licensure was reinstated took several years. Now PCAST is suggesting this model be not only reestablished, but reestablished across the country, and with our most vulnerable population as the target. Federal and state regulations governing who can dispense hearing aids and requirements associated with the sale are a necessary safeguard and must be maintained in order to prevent the widespread abuse and mistrust that would inevitably arise out of the establishment of an OTC hearing aid classification. The lessons learned from Colorado’s failed experiment should not be ignored.

Recommendation 2. PCAST encourages the FDA to withdraw its 2013 guidance on personal sound amplifiers (PSAPs) and instead revert back to the 2009 guidance. **IHS opposes this recommendation.**

³ Yuch et al., *Screening and Management of Adult Hearing Loss in Primary Care*, 289 JAMA 1976-85 (2003).

While presumably well-intentioned, the impact of the 2009 guidance was a flood of new PSAP retailers in the marketplace, many of whom were selling what appeared to be hearing aids to people with hearing loss. This was evidenced in the marketing of the devices. For example, as recent as January 2014 and even after the release of the 2013 draft guidance, we observed marketing online by PSAP retailers making claims, such as “You’re probably one of the 95% of persons with a hearing issue we can help,”⁴ and “It’s Affordable – Thousands less than most hearing aids.”⁵ These examples, we believe, would suggest to the public that these devices are intended to be used by those with hearing loss. Even today, these PSAP retailers continue to advertise to people with hearing loss – even though they may use interchangeable terms like “hearing dysfunction” and “hearing issues” when referring to hearing loss.

“If you’re reading this, you’ve probably experienced some form of hearing ‘dysfunction’. For many, as we get a little older, our ability to clearly hear and define spoken words gets harder and the surrounding ambient noises of everyday life tend to get confused and mixed in with the words people around you are speaking...Does this sound familiar? Don’t worry; there is nothing to be ashamed of. In fact, we have a simple, cost effective solution that helps 95% of the people experiencing the same hearing issues you are. Did you know that on average, someone experiencing some form of hearing loss will wait over eleven years to address the problem? 11 years!...You’re probably one of the 95% of persons with a hearing issue we can help, and we’ll set you up in the privacy of your own home and let you try and hear the difference and experience the benefit first hand.”⁶

It is important to note that the figures being cited, “95% of persons,” “on average...11 years,” are consistent with rhetoric used to describe hearing loss patterns.

IHS takes no issue with the sale of PSAPs to consumers for the purpose of providing normal hearing individuals with a boost. We do, however, take issue with PSAP retailers targeting hearing-impaired individuals and knowingly bypassing federal regulations that assure safety and effectiveness, and professional intervention that identifies potential underlying pathology, and ensures consumers are purchasing appropriate hearing devices for their loss. As stated previously, individuals are not equipped to self-identify their cause of hearing loss. To suggest that people experiencing age-related mild to moderate hearing loss, who have self-identified this loss, and are beginning the process of obtaining hearing help should self-treat with a PSAP, which requires no professional evaluation or examination, is inappropriate and serves no one but the consumer electronics industry – an eager participant in the PSAP marketplace. Instead, people experiencing loss for the first time should seek a hearing evaluation with a licensed provider. Once they know the cause of their loss and options available, they will be better positioned to make an informed decision – which may include the use of a hearing aid, or if they so choose, a PSAP.

IHS asks PCAST to revise its recommendation to instead encourage the FDA to make final its 2013 guidance on PSAPs, which will establish necessary policy to reduce consumer confusion and better ensure that consumers are purchasing the devices that are best suited for their personal and medical needs. The Office of the President should be concerned with the growing incidence of retailers who are knowingly violating federal laws and rules governing hearing aids and PSAPs, and the FDA should be given the resources necessary to engage in enforcement activities against these non-compliant and profit-driven retailers.

⁴ <http://neutroniccar.com/neutronic-difference/benefits-uses/>, retrieved 1/31/14

⁵ <http://www.firststreetonline.com/Electronics+amp+Gadgets/Audio/Perfect+Choice+HD.axd>, retrieved 1/31/14

⁶ <http://neutroniccar.com/neutronic-difference/benefits-uses/>, retrieved 11/16/15

Recommendations 3 and 4. Recommendation 3 seeks to have the FTC develop rules similar to the “Eyeglass Rule” and “Contact Lens Rule” that would 1) require hearing care professionals provide customers with copies of their hearing evaluation and programmable audio profiles at no additional cost and in a transferable format, and 2) define a process to enable patients to authorize hearing aid vendors to obtain a copy of a patient’s hearing evaluation and programmable audio profile. The availability of these tests shall not be contingent upon a purchase of goods or additional services. **IHS believes this recommendation is unnecessary and inappropriate, and therefore opposes the recommendation.**

While on the surface, comparing the dispensing of eyeglasses and contact lens to hearing aids may seem a similar enough comparison, in fact, the two are quite different. The Contact Lens Rule for example requires just four points of information in order to fill a prescription: contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate. These four points of data provide the contact lens vendor – be it an optometrist or online seller, for example, with the specifications needed to provide the patient with a well-fitting contact lens that returns him or her to 100% full vision in that eye, barring any unrelated ophthalmologic issues. It is also important to point out that the contact lens rule requires that a prescription for contact lenses expire after one year. A patient has to go back to the clinician for a medical eye exam every year thus ensuring the possibility that ophthalmic pathology will not go undiagnosed. The PCAST recommendations provide no such protections.

Hearing aids on the other hand are not prescriptive devices. The programming of a hearing aid relies not only on the information captured in an individual’s audiogram, but must also consider a variety of other influencers including findings from speech, bone conduction, immittance, speech in noise and functionability testing. While hearing aids can be programmed off an audiogram alone, their effectiveness will be significantly diminished without compensation for these other factors. Further, best practices require a proper fitting, which includes the adjustment of the hearing aid’s settings real-time with the patient, which can involve up to 14 parameters across the spectrum of hearing aid products using varying algorithms. Counseling and aural rehabilitation are also critical components of the process, which cannot be adequately realized by individuals who may choose to purchase their hearing aids through a “hearing-aid vendor.”

This fact is supported by the results of Better Hearing Institute’s MarkeTrak VIII study and outcomes data, released in part in *The Hearing Review* in April 2010 in an article, “MarkeTrak VIII: The Impact of the Hearing Healthcare Professional on Hearing Aid User Success.” The authors conclude in part, “the primary mistake [in the hearing aid fitting] ... was non-use of probe-microphone real-ear measurement (REM) by audiologists and hearing instrument specialists to objectively quantify the acoustic output or gain of the hearing aids in the patient’s ear canal. REM is objective and accurate, and offers a more meaningful metric than measures of functional gain. These measures are critical for assessing audibility, appropriate output for different input levels, and verification of prescriptive algorithms. Indeed, a most compelling reason for REM is that several studies have confirmed that the manufacturer’s initial-fit algorithm often is an inadequate amplification prescription, sometimes providing less-than-prescribed gain in the high frequencies by as much as 20 dB. A study conducted in England confirmed these findings and found an 18% improvement in patient satisfaction for those fit using REM versus those not fit with REM.” An alternate risk is the initial fit providing a more-than-prescribed gain, which could damage a person’s hearing further.

As you can see, the concept of a programmable audio file that could be transferrable and be used to program any hearing device is simply unworkable. The technology does not allow for that, nor would the settings for one hearing aid necessarily be appropriate for the setting of another device given the variation in

hearing aid structure, algorithms, and interoperability. Some of these are tied to the manufacturer's intellectual property and proprietary programming. Would an online retailer who has sold a hearing aid direct to a consumer, conversely be required to share with the consumer's hearing healthcare professional the programmable audio file, which may reveal the technology and algorithms behind their products, as well? Should the system become an open system, all hearing aid dispensers and vendors should be treated equally as it relates to file sharing.

In terms of providing test results, hearing aid dispensing professionals – audiologists and hearing aid specialists – the vast majority of which are covered entities under Health Insurance Portability and Accountability Act (HIPAA) are already obligated to produce a copy of a patient's audiogram upon request. That being said, all hearing aid dispensing professionals adhere to state licensing laws and professional codes of ethics. Good business practices and professional ethics would lead the professional to make available a patient's hearing test. During the November 20, 2015, meeting of PCAST, Dr. Cassel suggested the recommended mandate will help with a select number of instances in which there are practitioners who are making the availability of a hearing test contingent upon the patient purchasing a hearing aid or other goods. Should this be the case, these individuals should be referred to their licensing boards for potential disciplinary action. Addressing unscrupulous or deceptive practices through federal policy-making when legal processes already exist is not only duplicative but is bad policy.

Further complicating this issue is the pricing structure for hearing aids, which may include the offering of free hearing tests or a bundled pricing structure. To require hearing aid dispensing professionals who traditionally offer "free" hearing tests to provide these tests to patients without being able to charge a professional fee would not only be an unfair mandate on small business owners, but could also diminish the professional relationship between the provider and patient. All hearing aid dispensing professionals should be ensured the right to charge a patient for the performance of a hearing test.

For the aforementioned reasons, IHS cannot support PCAST's recommendations and we strongly encourage you to reconsider your report and recommendations.

Hearing aid dispensing professionals work with those with hearing loss all day long, hour after hour, minute after minute. The hearing aid alone is not an answer, as PCAST may perceive. It's not like a contact lens you would put on and simply go about your day. Those who use hearing aids need a helping hand - a professional to listen to them, to guide them, and keep them encouraged...a coach like no other that understands what a quiet world is like and how the journey to hearing takes time, ongoing support, homework, patience and self-acceptance – something we can choose to grant to ourselves.

If the frustration takes over, the hearing aid goes into a drawer and the person's hearing does, too. We cannot let our aging population retreat from their lives. These amazing devices attach to a person's body, act as a nerve that is otherwise damaged, and have the ability to mimic human hearing. But, the journey is not instant or perfect. The chance of success over the long term without a professional being involved is minimal.

As stated in our previous letter to PCAST, IHS believes there are several alternative actions for which PCAST could lend its support that could help promote hearing healthcare access and ultimately drive more Americans to adopt technology that fall within the purview of the council:

- Encourage the Federal Motor Carrier Safety Administration to release recommendations to the states to urge the use of hearing screenings as a condition of obtaining a drivers' license, which could

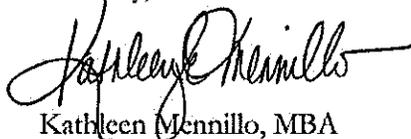
be similar to existing Federal Motor Carrier Safety Regulations Guidelines related to hearing testing. The existing guidelines, which pertain to certain professionals, requires a whisper test or audiometric test to determine whether hearing loss exists, and if so, permits a driver wearing an operational hearing aid to satisfy this requirement, with exception for those who can show adequate compensation for the deficit.

- Encourage the Centers for Disease Control to identify hearing loss as a major public health issue and expand its existing focus of children as a vulnerable population to include all adults.
- Encourage the U.S. Preventative Services Task Force to modify their existing recommendations regarding hearing screenings to support screenings for hearing loss in the population in which you target. In August 2012, to the disappointment of the hearing healthcare community, the “USPSTF conclude[d] that the current evidence is insufficient to assess the balance of benefits and harms of screening for hearing loss in asymptomatic adults aged 50 years or older.” Even in the past few years, several respected studies have been released that tie hearing loss to health conditions such as dementia, Alzheimer’s, and cognitive decline, and as PCAST purports, bringing more people into the hearing health system could have a dramatic impact on the overall health of Americans with hearing loss.
- Launch a national public awareness campaign to encourage annual or biennial hearing checks, and educate the public about the impact of untreated hearing loss
- Encourage Congress to pass legislation establishing a hearing aid tax credit, which would help alleviate some of the cost burden and encourage hearing aid adoption by those who cite cost as a factor for not purchasing hearing aids. Bills are pending in both the House and Senate that would accomplish this goal.

Finally, during her remarks to the IOM, Ms. Cassel stated that the PCAST sought out input from a wide-range of industry and professions. IHS was never solicited for input despite representing approximately half of all providers that dispense hearing aids in the private market today. We believe that if IHS had been asked to provide input from early on in the process, it would have better informed the working group of the role of hearing technology, existing challenges, and potential areas of opportunity. Instead, the public was provided a very short window following the September 18, 2015, PCAST meeting at which time it appeared the recommendations were all but finalized, based on the comments of the working group.

Thank you for your consideration. With any questions or to discuss further, please feel free to contact IHS Government Affairs Director Alissa Parady any time [REDACTED]

Sincerely,



Kathleen Mennillo, MBA
Executive Director



----- Original Message -----

Subject: PCAST: A scientific alarm by Larry Summers; Developments: The Optimistic Case for Rapid Learning Economics
From: "Lloyd Etheredge" <[REDACTED]>
Date: Thu, December 10, 2015 4:35 pm
To: "[REDACTED]" <[REDACTED]>
Cc: "Lawrence Summers" <[REDACTED]>

Dear Co-Chairs Holdren and Lander, Vice-Chairs Press and Savitz, and Members of the President Obama's Council of Advisers on Science and Technology:

I enclose a discussion and a scientific alarm (in an Op Ed by Larry Summers). He discusses the probability, based on historical experience, that an economic recovery in the US and other nations will be derailed by a recession within two ($p=.5$) to three ($p=>.67$) years.

There is nothing, scientifically, that we can do to prevent this. My earlier communication ("The Optimistic Case for Rapid Learning

Economics") reviewed CBO data, comparing two year forecasts of government and about 50 Blue Chip forecasting models since 1976.

Summers agrees with CBO and the scientific consensus that current models and data systems do not have the variables that allow us, specifically, to predict, monitor, or prevent recessions in the US and other countries. Summers also is sounding the alarm that governments do not have the scientific models, data systems, and policy tools, in a changed world, to mitigate these recessions when they occur.

This unexpected scientific stagnation is falling between the stools in Washington. Whatever agency or Presidential advisers that you imagine are responsible for solving this problem, and briefing the President about the option for rapid learning, they do not recognize the scientific challenge in their job descriptions. CBO, and everybody else, for several decades, simply report that the models and the government's (legacy) data systems "are not good at turning points" and keep using them.

You might ask the NSF Director: I do not believe that she will disagree with any of the scientific points that Larry Summers makes.

This is important: I think you will agree that the President really should be briefed swiftly and candidly by John Holdren. Members of PCAST also have unique qualifications to understand the new data and machine-learning capabilities, being used by NIH, that can be deployed for a rapid learning economics system. A good rapid learning design will include international scientific cooperation and private partnerships.

As a second example of our national system-level scientific breakdown, I also forward an Op Ed by Nobelist Robert Shiller surveying competing theories of the response of financial markets to pending interest rate changes by the Fed. You might think, by now, that the Federal Reserve system, or NSF, or the CEA, or CBO, or the academic economics profession (etc.) would have recognized a responsibility to design wider data systems with the behavioral variables to test these competing theories and forecasts. Actually, no.

Earlier, I would have suggested lighting a fire under people (e.g., at NSF). Now, I am not sure that using current institutions will get us the answers in time. It's a problem that has to be addressed and solved at your level.

with my best wishes, Lloyd Etheredge

Dr. Lloyd S. Etheredge, Project Director - Government Learning Policy Sciences Center, Inc.c/o [REDACTED]

[REDACTED] URL ><http://www.policyscience.net>< The Policy Sciences Center is a public foundation that creates and develops knowledge and practice to advance human dignity. It was founded in 1948 in New Haven, CT by Harold Lasswell, Myres McDougal, and George Dession, members of the Yale faculty. Information about the Center, the Society of Policy Scientists and the Policy Sciences journal is available at >www.policyscience.org<.

December 9, 2015

To: Interested Colleagues

From: Lloyd Etheredge¹

Re: **The Growing Case for Rapid Learning Economics: New Contributions by Summers and Shiller**

In support of “The Optimistic Case for Rapid Learning Economics” (11/19/15), I enclose two recent Op Ed pieces, by Larry Summers and Robert Shiller, for your attention.

Larry Summers

Larry Summers (12/6/15) raises the alarm. Statistically, any economic recoveries in the US and other nations will be derailed by a recession within two ($p = .50$) or three ($p = .67$) years. Policymakers do not have the earlier tools (in a changed world) to mitigate new recessions. Also, there is a professional agreement (discussed in my earlier paper) that the (“not good at turning points”) universe of current forecasting models and legacy data systems actually are missing the variables that would allow monitoring of causal processes, prevention, and provide (perhaps) unexpected clues to useful policy tools.

Implicitly, Summers raises the challenge of urgency: Can new, inclusive R&D data systems be available in time, for the US and other economies?

Robert Shiller

Robert Shiller’s Op Ed (12/4/15) discusses the effects of the (pending) raise of interest rates by the Federal Reserve. Economic theorists have created opposing predictions about the direction and size of effects (if any) and competing explanations of the different mechanisms that will underlie these observed effects, whatever they are.

Also, there are opposing predictions and competing ideas about causal mechanisms that will link the response of financial markets to behavior of the “real” economy.

The existence of these theoretical disputes strengthens the optimistic case for the benefits of a rapid learning system. We can make scientific progress by creating new, inclusive data systems that allow scientists (and, with the NIH method, supercomputers running 24x7) to discover and interpret the causal pathways creating the effects that we observe.²

¹ Director, Government Learning Project. Policy Sciences Center Inc. The Policy Sciences Center, Inc. is a public foundation created by Harold Lasswell, Myres McDougal, and George Dession in 1948 in New Haven, CT to apply knowledge of behalf of a world commonwealth of human dignity. URL: www.policyscience.net; [REDACTED]

² This will be a good initial investment: There will be a stream of future decisions, by the Fed and other central banks, to observe and explain.

Let me add three conceptual points about Shiller's paper and rapid learning:

Shiller and Designing a Rapid Learning System for Financial Market Behavior

- 1.) The market behavior that we will (soon) observe may be generated at another level, beyond the experiments with ordinary human psychology studied by behavioral finance. As Shiller knows, modern global financial markets increasingly operate with huge sums, traded rapidly and daily by analytic software and supercomputers. Hedge funds also can trade in micro-second learning cycles, conducting continuous probes and experiments. Specifically: today's sophisticated computer programmers have known that a rate hike is coming and that their earlier homework assignments [i.e., in courses like Shiller's], soon, will be real-world exam questions in battles with billions of dollars at stake. Other players can include new "smart," rapid learning software that will try to outsmart individual investor psychology and other computer programs. [[The aggregate systemic results also could be unexpected: These programs might be capable of swiftly creating, or unwittingly (collectively) colluding to create, bubbles, or push stocks downward to induce sales, creating volatility, etc. . . .]]
- 2.) Any observed market behavior will be an averaged response. A leading edge scientific challenge is to create computer software and machine learning that looks at the distribution of different causal pathways and mechanisms of different actors. (For NIH rapid learning, it has been useful to look behind averages: the typical cancer drug, given to the typical cancer patient, does them no good and chemotherapy has used combined cocktails to improve the average response. Only now, after creating Everything Included databases, can physicians begin to identify and use precisely the right drug, in the right dose, for each patient.)
- 3.) Economic behavior occurs within wider social and political contexts, whose higher-order causal effects may be relevant to interpret observed coefficients. In biomedical research the straightforward model of genetic effects on health has evolved to include a recognition of epigenetic "switches" (e.g., environmental stress like unemployment) that can turn genes "on" or "off." By analogy, a current mood related to terrorist attacks or a lack of confidence in government and financial institutions could activate mechanisms of fear and caution, a context that needs to be measured to interpret a response to Fed actions at a specific date.

Enclosures

Robert Shiller, "Don't Assume a Fed Action Will Move the Market," The New York Times, December 4, 2015.

Larry Summers, "Central Bankers Do Not Have as Many Tools as They Think," Financial Times, December 6, 2015.

Central bankers do not have as many tools as they think



Lawrence Summers

The unresolved question is how policy can delay and ultimately contain the next recession



©AFP
Federal Reserve chair, Janet Yellen

While debate about the relevance of the [secular stagnation](#) idea to current economic conditions continues to rage, there is now almost universal acceptance of a crucial part of the argument. It is agreed that the “neutral” interest rate, which neither boosts nor constrains growth, has declined substantially and is likely to be lower in the future than in the past throughout the industrial world because of a growing relative abundance of savings relative to investment.

The idea that real interest rates — that is, adjusted for inflation — will be lower than they have been historically is reflected in the pronouncements of policymakers such as [Federal Reserve](#) chair Janet Yellen, the medium-term forecasts of official agencies such as the Congressional Budget Office and the International Monetary Fund and the pricing of government bonds whose payments are tied to inflation.

This is important progress and has contributed to more prudent monetary policies than otherwise would have been made and the avoidance of a deflationary psychology taking hold particularly in Europe and Japan. Policymakers, despite having adjusted their views, still overestimate the extent to which neutral real interest rates will rise.

Neutral real interest rates may well rise over the next few years as the American economy creates jobs at a rapid rate and the effects of the financial crisis diminish. This is what many expect, though the fact that an imminent return towards historically normal interest has been widely expected for the past six years should invite scepticism.

A number of considerations make me doubt the US economy's capacity to absorb significant increases in real rates over the next few years. First, they were trending down for 20 years before the crisis started and have continued that path since. Second, there is at least a significant risk that as the rest of the world struggles there will be substantial inflows of capital into the US leading to downward pressure on rates and upward pressure on the dollar, which in turn reduces demand for traded goods.

Third, the increases in demand achieved through low rates in recent years have come from pulling demand forward, resulting in lower levels of demand for the future. For example, lower rates have accelerated purchases of cars and other consumer durables and created apparent increases in wealth as asset prices inflate. In a sense, monetary easing has a narcotic aspect. To maintain a given level of stimulus requires continuing cuts in rates.

Fourth, profits are starting to turn down and regulatory pressure is inhibiting lending to small and medium sized businesses. Fifth, inflation mismeasurement may be growing as

the share in the economy of items such as healthcare, where quality is hard to adjust for, grows. If so, apparent neutral real interest rates will decline even if there is no change in properly measured rates.

All of this leaves me far from confident that there is substantial scope for tightening in the US and there is probably even less scope in other parts of the industrialised world. The fact that central banks in countries, including Europe, Sweden and Israel, where rates were zero found themselves reversing course after raising rates adds to the cause for concern.

But there is a more profound worry. The experience of the US and others suggests that once a recovery is mature the odds of it ending within two years are about half and of it ending in less than three years over two-thirds. As normal growth is below 2 per cent rather than the historical near 3 per cent, the risk may even be greater. While recession risks may seem remote given rapid growth, no postwar recession has been predicted a year ahead by the Fed, the administration or the consensus forecast.

History suggests that when recession comes it is necessary to cut rates more than 300 basis points. I agree with the market that the odds are the Fed will not be able to [raise rates](#) 100 basis points a year without threatening to undermine recovery. Even if this were possible, the chances are very high that recession will come before there is room to cut rates enough to offset it. The knowledge that this is the case must surely reduce confidence and inhibit demand.

Central bankers bravely assert that they can always use unconventional tools. But there may be less in the cupboard than they suppose. The efficacy of further quantitative easing in an environment of well-functioning markets and already very low medium-term rates is highly questionable. There are severe limits on how negative rates can become. A central bank forced back to the zero lower bound is not likely to have great credibility if it engages in forward guidance.

The Fed will in all likelihood raise rates this month. Markets will focus on the pace of its tightening. I hope their response will involve no great turbulence. But the unresolved question that will hang over the economy is how policy can delay and ultimately contain the next recession. It demands urgent attention from fiscal as well as monetary policy-makers.

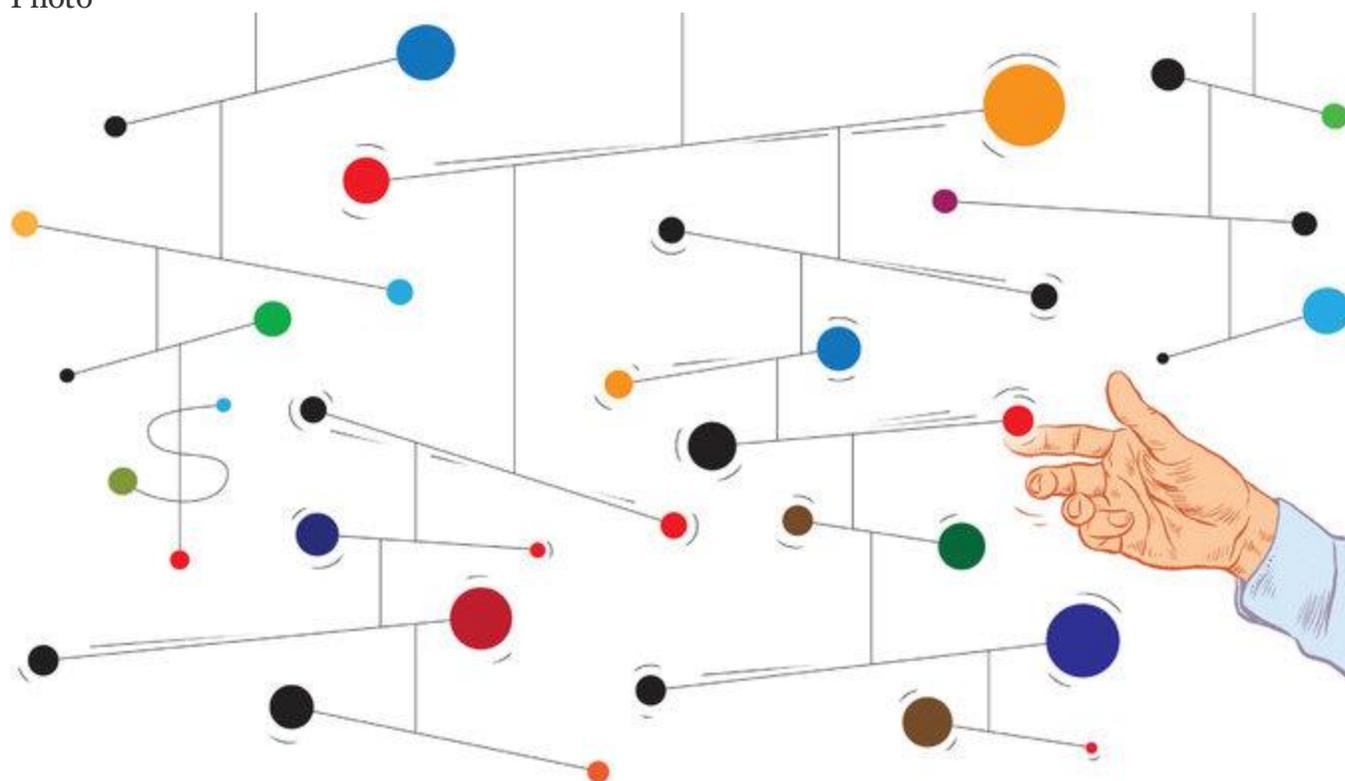
The writer is Charles W Eliot university professor at Harvard and a former US Treasury secretary

THE UPSHOT EDITED BY DAVID LEONHARDT

Don't Assume a Fed Action Will Move the Market

DEC. 4, 2015. Robert Shiller. The New York Times.

Photo



The forthcoming decision of the Federal Reserve on interest rates is a humbling example. Consider that after seven years of virtually zero percent short-term interest rates, the Federal Open Market Committee is almost universally expected to raise rates slightly at its Dec. 15-16 meeting.

What this means for the markets isn't clear, however. We can't rely on historical precedent. The last time rates rose after remaining very low for so long was in 1941. That was a long time ago, and when there has been only one previous example, in very different circumstances, historical statistics won't prove much of anything.

There are other ways of analyzing the likely effects of the Fed actions, but all have severe limitations.

First, logic tells us that if short-term Treasury rates rise, low-risk Treasury bills may become more attractive in comparison with riskier alternatives like stocks. That suggests that the stock market should weaken because people will become even more wary than they may be right now about share prices, which have tripled since 2009. Home prices should weaken too, because rising interest rates can be expected to make mortgages more expensive. In other words, this line of thinking is quite negative about the general effect of a rate increase on market prices.

There is another way to look at this, though. If the Fed raises rates in December it could be seen as good news because the Fed wouldn't take that action unless it viewed the economy as relatively strong. That could buoy market prices.

This approach immediately leads to further complications. Good news about the economy might be bad news about inflation, which tends to rise when economic growth picks up. On the other hand, if inflation rises, even if the Fed raises rates slightly, the real, or inflation-corrected, interest rate might actually be lower, not higher. Confused? That is understandable: This line of thinking might lead us into a muddle very quickly. But don't be surprised if you hear circuitous commentary like this in the weeks ahead.

Then again, the prevailing wisdom might be reflected in yet another common argument, which may be summarized in one word: boring. The markets already know everything there is to know about rates, or so this line of thinking goes, and because a rate increase is expected it should already be "discounted into" current share prices. This is a very simple version of the efficient markets theory, which holds that all available information is already fully reflected in market prices, so only true surprises really matter.

It could be argued that the Fed will surprise people only if it *doesn't* raise rates after Friday's strong [jobs report](#), or raises them *less* than expected or issues a statement that is weaker than expected. Something like that may have happened on Thursday when the European Central Bank's stimulus measures evidently [disappointed](#) the markets.

All of which is to say that we don't know what will happen if and when the Fed raises rates. And the problem becomes much more complicated when you include human psychology in your economic analysis, as we try to do in the emerging field of behavioral finance. In fact, from a psychological perspective, the whole efficient markets idea that only real surprises matter and there should be no reaction

to “news” that is well known in advance is a little off base. People often don’t know in advance how they will react until news becomes real.

The psychologists Eldar Shafir and Amos Tversky in 1992 called this phenomenon [nonconsequentialist reasoning](#), by which they meant that we often just can’t discipline ourselves to think through the likely consequences of possible events, so instead just let ourselves be buffeted by news as it happens. This suggests that an interest rate rise might not be boring at all: We will have to wait and see.

After all, with rates this low, some people may have been engaging in behavior that isn’t entirely rational and that has a basis in well-documented wishful-thinking bias. As Janet Yellen, the Fed’s chairwoman, said in her [Semiannual Monetary Policy Report to the Congress last July](#): “The committee recognizes that low interest rates may provide incentives for some investors to ‘reach for yield,’ and those actions could increase vulnerabilities in the financial system to adverse events.”

Reaching for yield — taking actions without fully considering risk, to try to earn greater returns than are found in traditional safe investments — may be a form of wishful thinking known as exaggerated expectation, which has been studied in many areas of life. For example, the psychologist Elisha Babad showed that [sports fans often have exaggerated expectations](#) for their teams, much as [voters exaggerate the probability](#) that their preferred candidate will win.

In the near zero-interest-rate environment of recent years, people have naturally searched for alternative investments, and that may have led them into wishful thinking. People might be viewing high prices in the stock and housing markets as evidence of the inherent worth of these assets, disregarding the role that low interest rates

have played in bolstering those prices. Some people have undoubtedly taken personal pleasure in their investing success, interpreting it as proof of their own self-worth. Identity and ego may be an issue, and that can be very dangerous.

People may have strong reactions when their identity is connected to things that turn out to be disappointing, after the initial reason for their excitement is gone. After the financial crisis in 2008, for example, many highfliers found that their identities as smart stock pickers or home buyers were severely challenged. It could happen again. But I'm afraid we will just have to wait and see.

Robert J. Shiller is Sterling Professor of Economics at Yale.

November 19, 2015

To: Interested Colleagues

From: Lloyd Etheredge ¹

Re: **The Optimistic Case for Rapid Learning Economics**

This memorandum outlines, from three perspectives, an optimistic scientific case that a rapid learning system for macroeconomics is possible. Such an achievement, by using the best scientific methods, is likely to provide a better future for billions of people. The three perspectives are: 1.) The existence of “upgrade” variables, widely acknowledged by the profession; 2.) The existence of competing theories that will produce scientific learning about important challenges as new data systems allow them to be tested; 3.) The existence of improved scientific methods for data analysis and fast machine-assisted learning, developed by NIH and the biomedical sciences, that can yield rapid discoveries for US and other G-20 economies.

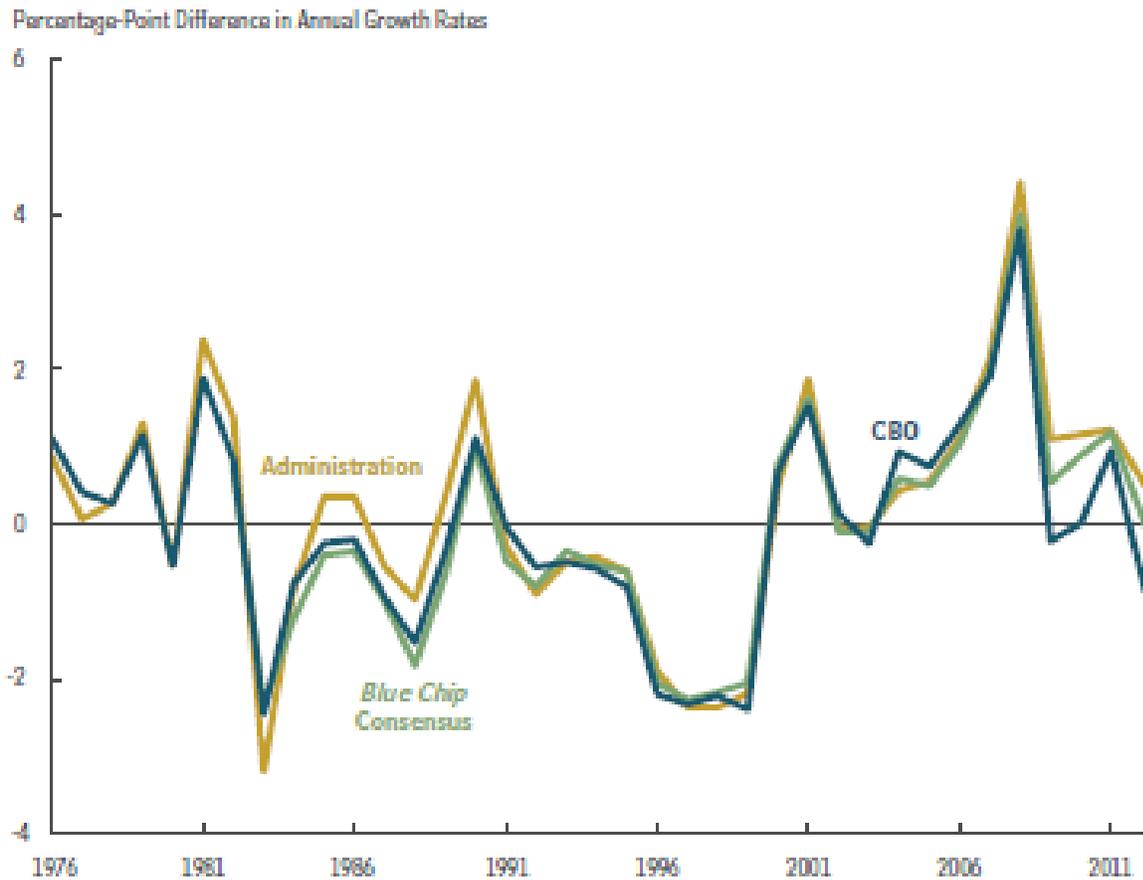
I. Missing “upgrade” variables acknowledged by professionals

The following graph compares the two-year GDP forecasting errors of the Congressional Budget Office, Administration, and about 50 private sector “Blue Chip” models since 1976.² They closely track one another. This is a highly competitive business. Almost everybody uses the same government data, traditional

¹ Director, Government Learning Project, Policy Sciences Center, Inc., a public foundation. URL: www.policyscience.net; [REDACTED]

² Congressional Budget Office, CBO’s Economic Forecasting Record: 2015 Update (Washington, DC: Congressional Budget Office, February 2015). Online. Comparing Federal Reserve two-year forecasts produces similar results.

Table 1



Forecast Minus Actual Growth in Inflation-Adjusted Output: Two-Year Forecasts

Source: Congressional Budget Office, CBO's Economic Forecasting Record, 2015 Update, (Washington, DC: Congressional Budget Office, February 2015), p. 16. The Blue Chip Consensus is based on about 50 private forecasting models.

conceptual frameworks, and linear regression analysis of quarterly time series data. We should not wait for further progress from the current data system.³

³ The average (root mean square) forecasting error of 1.8, compared to an actual growth rate that might be 3.0, is large for scientific models in most fields, perhaps another reason to be optimistic.

There is professional agreement that there are several types of missing variables:

1.) The “mystery” variables that cause recessions/collapses and recoveries are missing: as CBO reports, forecasting equations miss "turning points";⁴

2.) By design, the predictable nonrational psychological mechanisms and societal forces (discovered by the other social sciences) that might affect economic behavior are missing. [Macroeconomic forecasting uses aggregate variables defined by accountants and the tax code; the coefficients are (without independent verification) *interpreted* as rational choices, although they might be compounds of several individual cognitive processes and emotions or organizational or cultural characteristics;

3.) New structural or systemic changes in the world – e.g., information age technologies and technologies (plus other factors) that change oil prices, sociological/cultural changes, and a globalizing economy - are missing. The analysis of standard quarterly time series data, with coefficients averaged across history, slows learning, limits reliability, and this also (as we will see below, in Larry Summers’s argument) might be dangerous.

Other recognized limitations and upgrade opportunities might be discussed. However, for current purposes, this inventory makes the point: The message is

⁴ *Op cit.*, pp. 7-11.

optimistic. Although nobody can know the results of new scientific research in advance, there already is broad professional agreement about several types of plausible variables for a To Do list and scientific upgrade.

II. Competing Theories and Policy Disagreements to Establish Initial Priorities

The second perspective that gives optimism for rapid learning is that there already are well-structured disagreements, with policy relevant implications, that can be tested quickly to improve economic science in the US and other G-20 nations. For example, here are five controversies:

A. “The Global Economy is in Serious Danger.”

The attached Op Ed piece (last month) by former Harvard President and former Treasury Secretary Larry Summers, “The Global Economy is in Serious Danger,” argues that there have been fundamental global changes.⁵ The coefficients have changed and there are new variables. Thus, it is dangerous to use conventional economic models and rely upon current economic science. The global economic recovery (that already has taken twice as long as estimated by conventional equations) will take much longer and the future could be surprisingly worse than we expect. [This argument requires that missing variables be identified, coefficients re-estimated, and deeper causes of changed coefficients (if they are found) be understood – and much sooner than the analysis of historical time series can achieve].

⁵ Larry Summers, “The Global Economy is in Serious Danger,” Washington Post, October 7, 2015.

B.) Economic science doesn't need further learning. Governments only need to listen to economists.

The attached Op Ed piece (earlier this month) by Nobelist Paul Krugman, “Austerity’s Grim Legacy,” argues that there are no missing variables of consequence.⁶ Economic recovery has been delayed, in the US and abroad, simply because governments stopped listening to the equations and sound policy advice.

This is a challenging counter-factual argument. A task for Krugman’s thesis is to explain apparently unreliable equations that scared people. G-20 governments listened when the crisis began but, after initial success, the fiscal stimulus policies also faltered in their prediction of recovery. Economic forecasters had no reliable estimates of how much time and money would be required to achieve the turning point. If we should renew the large fiscal stimulus solutions, can there be rapid learning to address the risk of new failure + massive national debts without achieving healthy growth?

C.) Linear equation models are giving the wrong result.

“How reliable are these tools? They work, but they don’t work great. People and institutions find ways around them.” - Olivier Blanchard⁷

The International Monetary Fund’s former Chief Economist, Olivier Blanchard, implies that global economic science can become more realistic by upgrading from physics-like linear regression forecasting models to game-theoretic models.

⁶ The New York Times, November 6, 2015. Online.

⁷ Cited in Lloyd S. Etheredge, “A Rapid Learning System for G-20 Macroeconomics: From Greenspan to Shiller and Big Data.” Unpublished, online at www.policyscience.net at I. A., p. 29.

Today, smarter people, with growing asymmetries of brainpower and funds for lobbying, can outsmart many national governments. The force of his argument is backed by IMF data (not widely known to the public) that the world, from the late 1970s to 2003, had 117 banking crises in 93 countries in which much or all of the banking capital was exhausted. Many financial institutions developed strategies for privatizing the gains (during the upside of the bubbles) then secured government bailouts during the crisis phase. In 27 of the cases, they dumped onto governments and taxpayers added national debt equal to 10% of GDP, often much more.⁸ This is not Tulipmania anymore. The problems are not “irrational exuberance” of mass investors but brilliant strategies by alpha predators who can penetrate political systems and shape policy, a phenomenon hidden by missing variables and averaged-coefficient equations.

The better prediction equations of the new domestic and global reality may be the Lotka-Volterra predator-prey equations.

D.) The Ayn Rand novel model of life and the economy has valuable insights.

Former Federal Reserve Chairman Alan Greenspan has challenged the academic members of his profession to improve their forecasting by including a priority list of psychological and cultural variables.⁹ Specifically: although Greenspan has mastered the data and ideas in economic forecasting models he also believes that all of us (and the economy) live inside an Ayn Rand novel, a drama in rela-

⁸ Etheredge, *Op. cit.*, p. 25. Drawn from a discussion by Martin Wolf.

⁹ The Map and the Territory (NY: Penguin Press, 2013).

tionship to government and other institutions. The list of variables should recognize basic psychological truths about life, taking responsibility, the work ethic, relations to government (and all authority) and the goal of healthy self-starting, motivated individuals. His views are similar to Governor Romney's psychological diagnosis of 47% of Americans and to the psychological counseling of Reaganomics and Margaret Thatcher, and to the defining economic/psychological truths believed by Paul Ryan, the new Republican Speaker of the House of Representatives. [These views – the “Ayn Rand novel” model – have been acknowledged as a coherent and serious model, held by intellectual leaders of Republicans in Congress, by Paul Krugman (although he thinks that they are dangerous fools).]

It is sometimes alleged that people like Greenspan or Paul Ryan are ideologues who “ignore data.” Although the Krugman’s of the world may eventually prove them wrong, this is partly unfair. Sometimes, their data comes from personal experience and truths that shape their identity. And, while it may have been an historical artifact, econometric modeling evolved from a conventional national accounting system of variables that excluded their ideas from the databases and any Honest Broker estimates from the forecasting models.^{10 11}

¹⁰ Lloyd S. Etheredge, “President Reagan’s Counseling,” Political Psychology (1984), online at www.policyscience.net.

¹¹ Civic optimism also might be possible. Rapid learning about these Republican-model missing variables, with Honest Broker testing, might shift votes, at the margin, to produce creative legislative compromise and improve agreement in Washington. The simple step of including a consumer “mandate” for individual responsibility to buy health insurance – a provision derived from Governor Romney’s compromise health plan In Massachusetts – preserved an essential element of moral and civic health (in the Republican model) and achieved passage of Obamacare.

E.) Breakdowns of Moral Credibility and Trust in Major Institutions

I also derive optimism because there are new theories (that I have suggested) to explain why policies derived from conventional equations (e.g., low interest rates and fiscal stimulus) misdiagnosed the current breakdowns and do not restore confidence reliably. The current crisis was a sudden and frightening breakdown of trustworthiness and moral credibility by major institutions - governments, political systems, and financial institutions. Confidence in the future cannot be restored by traditional remedies alone because these major institutions have not restored confidence in themselves.¹² If true, science-based learning can help to invent better options.

III.) New Rapid Learning Technology

A third perspective also gives optimism about the possibility of a rapid learning system for economics, which might swiftly benefit economic recovery and the future well-being of billions of people.

Specifically: We have new supercomputer-assisted learning technologies that can be applied to Everything Included databases and produce unexpected discoveries quickly. NIH has shown the new rapid learning systems to be stunningly successful and that they can be routinely applied even to 100,000+ variables/case

¹² Lloyd Etheredge, "Animal Spirits' and Economic Recovery: Reading the Lessons Correctly," online at www.policyscience.net at I. A. See also Robert Shiller: "I suspect that there is a real, if still unsubstantiated, link between widespread anxieties and the strange dynamics of the economic world we live in today" in his "Anxiety and Interest Rates: How Uncertainty is Weighing on Us," The New York Times, February 7, 2015. Online.

and tens of millions of cases: for many centuries cancers were classified by the site of occurrence – now we know, from genetic markers, that there might be ten types of cancer that occur in the breast, each with its own causal pathway and possibility of new, precision treatment. The cost of genetic analysis has dropped more than a million-fold.¹³ Last week, similar initial discoveries of three types of Type II diabetes were announced.¹⁴ And we are just at the beginning of the new rapid learning system.’

The new NIH computer and Big Data strategy also has invented a faster global discovery system. For example, initial discovery thresholds can be set at 0.70 confidence (rather than 0.95) and the results “published” to computer memory for fast further analysis with new samples and without delays for academic publication. Supercomputing analysis for discovery can operate 24x7 at almost the speed of thought, rather than the speed of an NIH or NSF grant process.

The Nobelist Robert Shiller (although without invoking supercomputers, machine-assisted discovery, and Big Data) has recommended this kind of strategy: an inclusive conceptual and data framework that builds economic theory and reliable economic policy on a foundation of how people actually behave. (I am in Shiller’s

¹³ ‘David Reshef et al, “Detecting Novel Associations in Large Sets of Data,” *Science*, 334, (December 16, 2011), pp. 1518-1524; Vogelstein et al., “Cancer Genome Landscapes,” *Science*, 339, (March 29, 2013), pp. 1546-1558.

¹⁴ Francis Collins, “Big Data Study Reveals Possible Subtypes of Type II Diabetes” NIH Director’s blog, posted online November 10, 2015.

camp)¹⁵ . . . There are no guarantees, but the possibility of rapid learning economics is more optimistic than if these technologies did not exist.

Attachments

- Larry Summers, "The Global Economy is in Serious Danger," Washington Post, October 7, 2015.

- Paul Krugman, "Austerity's Grim Legacy," The New York Times, November 6, 2015.

- Lloyd S. Etheredge, "President Reagan's Counseling," Political Psychology, 5:4 (1984), pp. 737-740.

- Francis Collins, "Big Data Study Reveals Possible Subtypes of Type II Diabetes" NIH Director's blog, posted online November 10, 2015.

¹⁵ Etheredge, "A Rapid Learning System . . ." *op. cit.*; NIH's Everything Included /machine-assisted learning strategy also allows an empirical redefining of all variables and classifications.

The global economy is in serious danger

By Lawrence Summers October 7, 2015. The Washington Post.

As the world's financial policymakers convene for their annual meeting [Friday](#) in Peru, the dangers facing the global economy are more severe than at any time since the Lehman Brothers bankruptcy in 2008. The problem of secular stagnation — the inability of the industrial world to grow at satisfactory rates even with very loose monetary policies — is growing worse in the wake of problems in most big emerging markets, starting with China.

This raises the specter of a global vicious cycle in which slow growth in industrial countries hurts emerging markets, thereby slowing Western growth further. Industrialized economies that are barely running above stall speed can ill afford a negative global shock.

Policymakers badly underestimate the risks of both a return to recession in the West and of a period where global growth is unacceptably slow, a global growth recession. If a recession were to occur, monetary policymakers would lack the tools to respond. There is essentially no room left for easing in the industrial world. Interest rates are expected to remain very low almost permanently in Japan and Europe and to rise only very slowly in the United States. Today's challenges call for a clear global commitment to the acceleration of growth as the main goal of macroeconomic policy. Action cannot be confined to monetary policy.

There is an old proverb: “You do not want to know the things you can get used to.” It is all too applicable to the global economy in recent years. While the talk has been of recovery and putting the economic crisis behind us, gross domestic product

forecasts have been revised sharply downward almost everywhere. Relative to its 2012 forecasts, the International Monetary Fund has reduced its forecasts for U.S. GDP in 2020 by 6 percent, for Europe by 3 percent, for China by 14 percent, for emerging markets by 10 percent and for the world as a whole by 6 percent. These dismal figures assume there will be no recessions in the industrial world and an absence of systemic crises in the developing world. Neither can be taken for granted.

We are in a new macroeconomic epoch where the risk of deflation is higher than that of inflation, and we cannot rely on the self-restoring features of market economies. The effects of hysteresis — where recessions are not just costly but also stunt the growth of future output — appear far stronger than anyone imagined a few years ago. Western bond markets are sending a strong signal that there is too little, rather than too much, outstanding government debt. As always when things go badly, there is a great debate between those who believe in staying the course and those who urge a serious correction. I am convinced of the urgent need for substantial changes in the world's economic strategy.

History tells us that markets are inefficient and often wrong in their judgments about economic fundamentals. It also teaches us that policymakers who ignore adverse market signals because they are inconsistent with their preconceptions risk serious error. This is one of the most important lessons of the onset of the financial crisis in 2008. Had policymakers heeded the pricing signal on the U.S. housing market from mortgage securities, or on the health of the financial system from bank stock prices, they would have reacted far more quickly to the gathering storm. There is also a lesson from Europe. Policymakers who dismissed market signals that Greek debt would not be repaid in full delayed necessary adjustments — at great cost.

Lessons from the bond market

It is instructive to consider what government bond markets in the industrialized world are implying today. These are the most liquid financial markets in the world and reflect the judgments of a large group of highly informed traders. Two conclusions stand out.

First, the risks tilt heavily toward inflation rates below official targets. Nowhere in the industrial world is there an expectation that central banks will hit their 2 percent targets in the foreseeable future. [Inflation expectations](#) are highest in the United States — and even here the market expects inflation of barely 1.5 percent for the five-year period starting in 2020. This is despite the fact that the market believes that monetary policy will remain much looser than the Fed expects, as [the Fed funds futures market predicts a rate](#) around 1 percent at the end of 2017 compared with the Fed's most recent median forecast of 2.6 percent. If the market believed the Fed on monetary policy, it would expect even less inflation and a real risk of deflation.

Second, the prevailing expectation is of extraordinarily low real interest rates, which is the difference between interest rates and inflation. Real rates have been on a downward trend for nearly a quarter-century, and the average real rate in the industrialized world over the next 10 years is expected to be zero. Even this presumably reflects some probability that it will be artificially increased by nominal rates at a zero bound — the fact that central banks cannot reduce short-term interest rates below zero — and deflation. In the presence of such low real rates, there can be little chance that economies would overheat.

Many will argue that bond yields are artificially depressed by quantitative easing (QE) and so it is wrong to use them to draw inferences about future inflation and real rates. This possibility cannot be ruled out. But it is noteworthy that bond yields are now lower in the United States than their average during the period of quantitative easing and that forecasters have been confidently — but wrongly — expecting them to rise for years.

The strongest explanation for this combination of slow growth, expected low inflation and zero real rates is the secular stagnation hypothesis. It holds that a combination of higher saving propensities, lower investment propensities and increased risk aversion have operated to depress the real interest rates that go with full employment to the point where the zero lower bound on nominal rates is constraining.

There are four contributing factors that lead to much lower normal real rates:

- **First, increases in inequality — the share of income going to capital and corporate retained earnings — raise the propensity to save.**
- **Second, an expectation that growth will slow due to a smaller labor force growth and slower productivity growth reduces investment and boosts the incentives to save.**
- **Third, increased friction in financial intermediation caused by more extensive regulation and increased uncertainty discourages investment.**
- **Fourth, reductions in the price of capital goods and in the quantity of physical capital needed to operate a business — think of Facebook having more than five times the market value of General Motors.**

Emerging markets

Until recently, a major bright spot has been the strength of emerging markets. They have been substantial recipients of capital from developed countries that could not be invested productively at home. The result has been higher interest rates than would otherwise obtain, greater export demand for industrial countries' products and more competitive exchange rates for developed economies. [Gross flows](#) of capital from industrial countries to developing countries rose from \$240 billion in 2002 to \$1.1 trillion in 2014. Of particular relevance for the discussion of interest rates is that foreign currency borrowing by the nonfinancial sector of developing countries rose from \$1.7 trillion in 2008 to \$4.3 trillion in 2015.

has now gone into reverse. According to [the Institute of International Finance](#), developing country [capital flows](#) fell sharply this year — marking the first such decline in almost 30 years, as the amount of private capital leaving developing countries eclipsed \$1 trillion.

What does this mean for the world's policymakers gathering in Lima? This is no time for complacency. The idea that slow growth is only a temporary consequence of the 2008 financial crisis is absurd. The latest data suggest growth is slowing in the United States, and it is already slow in Europe and Japan. A global economy near stall speed is one where the primary danger is recession. The most successful macroeconomic policy action of the past few years was European Central Bank President Mario Draghi's famous vow that the ECB would do "[whatever it takes](#)" to preserve the euro, uttered at a moment when the single currency appeared to be on the brink. By making an unconditional commitment to providing liquidity and supporting growth, Draghi prevented an incipient panic and helped lift European growth rates — albeit not by enough.

Any discussion has to start with China, which [poured more concrete](#) between 2010 and 2013 than the United States did in the entire 20th century. A reading of the recent history of investment-driven economies — whether in Japan before the oil shock of the 1970s and 1980s or the Asian Tigers in the late 1990s — tells us that growth does not fall off gently.

China faces many other challenges, ranging from the most rapid population aging in the history of the planet to a slowdown in rural-to-urban migration. It also faces issues of political legitimacy and how to cope with hangovers of unproductive investment. Even taking an optimistic view — where China shifts smoothly to a consumption-led growth model led by services — its production mix will be much lighter. The days when it could sustain global commodity markets are over.

The problems are hardly confined to China. Russia struggles with low oil prices, a breakdown in the rule of law and harsh sanctions. Brazil has been hit by the decline in commodity prices but even more by political dysfunction. India is a rare exception. But from Central Europe to Mexico to Turkey to Southeast Asia, the combination of industrial growth declines and dysfunctional politics is slowing growth, discouraging capital inflows and encouraging capital outflows.

No time for complacency

What is needed now is something equivalent but on a global scale — a signal that the authorities recognize that secular stagnation, and its spread to the world, is the dominant risk we face. After last Friday's dismal [U.S. jobs report](#), the Fed must recognize what should already have been clear: that the risks to the U.S. economy are two-sided. Rates will be increased only if there are clear and direct signs of inflation or of financial euphoria breaking out. The Fed must also state its

readiness to help prevent global financial fragility from leading to a global recession.

The central banks of Europe and Japan need to be clear that their biggest risk is a further slowdown. They must indicate a willingness to be creative in the use of the tools at their disposal. With bond yields well below 1 percent, it is doubtful that traditional quantitative easing will have much stimulative effect. They must be prepared to consider support for assets such as corporate securities that carry risk premiums that can be meaningfully reduced and even to recognize that by absorbing bonds used to finance fiscal expansion they can achieve more.

Long-term low interest rates radically alter how we should think about fiscal policy. Just as homeowners can afford larger mortgages when rates are low, government can also sustain higher deficits. If a debt-to-GDP ratio of 60 percent was appropriate when governments faced real borrowing costs of 5 percent, then a far higher figure is surely appropriate today when real borrowing costs are negative.

The case for more expansionary fiscal policy is especially strong when it is spent on investment or maintenance. Wherever countries print their own currency and interest rates are constrained by the zero bound, there is a compelling case for fiscal expansion until demand accelerates to the point where interest rates can be raised. While the problem before 2008 was too much lending, many more of today's problems have to do with too little lending for productive investment.

Inevitably, there will be discussion of the need for structural reform at the Lima meetings — there always is. But to emphasize this now would be to embrace the macroeconomic status quo. The world's largest markets are telling us with ever-

increasing force that we are in a different world than we have been accustomed to. Traditional approaches of focusing on sound government finance, increased supply potential and avoidance of inflation court disaster. Moreover, the world's principal tool for dealing with contraction — monetary policy — is largely played out and will be less effective if contraction comes. It follows that policies aimed at lifting global demand are imperative.

If I am wrong about expansionary fiscal policy and such measures are pursued, the risks are that inflation will accelerate too rapidly, economies will overheat and too much capital will flow to developing countries. These outcomes seem remote. But if they materialize, standard approaches can be used to combat them.

If I am right and policy proceeds along the current path, the risk is that the global economy will fall into a trap not unlike the one Japan has been in for 25 years, where growth stagnates but little can be done to fix it. It is an irony of today's secular stagnation that what is conventionally regarded as imprudent offers the only prudent way forward.

Austerity's Grim Legacy

NOV. 6, 2015. by Paul Krugman, The New York Times

When economic crisis struck in 2008, policy makers by and large did the right thing. The Federal Reserve and other central banks realized that supporting the financial system took priority over conventional notions of monetary prudence. The Obama administration and its counterparts realized that in a slumping economy budget deficits were helpful, not harmful. And the money-printing and borrowing worked: A repeat of the Great Depression, which seemed all too possible at the time, was avoided.

Then it all went wrong. And the consequences of the wrong turn we took look worse now than the harshest critics of conventional wisdom ever imagined.

For those who don't remember (it's hard to believe how long this has gone on): In 2010, more or less suddenly, the policy elite on both sides of the Atlantic decided to stop worrying about unemployment and start worrying about budget deficits instead.

This shift wasn't driven by evidence or careful analysis. In fact, it was very much at odds with basic economics. Yet ominous talk about the dangers of deficits became something everyone said because everyone else was saying it, and dissenters were no longer considered respectable — which is why I began describing those parroting the orthodoxy of the moment as Very Serious People.

Some of us [tried in vain](#) to point out that deficit fetishism was both wrongheaded and destructive, that there was no good evidence that government debt was a problem for major economies, while there was plenty of evidence that cutting spending in a depressed economy would deepen the depression.

And we were vindicated by events. More than four and a half years have passed since Alan [Simpson and Erskine Bowles warned](#) of a fiscal crisis within two years; U.S. borrowing costs remain at historic lows. Meanwhile, the austerity policies that were put into place in 2010 and after had exactly the [depressing effects](#) textbook economics predicted; the confidence fairy never did put in an appearance.

Yet there's growing evidence that we critics actually underestimated just how destructive the turn to austerity would be. Specifically, it now looks as if austerity policies didn't just impose short-term losses of jobs and output, but they also crippled long-run growth.

The idea that policies that depress the economy in the short run also inflict lasting damage is generally referred to as "hysteresis." It's an idea with an impressive pedigree: The case for hysteresis was made in a well-known [1986 paper](#) by Olivier Blanchard, who later became the chief economist at the International Monetary Fund, and Lawrence Summers, who served as a top official in both the Clinton and the Obama administrations. But I think everyone was hesitant to apply the idea to the Great Recession, for fear of seeming excessively alarmist.

At this point, however, the evidence practically screams hysteresis. Even countries that seem to have largely recovered from the crisis, like the United States, are far poorer than precrisis projections suggested they would be at this point. And a [new paper](#) by Mr. Summers and Antonio Fatás, in addition to supporting [other economists' conclusion](#) that the crisis seems to have done enormous long-run damage, shows that the downgrading of nations' long-run prospects is strongly correlated with the amount of austerity they imposed.

What this suggests is that the turn to austerity had truly catastrophic effects, going far beyond the jobs and income lost in the first few years. In fact, the long-run damage suggested by the Fatás-Summers estimates is easily big enough to make austerity a self-defeating policy even in purely fiscal terms: Governments that slashed spending in the face of depression hurt their economies, and hence their future tax receipts, so much that even their debt will end up higher than it would have been without the cuts.

And the bitter irony of the story is that this catastrophic policy was undertaken in the name of long-run

responsibility, that those who protested against the wrong turn were dismissed as feckless.

There are a few obvious lessons from this debacle. "All the important people say so" is not, it turns out, a good way to decide on policy; groupthink is no substitute for clear analysis. Also, calling for sacrifice (by other people, of course) doesn't mean you're tough-minded.

But will these lessons sink in? Past economic troubles, like the stagflation of the 1970s, led to widespread reconsideration of economic orthodoxy. But one striking aspect of the past few years has been how few people are willing to admit having been wrong about anything. It seems all too possible that the Very Serious People who cheered on disastrous policies will learn nothing from the experience. And that is, in its own way, as scary as the economic outlook.

The Forum

President Reagan's Counseling

Lloyd S. Etheredge'

President Reagan's psychological model of economic behavior is a very different idea of how society operates than the individual rational choice models used by economists. It would be a major contribution to American public policy to develop direct measures of imagination and determine whether people do relate to government, as a higher presence, from within a larger-than-life drama.

KEY WORDS: political economy; mass psychology; leadership; imagination therapy.

For decades, economic policy has been the territory of economists, governed by their idea that we are a nation of rational choices. President Reagan has changed the assumptions. He is using ideas familiar to psychoanalysts and clinical psychologists to diagnose the problems of the American economy and design a course of treatment. He has posed a set of problems which political psychologists can solve with great benefit to the intelligence of national policy.

The president's idea is simple. He says our economy's lack of vitality is produced because government has become a powerful, substantial presence "above" us here in America. Over the past 30 years as, in our national imagination government became "bigger," we grew subjectively smaller to develop a national dependence. There was a "zero-sum" effect on each person's mind: As "it" (government) assumed more responsibility in national life, "we" (the people) took less. The work ethic disintegrated; productivity increases stopped; the economy stalled.

The president's economic policy follows logically. It is intellectually serious and urgent: He must provide national psychotherapy for a depressed, passive nation that expects its therapist to have a prompt and magical solution.

To effect the change he desires, our president-psychiatrist has designed a national psychodrama to inspire us, to create open space, and to reduce our idealized illusions. He is warm and supportive. He is cutting taxes and expenditures to make government above us "smaller." It may not be a cure we like, and there will be painful withdrawal symptoms, but we must again take responsibility for our own lives.

From personal experience, Dr. Reagan knows he is right. The dire predictions of his theory, made 30 years ago, appear correct to him. And in his autobiography, *Where's the Rest of Me?*, he sketches how he, too, was once dependent, in his case on the Hollywood studio system. He was well paid but unhappy, reading scripts written by others, never getting the leading dramatic roles he wanted to play. But then he became more assertive, struck out on his own. Once he became his own man, life started to work for him. He made a successful second marriage. Speaking his own ideas, he was elected Governor of California. Now he has the leading role in the country.

Other aspects of the president's life and experience confirm the same intuitive truth. He enjoys exhilaration, and a sense of freedom, when he rides the open range on horseback, the experience of the open range for free entrepreneurship he has told us we will regain in our national psychology by cutting back that "big government" in the sky. When he escapes to California from Washington and clears brush on his ranch, he feels recharged. He knows we will feel that way too, as the American Congress "stays the course" to effect the psychological transformation he wants.

To be sure, this is a closed system of beliefs. Evidence is always interpreted in the light of what the president calls his "basic principles." If the economic recovery is slow, it only means problems of dependency and addiction to big government are deep in our national psyche. So he is under an even greater obligation to persevere until we regain our independence and self-confidence and restart the economy. He has no choice.

From the president's perspective there is likely a second cause of a slow recovery, a cause psychoanalysts and clinical psychologists often cite: We are resisting. To an unprecedented degree, American news media refuse to discuss a national problem in the language a president uses. He has been stonewalled. *CBS News* has run nightly stories about the sufferings imposed by Reaganomics but has not yet discussed the real national problem, our psychology of dependency. It is as though the Eastern liberal news media are so addicted to the drama of an activist government, so psychologically dependent, so accustomed to demand that the president do something, that they will never admit even the possibility he could be profoundly right.

If Reagan is right, these skeptics slow the cure. The president can cut taxes and expenditures; these are actions in physical reality. But the stakes

are *psychological* reality. For the therapy to work we must agree — that the diagnosis of dependency is right, that big government is receding, that the therapist knows what he is doing.

It is also possible our actor-president is wrong. A powerful bond to government may be true of only 2% of the population: actors, intellectuals, reporters, the people who give money to political causes or end up in Washington. How can we tell?

The president has profoundly challenged the discipline of economics. His idea about how the economy works does not come from the hundreds of complex equations of their mathematical models. The basic problem, in his view, is simple: The economy is deeply *political*; we orient ourselves dependently toward government in a larger-than-life drama.

Lacking objective evidence, we now are adrift and debates about economic policy are decoupled, without intellectual integrity. Administration economists have given no evidence to support the intuitive psychological ideas about the economy the president uses to set policy. They have developed no national indicators for the substantiality of images of a "big" government in the sky, for changes in achievement motivation, for the alleged zero-sum allocations of responsibility.

Now, as we "stay the course," we navigate blind, on faith alone. Congress has applied no rules of evidence. The *Report* of the U.S. government's Council of Economic Advisers is intellectually irrelevant; it would be rejected as a test of the president's theories by any psychology department.

If the president is right, good national psychological indicators will tell us. And, refining our understanding, they might improve the president's policy. John F. Kennedy cut taxes and the economy leaped ahead — but Kennedy also talked about achievement — a New Frontier, a man on the moon by 1970. If psychodrama is needed, perhaps these are the themes to emphasize.

The president is not speaking in metaphors. He believes he is talking about our reality: solid, strong constituents of a national imagination, constituents so powerful in their effects as to destroy the health of a multitrillion dollar economy and our national spirit. His theories reflect ideas many psychologists have voiced seriously in the past: Psychoanalysts have told us that, via transference, many people relate to government authority, in our "mass psychology," the way as children they regarded their magically powerful parents; David McClelland of Harvard explained the economic rise and fall of civilizations by changes in the imaginations of citizens.

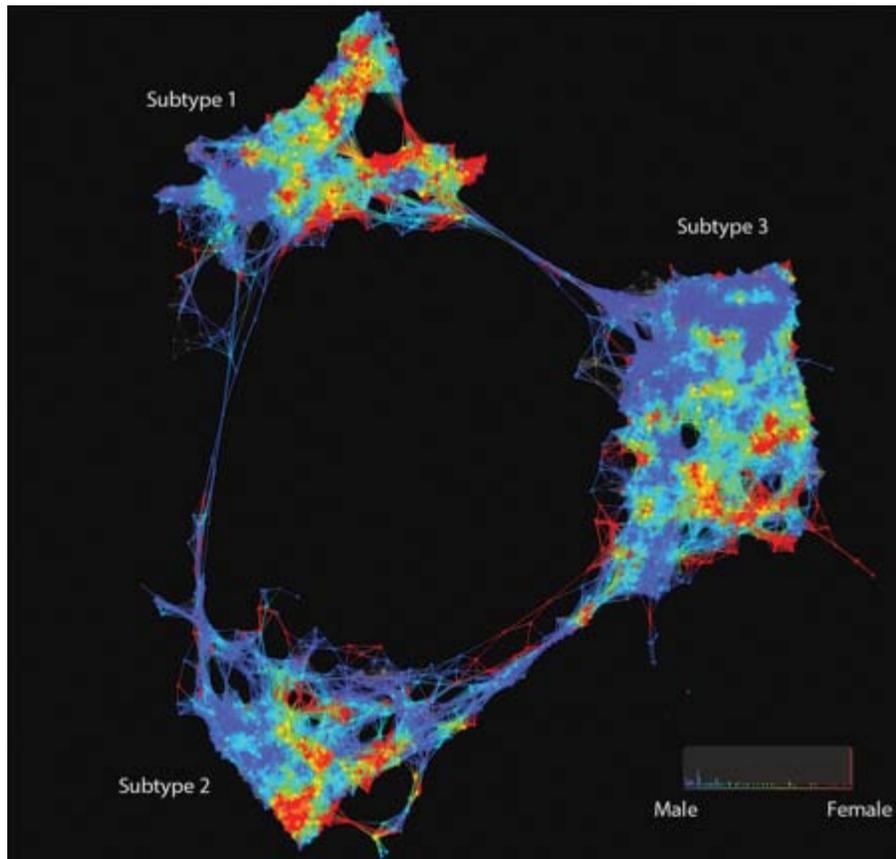
Currently, empirical evidence bearing upon the president's fundamental assumption is indirect and inconsistent. Self-report attitude measures seem to deny his model: Americans say they blame *themselves* for economic hardship. Yet macrolevel studies of election results, and individual-difference measures of self-interested and "socio-tropic" voting, suggest Reagan is cor-

rect and responsibility for management of the economy is assigned to the party in power.

Such measures of attitudes and voting are open to different interpretations as reflecting either rational and secular or psychodramatic processes. Alone, they cannot dispel the fog. The deeper question is the psychological nature of American government, and what is needed is that our public debates begin to be informed by evidence, from appropriate, clinically derived measures, of the location and substantiality of citizens' experience of government and the nature of the emotional bonds to it.

Big Data Study Reveals Possible Subtypes of Type 2 Diabetes

Posted on November 10, 2015 by [Dr. Francis Collins](#)



Caption: Computational model showing study participants with type 2 diabetes grouped into three subtypes, based on similarities in data contained in their electronic health records. Such information included age, gender (red/orange/yellow indicates females; blue/green, males), health history, and a range of routine laboratory and medical tests.

Credit: Dudley Lab, Icahn School of Medicine at Mount Sinai, New York

In recent years, there's been a lot of talk about how "Big Data" stands to revolutionize biomedical research. Indeed, we've already gained many new insights into health and disease thanks to the power of new technologies to generate astonishing amounts of molecular data—DNA sequences, epigenetic marks, and metabolic signatures, to name a few. But what's often overlooked is the value of combining all that with a more mundane type of Big Data: the vast trove of clinical information contained in electronic health records (EHRs).

In a recent study in *Science Translational Medicine* [1], NIH-funded researchers demonstrated the tremendous potential of using EHRs, combined with genome-wide analysis, to learn more about a common, chronic disease—type 2 diabetes. Sifting through the EHR and genomic data of more than 11,000 volunteers, the researchers uncovered what appear to be three distinct subtypes of type 2 diabetes. Not only does this work have implications for efforts to reduce this leading cause of death and disability, it provides a sneak peek at the kind of discoveries that will be made possible by the new [Precision Medicine Initiative's national research cohort](#), which will enroll 1 million or more volunteers who agree to share their EHRs and genomic information.

In the latest study, a research team, led by Li Li and Joel Dudley of the Icahn School of Medicine at Mount Sinai, New York, started with EHR data from a racially and socioeconomically diverse cohort of 11,210 hospital outpatients. Of these volunteers, 2,551 had been diagnosed with type 2 diabetes, which is the most common form of diabetes.

Without focusing on any particular disease or condition, the researchers first sought to identify similarities among all participants, based on their lab results, blood pressure readings, height, weight, and other routine clinical information in their EHRs. The approach was similar to building a social network with connections forged, not on friendships, but medical information. When the resulting network was color-coded to reveal participants with type 2 diabetes, an interesting pattern emerged. Instead of being located in one, large clump on this “map,” the points indicating people with type 2 diabetes were actually grouped into several smaller, distinct clusters, suggesting the disease may have subtypes.

To take a closer look, the researchers rebuilt the network to include only participants with type 2 diabetes. They then reanalyzed the EHRs based on 73 clinical characteristics, including gender, glucose levels, and white blood cell counts. That work confirmed that there were three distinct subtypes of type 2 diabetes among study participants.

Type 2 diabetes is associated with potentially serious complications, including nerve damage, vision problems, kidney disease, and an increased risk for cardiovascular disease. The study found differences in the distribution of such complications among the three subtypes of type 2 diabetes. People with subtype 1 were more likely to be diagnosed with microvascular complications, including blindness/vision defects. This group of participants was also the youngest and most likely to be obese. People with subtype 2 showed the greatest risk for tuberculosis and cancer. As for subtype 3, such people were more likely than others to be HIV positive, have high blood pressure, and develop arterial blood clots. Both subtypes 2 and 3 displayed a greater risk for heart disease than subtype 1.

Next, the researchers performed a genomic analysis, identifying hundreds of genetic variants that were enriched non-randomly in each of the three groups. Interestingly, some of the genetic variants linked to each subgroup were associated with genetic pathways that appeared relevant to the distinguishing clinical features of those subgroups.

These findings suggest that some of the clinical differences observed between the different type 2 diabetes subtypes are rooted in lifestyle or environment, and others may be influenced by inherited factors. Still, more research needs to be done to replicate and expand upon these findings. The hope is that by gaining a more nuanced understanding of type 2 diabetes, we may be able to identify more precise ways of helping to detect, manage, and, ultimately, prevent this serious, chronic disease that currently affects about 1 out of every 11 Americans [2].

References:

[1] [Identification of type 2 diabetes subgroups through topological analysis of patient similarity](#). Li L, Cheng WY, Glicksberg BS, Gottesman O, Tamler R, Chen R, Bottinger EP, Dudley JT. *Sci Transl Med*. 2015 Oct 28;7(311):311ra174.

[2] [Diabetes Latest Fact Sheet](#). 2014 June 17. (Centers for Disease Control and Prevention)

From: Jenna <[REDACTED]>
Sent: Tuesday, December 15, 2015 8:08 PM
To: [REDACTED]
Subject: Per Dr. Cassel's request.....

Dear Staff and PCAST members,

I wrote to Dr. Cassel concerning the amazing PCAST report that was recently released regarding hearing aids/assistive listening technology. I'm grateful that she responded. She asked if I would mind sharing my email with you, so please see it below. I truly appreciate your thoughts and voices in this matter.

All the best,

Jenna

Dear Dr. Cassel,

I just received an email regarding the upcoming webinar through HLAA. Quickly, I'm a 40 year old woman who is the VP of Marketing for an accounting firm in Los Angeles. I'm also Hard of Hearing and wear hearing aids in both ears. In addition, I'm also a member of HLAA.

I read the last PCAST report with great interest - I could have written it myself, and many of my cohorts said the same thing. I've been trying to lobby for HoH rights, and my pleas have mostly fallen on deaf ears, pun intended. It would be great if we could get someone fighting for advocacy that is actually hearing impaired. That being said, I see the title of the webinar is "Aging America...."

But there is a HUGE part of the population that is not aging, and yet we're suffering the same consequences: affordability, among many other things.

My question to you: is there any way we (the younger HoH segment of the population) can get our voices heard? Hearing problems are no longer, and have never really been, just a senior problem.

For example, one of my problems, aside from cost, is that hearing aids are not waterproof. We've had waterproof speakers since the 1970s. Why am I expected to swim in the pool or in the ocean deaf? That's dangerous, first and foremost. But it's also a problem that I can't converse with my own friends and family at a simple pool party.

I've been urged by many HLAA members to lobby for our rights. Does the NHQ have lobbying positions available? Or is there some kind of opportunity to get our voices heard?

I know you're very busy, and I thank you for taking the time to read this. I look forward to hearing back from you.

All the best,

Jenna

From: Dean Moretton <[REDACTED]>
Sent: Tuesday, December 15, 2015 3:28 PM
To: [REDACTED]
Subject: 2016 Public Power Utility study (Municipal Power Utilities)
Importance: High

Good afternoon Ms. Blumenthal and PCAST members.

I am currently working on a market survey project for American Public Power Administration (APPA), which mirrors a project I was commissioned by National Rural Electric Cooperative Association (NRECA) previously and which the White House leveraged data for a fact sheet.

My current project is a poll related to how America's Public Power utilities (municipal utilities) have used, or are planning to use over the next 5 years, renewable energy technologies (solar PV, and battery storage) to help them improve electric grid reliability, create distribution grid resiliency, and develop critical infrastructure disaster sustainability. I will contact 2,008 municipal energy utilities within the US beginning January and I wanted to see if your group, PCAST, would be interested in this research? Additionally, if you are looking for any current US statistical data related to Public Power utilities, I'd be happy to discuss adding that research to my polling before I begin.

Below is how my previous research manifested in a White House, Office of the Press Secretary. I believe this same type of information could be useful for calendar year 2016 related to Public Power utilities. The US has 905 Cooperative Utilities and 2,008 Public Power Utilities.

"FACT SHEET: President Obama Announces Commitments and Executive Actions to Advance Solar Deployment and Energy Efficiency." My research figures were represented in the following content "RURAL ELECTRIC COOPERATIVE LEADERS: Across the country, member-owned, not-for-profit rural electric cooperatives are deploying a variety of solar options, including more than fifty community solar projects. Today, America's electric cooperatives are announcing 199 rural electric co-ops in 27 states and American Samoa are planning solar installations that will provide over 150 MW of new solar capacity by 2020."

I look forward to discussing this further. I will be in the DC area the first week of January and would be willing to meet to discuss this effort in more detail.

Cordially,

Dean ...

Dean Moretton
Adaptive MicroGrids, LLC.

Mobile: [REDACTED]

From: Predith, Ashley
Sent: Wednesday, December 16, 2015 4:15 PM
To: [REDACTED]
Subject: FW: HIA Response to PCAST Report
Attachments: ATT00001.txt; HIA Response to October 2015 PCAST Report on Hearing Aids.pdf

From: Andy Bopp [REDACTED]
Sent: Wednesday, December 16, 2015 3:59 PM
To: Predith, Ashley <[REDACTED]>
Subject: HIA Response to PCAST Report



December 16, 2015

TO: Ashley Predith, President's Council of Advisors on Science and Technology (PCAST)

FROM: Andy Bopp, HIA

I am attaching a copy of HIA's Response to the recently released PCAST Report to the President on *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*. We have also forwarded today via FedEx copies with attachments to Chairmen Holdren and Lander as well as to Dr. Cassel. Please feel free to forward the attached to the full PCAST panel.

Please let me know if you have any questions about this Response or the attachments.

Response of Hearing Industries Association To October 2015 PCAST Report on Hearing Aids

1. Executive Summary

The Hearing Industries Association (“HIA”) has long recommended that the federal government give greater priority to hearing health, a condition which has been considered almost incidental or “just part of aging” for many years. We were pleased when we learned that the President’s Council of Advisors on Science and Technology (“PCAST”) launched a study on hearing aid technology, and eagerly awaited its recommendations on how to provide greater access to hearing aids. We expected that PCAST would base its findings on an open-minded understanding of hearing loss and the hearing aid industry, with a full appreciation of the tremendous technological advances which the industry has achieved and continues to pioneer.

In analyzing the PCAST report of October 2015, however, we were disappointed to find that it appears to contain more advocacy than science. As a result, we believe that PCAST jumps to erroneous conclusions about how to help Americans with hearing loss. PCAST’s recommendations would allow any company to market any electronic product it wished to address hearing loss. PCAST is effectively urging the U.S. to emulate the unregulated hearing aid distribution model from Japan where only 15 percent of people with hearing loss use hearing aids, and where only 36 percent of people who use hearing aids are satisfied with their performance – figures that are well below the current usage rate and the satisfaction rate in the U.S.

Unfortunately, it is apparent that PCAST’s findings and recommendations rest on: (i) flawed assumptions about and characterizations of hearing aids; (ii) acceptance of exaggerated performance claims made for Personal Sound Amplification Products (“PSAPs”); (iii) misinterpretations of governing law and regulations; (iv) downplaying the risks of the over-the-counter (“OTC”) hearing aids that PCAST proposes while ignoring the problems created by OTC hearing loss products in markets overseas; and (v) flawed comparisons between devices used to treat vision defects and devices used to treat impaired hearing. In making these fundamental errors, PCAST goes on to propose a dramatic weakening of current regulatory oversight by the Food and Drug Administration (“FDA”), which would have serious negative consequences. The laudable objective that PCAST strives for – increasing the use of products that would help consumers with age-related hearing loss – would actually be hindered by PCAST’s proposal to create a category of OTC hearing aids and allow PSAP manufacturers to claim that they can treat hearing loss without meeting any regulatory standards or conditions.

Specifically, HIA strongly opposes PCAST’s recommendation that OTC hearing aids be permitted in the United States, and its recommendation that these “basic” hearing aids be exempt from the FDA regulations that protect American consumers using medical

devices. HIA also believes that PCAST's recommendation that PSAPs be allowed to be promoted for hearing loss is contrary to the best interests of patients. Such deregulation would open the market for hearing products to a litany of claims made by any company that chose to market such products to people with hearing loss. Recommendations that the PSAP industry voluntarily self-regulate would fail to adequately protect the consumer. In addition to other flaws in the Report, the October 2015 PCAST letter to the President:

- Wrongly analogizes reading glasses to hearing aids, despite the serious public health consequences of the use of ineffective or unnecessary hearing devices compared to the benign consequences of a consumer's use of inappropriate OTC eyeglasses for reading;
- Mischaracterizes and misapplies FDA's regulatory scheme and ignores FDA studies, regulations, and policies that, since 1977, have recognized that permitting use of hearing aids without a physical inspection of the ear by a hearing professional will miss "red flag conditions;"
- Would exempt products intended to treat hearing loss from important FDA manufacturing, inspection, complaint-handling, and labeling regulations; and
- Assumes – incorrectly – that consumers with hearing loss will be able to comprehend and apply the complicated intended use definition that PCAST proposes for OTC hearing aids.

The PCAST Report also erroneously states that innovation has been lacking in the hearing aid industry, when advances in technology achieved by hearing aid manufacturers have already given consumers a wide range of options to address their hearing loss, either with basic – yet effective – models, or with highly advanced devices, many of which include wireless features. The hearing aid industry has in fact been at the cutting edge of technological innovation, including the development of:

- Hearing aids with wireless features that enable streaming of telephone, television, cell phone, music player (such as an iPod), tablet (such as an iPad), and other signals directly to the hearing aid, simultaneous ear-to-ear programming, and other features. Eighty-two percent of hearing aids sold in the U.S. in 2014 included wireless features;
- Algorithms that can classify up to six different situations, such as speech in noise, in music or even in a car (to allow directionality to the side or back for safety reasons) in order to identify and reduce environmental background noise, which is one of the major complaints of consumers;
- Hearing aids which are controlled by the person with hearing loss using an App on their smartphone, including iPhones. This includes volume control and the ability to switch programs to specific settings designed to enhance performance in specific environments;

- Digital technology that all but eliminates feedback, a problem that discouraged use of old-fashioned hearing aids due to hearing instrument “whistling” – a true technology challenge given the close proximity of the microphone and receiver;
- Directional microphone technology that can process environmental sound to increase clarity of voices in the front, side or behind a user while filtering out ambient noise using advanced technologies. Clinical studies show that people with hearing aids in noisy environments can hear as well as, or, in some instances, better than people without hearing aids;
- Most hearing aids have telecoils which allow direct communication to the hearing instrument in places of worship, theatres and even retail locations and taxicabs; and
- Some hearing aids can be programmed to alert users of the need to take medication at a specific time or to provide appointment reminders.

Hearing aid manufacturers are pioneers in wireless technology applications for people with hearing loss, and significant advances are certain to occur in the future, providing even greater connectivity through hearing aids. Many other innovations are in the works to further enhance hearing aid performance spurred by the hearing aid industry’s annual research and development budget of approximately \$600 million. A 2014 article in *Hearing Review* magazine, which PCAST itself references for price statistics, accurately describes “an industry that is witnessing some major changes in response to new technology being offered by hearing aid manufacturers.” The PCAST report, nevertheless, refers sarcastically to “beige plastic hearing aids” (PCAST Report at 7) and implies that the hearing aid industry has failed to adapt new technology, let alone innovate, and that there has been no “disruptive innovation” in the hearing aid distribution model. This paints a grossly inaccurate picture.

In sum, PCAST’s report is seriously flawed in multiple respects.

Although HIA does not support the primary recommendations of the PCAST Report regarding OTC hearing aids or the marketing of PSAPs for hearing loss, HIA does agree with PCAST that each individual with hearing loss should have access to hearing aids that will appropriately address his or her needs. We also agree that once the hearing professional has identified the appropriate communication and amplification requirements for an individual, that person should have access to his or her test results (including an audiogram) and to have hearing aids fitted by any hearing healthcare provider. In other words, HIA supports the ability of each patient to select the professional to conduct the necessary evaluation and testing, and then to purchase the device through any legal distribution channel.

HIA believes that “disruptive” distribution models have already had a dramatic impact on hearing aid affordability and accessibility, and that this trend will strengthen in the coming years. In fact, the same 2014 *Hearing Review* article cited by PCAST states

the hearing aid distribution chain is already changing in response to “the Internet and Big Box retailers, pricing pressure exerted from forces both within and outside the traditional hearing industry, and the demands of the aging Baby Boomer generation.” In addition, rapidly evolving distribution networks have given consumers greater ability to “shop around” than at any time in the past, with relative newcomers such as Costco, Sam’s Club and BJ’s Wholesale gaining significant market share on a national scale. Moreover, the nation’s largest pharmacy chains, Walgreens and CVS, are both conducting pilot programs to offer hearing aids to consumers, while many online distribution models are evolving such as HearingPlanet.com, Hear.com, Audicus.com and EmbraceHearing.com. These retailers provide increased accessibility to hearing healthcare while reducing costs to consumers by increasing efficiencies and productivity across the distribution system. These advances, however, have not sacrificed the crucial element of professional involvement in diagnosis, fitting and follow-up. Conversely, the Japanese market, which enables people with hearing loss to by-pass hearing professionals in favor of OTC distribution, features low consumer satisfaction and poor rates of hearing aid usage by those with hearing loss. This is not a model that should be imported into the United States.

In addition to broadening the distribution network for hearing aids, the federal government should take other measures to expand adoption of hearing aids, by encouraging physicians to focus on hearing loss, by launching a public awareness campaign, and by enacting a hearing aid tax credit, as will be discussed further below.

2. Background: Untreated Hearing Loss Is Debilitating and Dangerous.

As the PCAST Report correctly observes, an estimated 30 million people in the U.S. suffer from age-related hearing loss. Approximately a quarter of individuals in their 60s, about half of individuals in their 70s, and the vast majority of those in their 80s suffer from some form of hearing impairment. Studies have shown that untreated hearing loss is a significant cause of “social isolation; depression; dementia; falls with injury; and inability to work, travel or be physically active.” PCAST Report at 1. Hearing loss is particularly debilitating for senior citizens with diabetes, cardiovascular, and kidney disease, because diminished hearing negatively affects their ability to comprehend and follow instructions from doctors, pharmacists, other medical professionals, and caregivers.

These clinical issues make it particularly important that consumers with hearing loss receive appropriate treatment. Providing consumers with ineffective hearing therapies leaves them vulnerable to the very risks cited by PCAST. Yet the PCAST Report explicitly endorses exempting hearing loss products from FDA regulations that currently apply to hearing aids to ensure that they are safe and effective. Despite acknowledging the clinical importance of properly treating hearing loss, PCAST’s proposals undermine the regulatory framework that assures consumers will actually receive effective products.

Hearing aids – when properly selected, programmed, and fitted, with professional counseling on their use – are highly effective in treating hearing loss. Survey information discussed in more detail below demonstrates that more than 80 percent of hearing aid users in the U.S. are satisfied with their hearing aids, and the rate of satisfaction is higher among people with newer devices due to recent technological advances. Hearing aids enable people with hearing loss to engage with family, friends, and others, while maintaining the ability to work to their full potential. Failure to adequately address hearing loss, on the other hand, can result in diminished earning potential, social isolation, and enhanced risk for serious medical conditions.

3. FDA Regulation of Hearing Aids Protects and Promotes Public Health.

Hearing aids are used to treat a disease or condition. Thus, they are devices under the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 321(h), and have been regulated by FDA since 1976. For more than 30 years, these requirements have also included the Quality System Regulation (“QSR”) (found at 21 C.F.R. Part 820).

The governing statute and FDA’s regulations provide, among other things: (i) a requirement that appropriate facilities and equipment and properly trained personnel produce and test the hearing aids; (ii) labeling that is accurate and encourages safe and effective use of hearing aids while warning of possible side effects or problems requiring further medical attention; (iii) complaint monitoring and investigation, with reporting to FDA of certain events, to ensure that unanticipated problems are recognized and addressed; and (iv) the ability for FDA to order medical device manufacturers to recall devices and that companies notify FDA of safety-related recalls they do conduct. In addition, hearing aids incorporating programmable software – which is virtually all modern hearing aids – must comply with FDA’s design control provisions. PCAST’s recommendations would remove these protections from consumers.

Moreover, since 1977, FDA has required consumers to undergo a medical examination in order to procure a hearing aid, or execution of a waiver form that informs patients they may be committing a mistake by skipping the medical examination. That regulation (21 C.F.R. § 801.420(c)(3)) requires that consumers may not purchase a hearing aid without a medical examination unless they execute a waiver that includes the following language:

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and is strongly discouraged.

Thus, while federal law does not technically classify hearing aids as prescription devices, they are devices that are restricted in terms of their distribution, effectively requiring either a prescription or a waiver.

i. Physical Examinations Prior to Use of Hearing Aids Are Vital to Identifying Red Flag Conditions.

The PCAST Report glosses over the fact that while hearing loss is often related to aging, a significant percentage of hearing loss is caused by other conditions, which cannot be self-diagnosed. These are referred to as “red flag” conditions by FDA. Some of them require timely intervention and treatment by a physician. These red flag conditions are not rare. Reports from two major national hearing aid retail chains covering more than 250,000 individual visits around the country indicate that approximately 4-5 percent of people who visited their stores for a hearing screening required a medical referral for a red flag condition. This means that if all of the approximately 30 million Americans with hearing loss were to purchase OTC hearing devices, about 1.5 million of them would be deprived of the opportunity to treat a medical condition that would have been identified if examined by a competent professional.

A range of physical conditions can create hearing impairment: exposure to noise, genetic effects, infections, aging, and accidents, among others. Some of the underlying causes of hearing loss are related to serious medical conditions that must be addressed by a physician, and can only be detected during a professional physical examination of a person’s ear.

The PCAST Report discounts the importance of these “red flag conditions” by highlighting one of the rarest conditions (acoustic neuroma) and stating that it occurs in “only 1 in 90,000 individuals.” PCAST Report at 5. But there are many other conditions that are routinely detected by hearing professionals that require medical treatment to either resolve hearing loss without use of a hearing device (removal of ear wax, or cerumen, to open up blocked auditory canals) or to address other serious medical complications for which hearing loss is a symptom.

FDA, after careful analysis, in 2004 rejected a Citizen Petition which sought creation of a classification for an OTC hearing aid. FDA stated that providing hearing aids without medical examinations would result in patients suffering from these undiagnosed “red flag ear conditions” including “visible congenital or traumatic deformity of the ear; history of active drainage or bleeding from the ear within the previous 6 months; sudden or rapidly progressive hearing loss in either ear within the previous 6 months; air-bone gap of 15 decibels or greater at 500 Hz, 1,000 Hz, and 2,000 Hz; asymmetric hearing loss; acute or chronic dizziness; visible evidence of excessive ear wax (cerumen) or a foreign body in the ear canal; and ongoing pain or discomfort in the ear.” Response to Citizen Petition filed by Gudhear, Inc., from Beverly Chernaik Rothstein, Acting Deputy Director for Regulation and Policy, Center for

Devices and Radiological Health (“CDRH”), FDA, 2 (Feb. 13, 2004) [hereinafter “Gudhear Citizen Petition Response”] (copy attached as Exhibit 1). PCAST would substitute an undefined “warning” to be included with the OTC hearing aid for the existing consumer protections, while providing no evidence that this warning would address concerns related to self-diagnosis of FDA’s Red Flag conditions. PCAST at 5. PSAP purchasers would be even more vulnerable, because FDA could not mandate a warning for them since PSAPs are not devices.

FDA emphasized the importance of professional examinations before individuals are fitted with hearing aids in its simultaneous rejection of another Citizen Petition as well, saying both that “the safe and effective use of hearing aids depends on the collateral measure of a physical examination to ensure that a hearing aid, rather than medical or surgical treatment, is the appropriate solution to a particular person’s hearing impairment” and that provision of hearing aids without professional examinations would result in patients suffering from undiagnosed “red flag ear conditions.” Response to Citizen Petition filed by Etymotic Research, Inc., from Beverly Chernaik Rothstein, Acting Deputy Director for Regulation and Policy, CDRH, FDA, 3 (Feb. 13, 2004) [hereinafter “Etymotic Citizen Petition Response”] (copy attached as Exhibit 2). PCAST’s Report never mentions FDA’s analysis of the risks of OTC hearing aids. Although the PCAST Report dismisses FDA’s regulations as over 40 years old (PCAST Report at 4, 7), FDA rejected OTC hearing aids only 11 years ago, and placed any hearing aids using wireless technology under more rigorous regulations only four years ago (*see* discussion below).

The FDA regulation cited above requires that hearing aids not be dispensed without an examination by a hearing professional, in the absence of a suitable waiver. A hearing aid also may not be distributed until the consumer receives a “User Instructional Brochure” that stresses the importance of physical evaluation by a qualified healthcare professional, and waivers are permitted only when the potential recipient has been informed of the importance of a professional examination “orally or in the predominant method of communication used during the sale.” 21 C.F.R. § 801.420(c); Gudhear Citizen Petition Response at 2; Etymotic Citizen Petition Response at 2. This User Instructional Brochure also provides important safety information to consumers. By endorsing PSAPs and OTC hearing aids, PCAST is recommending an approach which will mean consumers are less informed. Adopting PCAST’s recommendation would deprive consumers of essential health information.

ii. The PCAST Report Incorrectly Discusses Regulatory Status of Hearing Aids.

The PCAST Report erroneously characterizes (at 6) most hearing aids as being Class I devices, the lowest risk level for medical devices, and then recommends that hearing aids be deregulated accordingly. However, under FDA regulations in effect for four years, 82 percent of the hearing aids currently sold in the U.S. are Class II devices,

i.e., moderate risk devices. Significantly, FDA’s decision to create a new classification four years ago was spurred by technological progress: hearing aids that include wireless features. *See* 21 C.F.R. § 874.3305 (promulgated June 15, 2011). The fact that many hearing aids are regulated as Class II devices demonstrates that FDA has concluded that not all hearing aid features are innocuous. In fact, FDA required that these hearing aids need special controls.¹ *Id.* These controls are intended to minimize risks that FDA identified, such as ensuring that the hearing aids do not create undue risk of interference with other electromagnetic devices, such as pacemakers, or danger from non-ionizing radiation, that their “wireless technology functions” are supported by data showing proper design and performance, and that appropriate warnings relating to radiation and electromagnetic compatibility are included in labeling. *Id.* § 874.3305(b)(1)-(3). As medical devices – such as neurotransmitters, wireless insulin pumps and a growing host of others with wireless features – enter the market, hearing aid manufacturers must ensure that their products do not cause interference with these new medical technologies. Thus, deregulation of hearing aids poses a potential threat to the safe use of other medical products.

The PCAST Report wants to unleash technological change in hearing aids, but without external oversight or controls. It never considers what risks these changes might bring, or how those risks will be managed.² Consequently, the recommendation by PCAST that hearing aids should be available for purchase as OTC products is not supportable from a regulatory perspective, and is contrary to the well-being of consumers.

iii. Intended Use Is Critical to FDA Designation of Medical Devices.

The PCAST Report treats FDA’s distinction between PSAPs and hearing aids – based on intended use – as an “artificial distinction.” PCAST Report at 7. But, in fact, “intended use” is a bedrock principle of FDA regulations, and of the FDCA.

¹ Failing to conform with a special control applicable to a Class II device pursuant to 21 U.S.C. § 360c(a)(1)(B) causes a device to be adulterated. 21 U.S.C. § 351(e)(1), cross referencing 21 U.S.C. § 360d. It is unlawful to distribute an adulterated device in the U.S. 21 U.S.C. § 331(a). Failing to comply with a voluntary industry standard, as PCAST suggests, carries no penalties.

² The FDA has also developed guidelines to enhance cybersecurity of devices. FDA, Guidance for Industry and FDA Staff, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Oct. 2, 2014). These consumer protections would not apply to PSAPs intended to treat hearing loss, and if OTC hearing aids are deregulated, these guidelines presumably would not apply to them either.

The very definition of devices under FDA’s authorizing statute begins with looking at the intended use of the product. A device is defined as either a product recognized as a device in authoritative compendia or:

intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . or intended to affect the structure or any function of the body of man . . . which does not achieve its primary intended purposes through chemical action . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

FDCA § 201(h), 21 U.S.C. § 321(h) (emphasis added). Multiple federal courts have classified a product based on its intended use.³ The intended use of a product routinely drives whether and how that product is regulated. In its desire to encourage widespread PSAP use by lifting restrictions on promoting PSAPs for treating impaired hearing, the PCAST Report (at 7-8) undermines one of the fundamental principles of FDA law: a product’s regulatory classification is a function of intended use. For FDA to say that a product intended to treat a medical condition – hearing loss – is not a device would create a far-reaching precedent that would potentially affect the regulation of numerous other products.

iv. Over-the-Counter Classification of Hearing Aids Would Be Inappropriate.

PCAST correctly summarizes FDA standards and policy relating to when a device can be considered for OTC use (in the parlance of the FDCA, a device other than a “restricted” device). A device requires a prescription or order if, “because of its potentiality for harmful effect or the collateral measures necessary to its use,” FDA “determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.” 21 U.S.C. § 360j(e)(1). More specifically, a restricted device can be sold, distributed, or used only “upon the written or oral authorization of a practitioner licensed by law to administer or use such device” or “upon such other conditions as [FDA] may prescribe in such regulation.” *Id.*

Prescription devices are those that cannot and should not be used without direction from a qualified healthcare provider: prescription devices treat conditions not susceptible to diagnosis and treatment without oversight from a physician or other medical professional with prescription authority. OTC designation is only appropriate when conditions are capable of self-diagnosis and determination by a lay person of the

³ See, e.g., *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121-22 (2000); *United States v. Articles of Drug for Veterinary Use*, 50 F.3d 497, 500 (8th Cir. 1995).

appropriate method of using a medical device. PCAST cites no evidence that consumers could correctly determine when a hearing aid would be suitable for them. For a device to obtain OTC status, FDA requires the manufacturer to provide supporting data. The PCAST Report substitutes the belief that consumers can self-diagnose and self-treat for data.

In addition, PCAST urges FDA to designate as a distinct category non-surgical, air-conduction hearing aids intended to address bilateral, gradual onset, mild-to-moderate age-related hearing loss and adopt distinct rules for such devices. Since air-conduction hearing aids are used for people with all ranges of hearing loss, and fitted not according to the cause of the loss, but rather to the specific needs of the patient, it is impossible from a regulatory or technological standpoint to differentiate such products based on their status as an air-conduction hearing aid. It also cannot be assumed that, because a person is aging or elderly, a person's hearing loss is age-related. PCAST is essentially asking FDA to leave it to the consumer to self-diagnose three key elements: (1) whether they have a hearing loss; (2) the cause of the hearing loss; and (3) the severity of that hearing loss.

v. FDA's Policy on PSAPs Is Necessary and Appropriate to Protect the Public.

Catering to the widespread misunderstanding that hearing loss can be addressed simply by amplifying sounds, numerous consumer electronics manufacturers have widely offered – and, in some cases, illegally promoted⁴ – products that are worn either behind the ear or in the ear and amplify noise. These devices have been recognized by FDA as having some utility in limited situations (such as hunting or bird watching, where faint sounds made by animals can be magnified to sharpen human hearing). But FDA, using experts well-versed in the science and public health policy of treating hearing loss, has

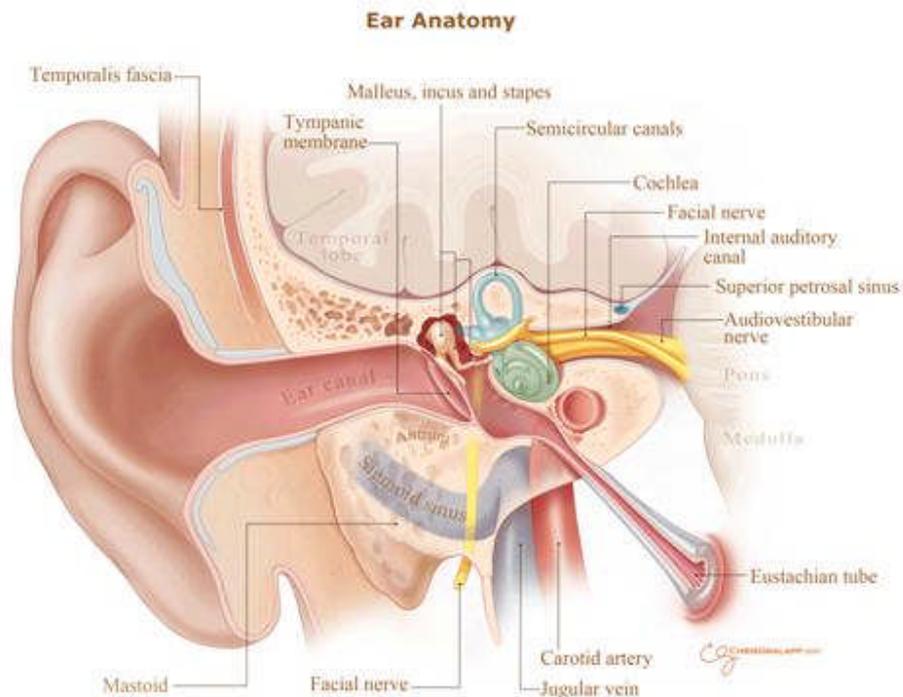
⁴ For instance, although FDA policy clearly exempts from regulatory oversight only those PSAPs which are not intended or promoted to treat hearing loss, multiple advertisers have made illegal claims for PSAPs, including that they are a lower-cost “alternative” to hearing aids (NeutronicEar®), that the Personal Sound Amplifier is a “highly affordable solution” for Americans with “impaired hearing” (Audiovox); that they are ideal if you “strain to hear conversations” or “ask others to repeat what they say” (Tweak Hearing); that the product is a “Personal Sound Amplifier, available only through hearing professionals” and that it is ideal if “it seems like a lot of people are mumbling” (Plaid); that “Personal Sound AMP” is “intended for anyone with mild to moderate hearing loss” (Able Planet); and featuring testimonials such as “I recommend trying these before shelling out for hearing aids” (Sound World Solutions). PCAST's recommendations would allow these – and even stronger medical claims where PSAPs are promoted as interchangeable with hearing aids – to be made for consumer products.

determined that these products are not appropriate for treating hearing loss. PSAPs are consumer products, not medical devices. As FDA has determined, PSAPs are largely ineffective in treating hearing loss, and may well result in frustrating purchasers. Consumers may decide after using an ineffective PSAP – especially one that is promoted as remediating impaired hearing – that nothing can help them hear better, and they may not seek hearing aids, which could actually alleviate their condition.

After thoroughly studying PSAPs, FDA – the agency with the most extensive knowledge of the use of medical devices in the U.S. – has refused to blur the lines between PSAPs and hearing aids. FDA policy has been thoroughly considered. Under FDA policy, products that are intended to treat hearing loss are hearing aids, regulations require the person to see a physician or sign an informed waiver, and hearing aids are required to comply with the general requirements governing medical devices, including, e.g., compliance with the QSR, and, in addition, are subject to specific requirements for labeling and sale discussed elsewhere. PSAPs, on the other hand, amplify noise, can be purchased directly by the consumer at retail locations or online, and are not controlled under any of the requirements that make and keep hearing aids safe and effective. PCAST wants to obliterate this distinction.

The reasons FDA came to these conclusions are based in part on the mechanics of hearing impairment, and the science of treating it. The PCAST Report glosses over the biology and physiology of hearing loss.

Hearing is a complex physiological process, much more so than vision. To properly perceive sound, the incoming signal must travel as sound waves through the external ear where it causes vibrations of the tympanic membrane. Vibrations of the tympanic membrane result in vibrations of a chain of bones in the middle ear leading to the vibration of the fluid inside the cochlea ultimately resulting in the stimulation of tens of thousands of sensory structures (hair cells) in the inner ear. Stimulation of the hair cells activates a series of neural events required for the transmission of nerve impulses to the brain, resulting in the perception of sound.



Brigham and Women's Hospital, Ear Infections and Disorders,
http://www.brighamandwomens.org/Departments_and_Services/surgery/services/otolaryngology/ear/ear-infections-and-conditions.aspx.

A variety of events can cause hearing impairment, including frequent exposure to excessive noise, genetic effects, viral and bacterial infections, structural malformation, foreign bodies, allergies, impacted cerumen, tumors, autoimmune disorders, trauma and aging. In many instances, some of the underlying causes of hearing loss are related directly to serious, chronic medical conditions, such as diabetes, kidney failure, and heart disease.

Because hearing is such a complex physiological process, the cause and consequences of hearing impairment can vary significantly from patient to patient. These conditions are not diagnosable by consumers. This variability between patients typically affects the perception of sound in one or more of the following ways:

1. Diminished audibility (the ability to hear soft sounds);
2. Diminished frequency resolution (the ability to perceive the difference between two different pitches);
3. Diminished temporal resolution (the ability to detect the timing of auditory events); or

4. Diminished loudness perception (a reduction in the range between the softest sound that can be heard and the loudest sound that can be tolerated).

Because abnormal auditory processing in any one or more of these factors may result in impaired perception of sound with significant consequences for communication, accurate diagnosis of the cause of impaired hearing requires an evaluation by a physician (preferably one specializing in diseases of the ear), or referral by a hearing professional to a physician after a physical examination of the ear. That hearing professional can then administer the appropriate battery of tests, select, fit, and program the hearing aid to address the person's specific hearing loss, and provide the necessary instruction, counseling, and after-fitting service to optimize the outcome of care.

In light of the above, PCAST's support for distributing "basic" hearing aids that are not tailored to individual patient needs and purchased without a proper hearing screening by a hearing professional takes a reductionist approach to the science of hearing. This lack of understanding is underscored by the fact that the PCAST Report describes the distinction between hearing aids and PSAPs as "artificial." Yet they are at the core of the differences between the underlying principles of operation.

PSAPs are intended to only amplify sounds. While increasing the volume of certain sounds may enable their detection, it will not permit the detection of sounds that are inaudible because of non-volume related reasons. In some respects, it is akin to using a megaphone to speak English slowly and clearly with a non-English speaker. It might result in the non-English speaker picking up a mono-syllabic word or two, but it will not result in full comprehension of the actual conversation if the listener does not understand English. Similarly, amplification with a PSAP may help a consumer perceive more sounds, but it will provide limited help in comprehension if the auditory problem is not related to volume.

Also, a hearing product that is not properly programmed for an individual can induce further damage, rather than ameliorating an existing hearing loss. Some PSAPs produce noise too loudly to be safely tolerated by the delicate ear structure for required proper hearing. A sampling of 27 PSAPs were tested in European laboratories, and were shown to generate sound as high as 120-135 decibels. AEA & EFHOH, *Paper on the potential risk of using "Personal Sound Amplification Products" PSAPs* (Dec. 2015) (attached as Exhibit 3). To illustrate the danger to consumers of such self-selected products, exposure to sounds above 85 decibels for eight or more hours is considered unsafe, while exposures at 110 decibels (the sound of a jackhammer) can cause damage in less than two minutes, and ambulance sirens, at 120 decibels, cause damage in under a minute, according to information posted on the Centers for Disease Control and Prevention website (CDC, Noise and Hearing Loss Prevention, <http://www.cdc.gov/niosh/topics/noise/noisemeter.html>). These high-volume PSAPs produce sounds comparable to firecrackers, which generate 125 decibels at the peak of

the explosion, presenting the risk of irreversible ear damage.⁵ With a PSAP that generates noise over 85 decibels, and potentially over 130 decibels, and that is not adjusted or fitted to the specific needs of a person with hearing loss, there is a real risk that hearing loss will actually be exacerbated, rather than alleviated. FDA regulations protect hearing aid users from harmful over-amplification. Under the PCAST Report, consumers with hearing loss who buy PSAPs will enjoy no such protection.

These concerns have been echoed by the European Federation of Hard of Hearing People (“EFHOH”) and the European Association of Hearing Aid Professionals (“AEA”). These organizations have urged the European Commission to ensure that PSAPs are strictly regulated under the risk management and general safety and performance requirements set out in Annex I and clinical evaluation section of the European Medical Device Regulation. Referring to PSAPs, the report says that, “[s]uch products have no medical purpose and can provide very high and dangerous sound levels;” and the difference between hearing aids and PSAPs is “decidedly unclear” to the public. EFHOH & AEA, *Paper in support of a proposed amendment to Annex XV – relative to Article 2(1) of the European Commission Proposal for a Regulation on medical devices*, 6 (Dec. 2015) (copy attached as Exhibit 4).

PCAST acknowledges such concerns by recommending that FDA participate with the consumer electronics companies that manufacture PSAPs to develop a PSAP standard. Since PSAPs are not devices, however, FDA has no statutory authority for participating in the writing, recognizing, or enforcing of standards. Ultimately, any standard would be toothless because PSAPs are not within the scope of FDA's regulatory authority.

Voluntary PSAP standards have already been suggested as a solution to this problem. The Consumer Electronics Association (“CEA,” now called the Consumer Technology Association) discussed ongoing efforts to develop a Voluntary Standard for PSAPs (ANSI/CEA-2051) at a recent Institute of Medicine Meeting, noting that such a standard would enable consumers to identify low-quality “junk” PSAPs that are widely available on the market today. Such a proposal, however, would do nothing to address the fact that PSAPs are a consumer product that is not regulated by FDA in any way. Moreover, even if a Voluntary PSAP Standard were developed, it could be ignored without regulatory consequence by any PSAP manufacturer. In addition, PCAST does not condition its recommendation of the use of PSAPs for hearing loss on the existence of a voluntary standard. Under PCAST’s approach, PSAPs could be marketed as substitutes for hearing aids for the hearing impaired even if no voluntary standard is ever adopted.

⁵ See Better Hearing Institute, 6 Easy Tips for Protecting Your Hearing This Summer (June 26, 2015), <http://www.betterhearing.org/news/6-easy-tips-protecting-your-hearing-summer>.

In addition, a Voluntary PSAP Standard could not possibly reach a level of universal public awareness. Nor could it match the consumer protections provided by mandatory FDA device standards which are applied to all hearing aids. Furthermore, a Voluntary PSAP Standard would do nothing to address the critical concerns related to the detection of “red flag conditions” by a hearing professional.

If the availability of PSAPs – and their promotional claims – is expanded as proposed by PCAST, consumers will lose other protections. In at least 28 states where 68 percent of Americans reside (including California, Texas, Florida, New York, Pennsylvania, Illinois, and Ohio), state law requires dispensers of hearing aids to accept returns of the hearing aids if users aren’t satisfied, and refund their money. In addition, hearing professionals in other states offer the same return guarantees, and most bundled hearing aid sales also include warranties and loss/damage policies from one to three years. If PSAPs become interchangeable with hearing aids, consumers would be at the mercy of the refund policy of retailers. Mandatory refund policies are for hearing aids, not consumer products. Ironically, in advocating access to PSAPs due to lower costs, the PCAST Report puts consumers in the majority of states at financial risk: they forfeit their statutory right to return products if dissatisfied.

vi. Summary of PCAST’s Recommendations.

PCAST proposes a new category of “basic” hearing aids, which PCAST defines as “non-surgical air-conduction devices intended to address bilateral, gradual-onset, mild-to-moderate age-related hearing loss.” PCAST Report at 5. PCAST’s “basic” hearing aids would be available OTC. There would be no requirement for a prescription from or examination by a healthcare professional. Also, they would be subject to either minimal or no regulation by FDA. (PCAST would exempt these products from QSRs; it is not clear if PCAST believes these devices should have to comply with any FDA requirements.) PCAST also requests that the FDA policy restricting promotion of PSAPs be jettisoned, *id.* at 7-8, deeming PSAPs to be substitutable for hearing aids.

PCAST justifies this laissez-faire approach in the belief that “inherent failure of the product to perform does not provide an increased health risk to the user.” *Id.* at 6. PCAST cites no evidence for this assertion. It is also wrong, as discussed elsewhere in this response. Instead, PCAST suggests that FDA permit manufacturers to follow voluntary standards developed “in conjunction with the [CEA],” the trade group for electronics manufacturers (including those who make PSAPs). *Id.* Thus, the PCAST Report endorses the use of standards crafted by the industry selling PSAPs.

Unlike FDA’s special and general controls that apply to hearing aids, these standards would have no enforcement mechanism. PCAST does not explain why it entrusts industry with writing new standards for itself or wants to discard existing standards developed by leading experts that have already been recognized by FDA. *See* 21 C.F.R. § 801.420(c)(4) (multiple standards governing hearing aids are promulgated by

the American National Standards Institute (“ANSI”).⁶ Overlooking the inherent shortcomings in self-administered hearing tests (discussed further below), PCAST also wants FDA to “approve for OTC sale, both in stores and on-line, tests appropriate to the self-fitting and adjustment . . . by the end user” of these “basic” hearing aids. PCAST Report at 8.

4. Widespread Distribution of Ineffective Devices Will Exacerbate – Rather than Ameliorate – The Serious Public Health Impacts of Hearing Impairment.

Distribution of PCAST’s proposed “basic” hearing aids, not tailored to individual patient needs and purchased without proper screening by a hearing professional – or expansion of the use of PSAPs – would threaten public health. Individuals may be able to determine whether they are experiencing hearing loss (or at least determine when they are not) through everyday experience and self-administration of a hearing screening, which is currently widely available online. But consumers are not capable of determining what hearing aid is appropriate for them, how it should be programmed to meet their hearing needs, or whether they need a hearing aid at all (since hearing loss may be due to easily treated conditions like excess cerumen, in addition to the dangerous conditions that can be overlooked if physical examinations are not conducted). Permitting prospective hearing aid customers to self-diagnose, to self-select hearing aids, to program the hearing aids without the intervention of a hearing professional, and to fit the hearing aid in their own ear without professional assistance, puts consumers at risk.

Many consumers would purchase OTC hearing aids that would fail to fully address their hearing loss, or that would mask an underlying condition. It cannot be assumed that someone would naturally proceed to visit a physician or a hearing professional to seek further help if their hearing were not fully restored by the OTC device. It is likely that many consumers will not recognize that the problem is with the specific device they have purchased or the fitting they selected – rather than with hearing aids in general. Having failed to improve their hearing, they may abandon any effort to treat their hearing loss, even though a properly fitted and adjusted hearing aid could help them.

5. Deregulated Hearing Aid Market in Japan Suffers from Low Consumer Adaptation and Satisfaction Rates.

Indeed, these factors may explain why unregulated hearing aids can result in low use of hearing aids by individuals afflicted with hearing loss. Japan allows residents to readily purchase hearing aids, without a professional examination, in a wide variety of

⁶ ANSI is a 97-year old non-profit organization with representatives from the government, non-profit organizations, companies, academia, and international bodies.

retail locations, such as electronics stores, jewelry stores, and over the Internet. The manufacture, distribution, and sale of hearing aids are fully deregulated in Japan. Yet only about 14 percent of the Japanese with hearing loss use a hearing aid, according to a 2012 survey of 15,000 people with hearing loss in Japan. This study was conducted using a similar format to the 2014 MarkeTrak survey in the U.S. which indicated that 30 percent of Americans with hearing loss used hearing aids in 2014.

In addition, information from the 2012 survey shows that only 36 percent of hearing aid users in Japan – who have access to all types of OTC hearing aids and consumer electronics (PSAPs) – were satisfied with their hearing aids. In comparison, 81 percent of users of hearing aids in the U.S. were satisfied. The absence of professional examination, fitting, programming, and follow-up is likely a major factor in the low user satisfaction rates in Japan. Notably, many of the reasons that Japanese gave for failing to use hearing aids they had purchased (discomfort, failure to work well in “noisy situations,” hearing aids “do not work”) are problems that are addressed through professional involvement in programming and fitting hearing aids, professional participation that PCAST states is unnecessary. A copy of the report on the 2012 survey is attached as Exhibit 5.

The PCAST Report assumes that providing American consumers unfettered access to PSAPs and OTC hearing aids will result in more treatment of hearing loss. This hope is belied by Japan’s experience. In Japan – a country where consumers have ready access to cutting edge technology – the deregulation of hearing aids has led to lower consumer satisfaction and lower adoption rates. Although touting the promise of “innovative new PSAPs” (PCAST Report at 7), PCAST never asks one of the key questions: What does the evidence show? Japan’s experience is a cautionary tale ignored by PCAST.

6. Study of OTC Sales in Hong Kong Corroborates Japanese Experience.

A 2015 study of hearing aid performance in Hong Kong, where low-cost OTC hearing aids are widely available, corroborates the Japanese experience. This study (<http://www.hindawi.com/journals/bmri/2015/827463>) was conducted by researchers at the University of Hong Kong and published by Biomed Research International. A prior study had indicated that most OTC devices were low-frequency-emphasis devices that are “unsuitable for elderly people with presbycusis, who were likely to be the major consumers of these products.” The goal of the new study was to determine whether these results were still valid given the dramatic advances in hearing aid technology during this period of time. The earlier study raised technical performance issues related to input-output characteristics, frequency response, equivalent input noise, harmonic distortion, and acoustic feedback.

In spite of the fact that hearing technology overall has leapt forward in the past 14 years, the 2015 study of OTC hearing aids concluded that “the electroacoustic characteristics of the selected, current generation OTC hearing aids are similar to those in previous studies over the past decades. There is no major improvement shown in the

performance of OTC hearing aids over the years. All were linear hearing aids with less than optimal volume controls. Most of them showed unacceptable electroacoustic performance, such as sharp peaks in the high frequency region of frequency response, low HFA [high frequency average] gain, poor amplification in high frequencies, and/or high EIN [equivalent input noise].”

The study authors note that “although conventional hearing aids are more expensive than OTC hearing aids, the benefits brought by conventional hearing aids may far outweigh their cost.” The report also notes that “the inadequate performance of such OTC hearing aids may cause wearers to decline to adopt hearing aid use,” which echoes the Japanese OTC experience as described above.

The PCAST Report assumes that new technology, by itself, can lead to favorable outcomes for patients with hearing loss who use OTC hearing aids or PSAPs. The data belie this expectation. Eliminating professional exams, fittings, and adjustments of hearing aids will almost certainly lower the up-front cost to the consumer, but the experience in Japan and Hong Kong demonstrates that people with hearing loss in those countries do not benefit from adopting the unregulated hearing health model. Such a model should not be imported into the U.S.

7. Self-Administered Hearing Tests Are Neither Valid nor Reliable.

PCAST recognizes that some type of hearing test is needed. PCAST Report at 5, 8, 9. Yet, self-administered hearing tests – like those recommended by PCAST – simply have not been shown to be valid or reliable to provide specifications for the programming of hearing aids. For example, hi HealthInnovations, a provider of hearing aids, offered an online self-administered hearing test on their website in 2011, from which consumers were urged to test their own hearing and order hearing aids online. The hearing test, effectively an audiometer, was removed from the website in 2012 after the company could not demonstrate to FDA that the device complied with FDA’s 510(k) requirements which ensure the safety and efficacy of medical devices. Letter from Steven Silverman, Director, Office of Compliance, CDRH, FDA, to Lisa Tseng, CEO, hi HealthInnovations (Mar. 28, 2012) (instructing hi HealthInnovations to remove hearing test from market) (attached as Exhibit 6). To date, the online audiometer has not been reintroduced to the market. In addition, research by independent audiologists of this online test found that the test incorrectly characterized multiple individuals as having impaired hearing even though they did not. When the same individuals took hearing tests administered by qualified healthcare professionals using calibrated equipment shortly before the online test, these individuals did not demonstrate impaired hearing. In a letter from the American Academy of Audiology and the Academy of Doctors of Audiology, the authors stated that “after taking the hearing test and hearing the softest sounds presented, we were ‘advised’ that we needed hearing devices for each ear, when in fact, normal hearing was previously determined by conventional audiometry, performed in a sound treated room.” Letter from Therese Walden & Bruce Vircks, Presidents, American Academy of

Audiology and Academy of Doctors of Audiology, to Lisa Tseng, CEO, hi HealthInnovations (Oct. 31, 2011) (attached as Exhibit 7). FDA forced the company in question to pull its self-test. Without FDA regulation, there will be no barrier to the sale of other flawed self-tests. Allowing the unregulated sale of self-hearing tests will predictably result in erroneous results. This will inevitably mean consumers will receive hearing loss products that do not help them and that could cause harm if programmed inappropriately, instead of fitted hearing aids that would help.

Online or other self-administered hearing tests should be offered only if they are properly validated. There are hundreds of models of headphones, earphones, earbuds, and headsets that are compatible with the numerous desktop computers, laptops, tablet computers, smart phones, and other devices that can be used to access an online hearing test. As a science-based entity, PCAST is undoubtedly aware of the need to ensure that a key diagnostic test would work in a variety of settings. Yet PCAST never addresses this pivotal issue. The widespread, unregulated use of self-administered tests will inevitably result in erroneous outcomes and poor results.

Hearing loss evaluation by trained professionals working in a controlled environment with calibrated equipment has a demonstrated track record. A “one-size-fits-all” online test has not yet been introduced, and it is not clear when – or if – such a product would be introduced. It is baffling that PCAST would recommend self-fitting of OTC hearing aids (or PSAPs) without ensuring that the prerequisite diagnostic tools can be developed and cleared for use through the 510(k) review process, or, at a minimum, design controls.

Online hearing tests that are self-administered can be a useful tool in identifying whether test subjects have experienced hearing loss, and they are used for that purpose. However, self-administered hearing tests are useful only in screening whether individuals have impaired hearing, and those tests (contrary to PCAST’s erroneous assumption) are already available online (for example, a screening test is available at no cost from the Better Hearing Institute, <http://www.betterhearing.org/check-your-hearing>). The utility of these tests, though, should not be overestimated. They cannot serve as the basis, without professional examination and consultation, for selecting or programming a hearing aid appropriate for a particular individual with hearing loss.

8. FDA Oversight of Hearing Aids Is Critical.

PCAST agrees that even the “basic” hearing aids that it proposes are medical devices. PCAST Report at 5 (“‘basic’ hearing aids,” like “reading glasses,” are “classified as ‘medical devices’”). But, inconsistently, PCAST laments that QSR regulations are applied to hearing aids, saying those requirements are more stringent than necessary. *Id.* at 6. Once again, PCAST provides no support for this assertion. PCAST does not explain how quality will be maintained if “basic hearing aid” manufacturers can forego controlling their designs, performing product release testing, reviewing complaints, or taking other basic quality steps.

As shown by the dozens of Warning Letters issued annually by FDA to device manufacturers, these regulations are vital to protecting against design and manufacturing flaws. Notably, hearing aid manufacturers have had an excellent record of complying with QSRs. PCAST's Report does not consider what would happen to product quality if new hearing aid manufacturers were exempted from QSRs and other FDA requirements.

PCAST bases its case against the application of QSRs to hearing aids on an argument that QSR "fundamentally conflicts with the nature of the consumer-electronics industry," with its emphasis on "fast innovation cycles for both design and manufacturing processes." *Id.* Of course, hearing aids are devices under applicable law. There is no exemption under the FDCA for devices because they are also considered consumer-electronic products. Nor is there an exemption based on the pace of innovation.

Moreover, air-conduction hearing aids, as PCAST correctly notes in its Report, are exempt from the clearance requirements applicable to most medical devices. PCAST does not explain why QSR compliance and "fast innovation" are incompatible. If the pace of innovation is so fast that it precludes ensuring that suppliers are suitable, 21 C.F.R. Part 820, or that equipment is calibrated, or that labeling is properly controlled, then product quality is in jeopardy. PCAST apparently would elevate innovation above quality. The experience of HIA's members shows this is a false dichotomy: consumers can receive both high quality and innovation.

As noted earlier, FDA placed wireless hearing aids in Class II because they represented a new technology that FDA believed potentially raised new risks. The PCAST Report ignores the possibility that new technologies in unregulated hearing aids can result in harm to consumers.⁷ Although not acknowledged by PCAST, the uncontrolled, unrestricted introduction of new technologies to treat hearing loss can present risks.

9. PCAST's Proposed Labeling is Unintelligible and Unusable.

As noted above, PCAST's recommendation completely discounts the safety concerns expressed by FDA in rejecting OTC hearing aids. Yet there is another fundamental problem: PCAST proposes an unworkable intended use population for OTC hearing aids. The definition in the PCAST Report of the basic hearing aid is that they are "non-surgical air-conduction devices intended to address bilateral, gradual onset, mild-to-

⁷ Innovation can present risks. A very recent report by FDA about new laboratory tests states that these new tests may cause harm to patients. *See* FDA, Office of the Commissioner, Office of Public Health Strategy and Analysis, The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies, (Nov. 16, 2015), <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM472777.pdf>.

moderate age-related hearing loss.” PCAST Report at 5. PCAST apparently makes this proposal since there is no way to technically distinguish “basic” hearing aids from other hearing aids, since nearly all hearing aids are air-conduction devices, including those used by people with a wide range of hearing loss from mild to severe. Other devices, such as cochlear implants or Auditory Osseointegrated Implants, are required for more severe or profound hearing loss. Thus, PCAST would rely on consumers to self-diagnose and evaluate whether their hearing loss level met the standard for OTC purchase. Yet, this definition is too complex for most consumers to understand. For example, the word “bilateral” is surely confusing to the average American. It is also difficult to apply. How will patients know whether their hearing loss is “mild-to-moderate” without the benefit of a properly administered hearing examination? There is no comparator an individual patient can use. How will patients know that their hearing loss is “age-related” without determination by a professional that it is not due to other causes? Simply because an individual is aging or elderly, it should not be assumed that his or her hearing loss is “age-related.” Indeed, why stop with mild-to-moderate? The rationale set forth by PCAST could extend to severe hearing loss as well.

Before a new type of device can be sold OTC, FDA requires a manufacturer to supply data showing that the medical condition can be self-determined by consumers and they can follow the relevant directions. *See* 21 U.S.C. § 360j(e)(1). Device manufacturers must supply studies using untrained consumers. PCAST dispenses with all data, and simply expects consumers to be able to understand and apply a complex definition and instructions.

10. PCAST’s Analogy to Over-the-Counter Eyeglasses Is Seriously Flawed.

PCAST claims that the distribution and purchase of OTC hearing aids should be similar to OTC reading glasses, which are commonly available at pharmacies, grocery stores, big-box stores, and even convenience stores. PCAST Report at 5. In making this recommendation, PCAST ignores the fact that vision and hearing (and vision loss and hearing loss) are different physiological and pathophysiologic processes. Sensorineural hearing loss is similar to macular degeneration, in that both affect the sensory structures. It is not akin to presbyopia, which is routinely addressed by consumers using OTC reading glasses.

PCAST ignores the fact that, although reading glasses are generally available without a prescription, glasses to correct other vision defects do require a prescription. Most – if not all – eyeglass vendors (including such large chains as For Eyes) will not distribute eyeglasses correcting near-sightedness without a prescription within the last year from a vision professional (optometrist, ophthalmologist, or doctor of optometry).

The PCAST Report also overlooks several other critical differences between eye care and hearing loss remediation. First, many Americans routinely have their vision checked by professionals (perhaps because of the requirement of current vision prescriptions to order prescriptive eyeglass). These eye examinations generally include

checks for other medical conditions, including glaucoma, cataracts, and macular degeneration, which are identifiable by medical professionals. By way of comparison, very few Americans visit hearing professionals for routine hearing evaluations, except for those who need or wear hearing aids, and even these visits may be deemed unnecessary by consumers if OTC hearing aids or PSAPs for hearing loss become available. Statistics show that only 28.6 percent of adults in the U.S. (aged 20 to 69 years old) in the last five years had a hearing examination, whereas in the prior year (a much more restricted period) an estimated 61 percent of the U.S. adult population had an eye exam. *See* <http://www.healthypeople.gov/2020/topics-objectives/topic/hearing-and-other-sensory-or-communication-disorders/objectives>; https://www.mesvision.com/includes/pdf_Broker/MESVision%20Facts%20and%20Statistics.pdf

Second, the consequences of purchasing the wrong pair of OTC reading glasses are benign. Consumers can quickly try multiple strengths in the store to see if they seem to work. If someone purchases a pair of reading glasses that turns out to be inappropriate in correcting far-sightedness, the user will easily recognize that their vision has not been sufficiently corrected, no further harm to the person's vision will be caused, and the user will likely visit a vision professional to determine whether there is a better solution. In contrast, an individual with hearing loss who purchases an OTC hearing aid or PSAP (under PCAST's proposal) could damage their hearing further by increasing the volume to dangerous levels. Furthermore, the consumer may think that if the hearing aid/PSAP does not work, there are no alternatives that would remediate their hearing problems. In that situation, as discussed above, even a medical condition that is causing the hearing loss would not be recognized during the self-diagnosis process, and treatment may never be sought.

For these reasons and one additional reason, FDA has rejected the analogy PCAST draws between OTC hearing aids and OTC reading glasses. Dr. Eric Mann, the Clinical Deputy Director for FDA's section for Ophthalmic and Ear, Nose, and Throat Devices (part of CDRH) noted in a 2014 speech that, in addition to not providing any benefit for more serious vision problems, reading glasses do not mask any more serious vision problems (like glaucoma, cataracts, or macular degeneration). However, Dr. Mann noted, PSAPs – and, for that matter, OTC hearing aids – could mask more serious conditions. An apparent improvement in hearing could cause the consumer to skip or

delay the intervention necessary to address serious underlying conditions. Thus, PCAST accepts an analogy that FDA itself has found flawed.⁸ The presentation of Dr. Mann is attached as Exhibit 8.

There is yet another distinction. Eyeglasses rely on a stable, mature technology. The eyeglasses sold today do not fundamentally differ from those sold centuries ago. As noted above, hearing aids have undergone dramatic changes in the past decade and more innovation is forthcoming. This large, increasing technological gap between simple, stable eyeglasses and complex, evolving hearing aids is another reason why the analogy is inapt.

PCAST challenges that distinction between hearing aids and reading glasses by erroneously saying that glaucoma is an optical condition that could be masked by reading glasses, and arguing that any masking effect of a hearing aid on a red flag condition is no more dangerous to patients. PCAST Report at 5. However, the use of reading glasses does not mask glaucoma, or any other serious ophthalmological condition. Glaucoma does not cause farsightedness, and reading glasses will not cause people with glaucoma to ignore their condition. As glaucoma worsens, a person with glaucoma may notice his or her side vision gradually failing. *See* Mayo Clinic, Glaucoma: Symptoms, <http://www.mayoclinic.org/diseases-conditions/glaucoma/basics/symptoms/CON-20024042>. That is, objects in front may still be seen clearly, but objects to the side may be missed, with or without reading glasses. Glasses do not cover up this condition. Conversely, Dr. Mann, an FDA expert on ophthalmic devices, has noted that hearing aids or PSAPs can mask serious conditions in the absence of a medical examination.

11. Lower-Cost Hearing Aids Are Already Available in the United States.

The PCAST Report (at 1) claims that the “market for hearing aids is characterized by high cost,” and states that a “2014 [sic] survey found that the average price of one hearing aid was \$2,363, with premium models costing \$2,898.”⁹ However, the Consumer Reports Hearing Aid Buying Guide as updated in September 2015 reports that consumers can expect to pay \$500 to \$3,000 for a custom-fitted hearing aid (or \$1,000 to \$6,000 for a **pair**), which is a far more realistic analysis, showing the broad range of options.

⁸ While eyeglasses are OTC devices, they are subject to an FDA regulation to ensure that lenses are impact resistant. 21 C.F.R. § 801.410. FDA determined that consumers needed protection “from the shattering of ordinary crown glass lenses.” *Id.* § 801.410(a). PCAST’s recommendation would mean purchasers of eyeglasses have a higher level of product-specific protection than consumers who buy hearing loss products.

⁹ The very title of the survey, as indicated in the relevant PCAST footnote, shows that it was a “2013 hearing aid dispenser survey.”

The Hearing Review survey referenced by PCAST opens with the statement that “[p]rices of hearing instruments are either flat or declining, binaural fittings have continued to increase in popularity, and low-cost hearing aid options are starting to make their way into the armamentarium of devices that dispensing professionals offer.” Karl Strom, *HR 2013 Hearing Aid Dispenser Survey: Dispensing in the Age of Internet and Big Box Retailers*, Hearing Review (Apr. 8, 2014), <http://www.hearingreview.com/2014/04/hr-2013-hearing-aid-dispenser-survey-dispensing-age-internet-big-box-retailers-comparison-present-past-key-business-indicators-dispensing-offices/>. It, furthermore, notes that “a picture emerges of an industry that is witnessing some major changes in response to new technology being offered by hearing aid manufacturers, the Internet and Big Box retailers, pricing pressure exerted from forces both within and outside the traditional hearing industry, and the demands of the aging Baby Boomer generation.” *Id.*

This is hardly the dire picture painted by the PCAST Report. This survey was conducted of 179 hearing care professionals in 42 states, which are “probably disproportionately weighted to independent practice owners” as a result of how the survey list was developed. *Id.* The article further reports that “this price would be considerably lower if the percentage of premium products dispensed, as reported by dispensers in this survey, was lower and more in line with the aforementioned estimates by manufacturing executives.” *Id.*

Additionally, more than 65 percent of the cost of providing hearing aids is associated with the patient testing and customization of the hearing aid to achieve optimal performance (conducting the hearing test, fitting the hearing aid correctly to the patient’s ear, programming algorithms to properly address spatial location of sounds to be emphasized, and all necessary follow-up treatment), rather than simply the cost of the device. As stated above, these services are essential to achieving the best outcome for patients.

Moreover, once again the PCAST report provides an incomplete picture: fully 10 percent of hearing aids purchased in the U.S. are now bought at so-called “big box” stores like Costco, Sam’s Club, and BJ’s Wholesale. These hearing aids cost as little as \$500, including diagnosis, fitting, and follow-up care to hearing aid users by hearing professionals. These new “disruptive” distribution channels have grown dramatically recently, making lower-cost hearing aids accessible to large numbers of Americans, and more growth is widely anticipated in this sector, which also includes recently announced pilot programs to provide hearing aids with professional fittings at CVS and Walgreens.

Further innovation is occurring with online distribution models such as HearingPlanet.com, Hear.com, Audicus.com, and EmbraceHearing.com, which provide Internet access to hearing aids without eliminating the essential services of a hearing professional. After an initial online or telephone consultation, consumers are directed to local hearing health professionals who conduct all necessary screenings and fit the proper

hearing aid and handle follow-up visits as needed. Such innovative access models are ignored by PCAST. FDA regulation and innovative distribution models are not incompatible.

The PCAST Report also misleadingly compares the cost of hearing aids to the cost of smartphones. Hundreds of millions of smartphones are distributed worldwide every year with very little variation in the manufacturing of the models available. In fact, Apple sold over 13 million iPhone 6S models in the first three days after launch in September 2015. Hearing aids, however, are used by a small fraction of the number of smartphone users worldwide, so the economies of scale available to manufacturers of smartphones are unavailable to hearing aid manufacturers. By comparison, the entire U.S. hearing aid industry sold a total of 3.1 million hearing aids, of all models to all markets, including the Department of Veterans Affairs, in 2014. And there are more than 300 different hearing aid models available on the market, providing a wide array of options for people with hearing loss. Moreover, hearing aids must be programmed to meet the hearing needs of each user, and must be custom fitted to the ears of the users for the vast majority of hearing aids. Despite these manufacturing and customization complexities, the retail cost of a new smartphone (now generally in the range of \$500 to \$600) such as the Samsung Galaxy is actually higher than sophisticated new hearing aids.

As big box and other “disruptive” options continue to grow in the hearing aid market (which includes evaluation, fitting, and follow-up by hearing professionals) the average cost of effective, customized hearing aids can be expected to drop still further. And it should be emphasized that these “disruptive” markets address cost concerns without eliminating the essential participation of a hearing healthcare professional in the process.

12. Innovation in Hearing Aid Design, Manufacture, and Distribution Has Been Robust.

The PCAST Report also denigrates the innovation achieved by hearing aid manufacturers as restricting innovation. PCAST partially blames market concentration. Given that there are two major operating systems for smartphones (iOS and Android) and that a handful of manufacturers dominate the U.S. market, it is difficult to understand how PCAST ascribes the purported lack of innovation in hearing aids to market concentration. The six global manufacturers of hearing aids have invested more than \$600 million annually, as noted above, in research and development. They collectively employ more than 6,000 engineers and scientists who work to develop sophisticated hearing aids and algorithms to process sound instantaneously, classify these sounds, and produce the highest level of audibility, sound quality, and spatial perception (i.e., localizing sound) that resembles natural hearing – all with minimal power consumption.

The work of these engineers and scientists has been ground-breaking. A few representative examples include wireless hearing aids; directional microphone technology, which compares sounds generated at different locations to increase clarity of

voices in front, to the side, or in back of a user while filtering out ambient noise; improved algorithms that can classify different situations (such as speech in noise, speech in music or even speech in a car), and reduce environmental background noise; direct wireless connections to smartphones, televisions, radios, laptops, and other Bluetooth devices; and digital technology eliminating feedback, a common problem until recently. Furthermore, and contrary to the implication in the PCAST Report that 3D printing technology would be something new in hearing aid manufacturing, such technology has been widely used for over a decade to make customized earmolds and hearing aids. In fact, some manufacturers provide scanners to hearing aid professionals to enable them to scan impressions directly for attachment to digital orders. Hearing aid manufacturers were early adapters of this technology,¹⁰ as well as wireless and other technologies.

13. PCAST Report Makes Numerous Errors Regarding State of Technology in Hearing Aid Market.

While HIA welcomes constructive recommendations related to hearing healthcare in the U.S., we believe the PCAST Report is based on fundamental misunderstandings of healthcare policy and regulatory law as outlined above. Beyond that, the PCAST Report fails to recognize that the hearing aid industry is on the cutting edge of technological advancement. The Report favors PSAPs, which it refers to as “fashionably designed as ‘bling’ in bright or metallic colors” over what it disparagingly refers to as “beige plastic hearing aids,” erroneously implying that no innovation has occurred in this sector. PCAST Report at 7. The reference to fashionable colors as a feature unique to PSAPs exhibits a failure to do thorough research into the hearing aid industry. Hearing aids in multiple colors and exotic patterns (such as zebra stripes) have been available for years in the hearing aid market. This is perhaps understandable since PCAST’s focus is on Science and Technology, not healthcare policy or medical device regulation; however, these errors are noteworthy as they appear to color PCAST’s recommendations.

PCAST ventures far from its core mission in offering its opinions about health policy on hearing aids, where the most relevant concerns are not grounded in science and technology.

- PCAST wrongly says hearing aids are Class I devices, when the majority are Class II;
- PCAST inaccurately claims that “inherent failure” of hearing aids “to perform does not provide an increased health risk to the user;”

¹⁰ Rhiannon Hoyle, *How 3-D Printing May Give Miners a New Dimension*, Wall Street J. (Nov. 11, 2015), <http://www.wsj.com/articles/how-3-d-printing-may-give-miners-a-new-dimension-1447275665>.

- Innovations in the design and manufacture of hearing aids (including 3D printing of hearing aids to better fit patients' ears) have been in place in the hearing aid manufacturing process for many years;
- Hearing tests to screen for impaired hearing are already widely available;
- Bluetooth capability is an option already available for many hearing aids, as are other similar wireless features;
- Due to directional microphone technology and programmable algorithms, “noise source identification and cancellation” and “speech localization and recognition” (as stated in the PCAST Report) are already available; and
- Although the percentage of hearing aids purchased but not used in the U.S. is actually about three percent (according to the 2014 MarkeTrak report), the PCAST Report says (at 4) that percentage is “as many [sic] as 12 to 18 percent.”

The PCAST report also does not acknowledge – much less address – concerns about OTC hearing aids that have been repeatedly expressed over the last four decades. Most strikingly, PCAST never acknowledges FDA’s rejection of citizen petitions requesting OTC status. The implication is that FDA has not reconsidered and updated hearing aid regulations since they were issued in 1978. Yet, the OTC concept was rejected after evaluation in 2004, and the Class II designation was created for the vast majority of hearing aids in 2011.

14. HIA Supports Greater Consumer Choice.

For the reasons stated above, HIA believes that neither PSAPs nor basic OTC hearing aids are in the best interest of consumers. Yet HIA does agree with PCAST in its underlying objective of promoting access to hearing aids that will help people address their hearing loss. HIA believes the right way to do this is to reduce barriers to getting the right hearing aids by encouraging people with hearing loss to choose from a broad range of hearing healthcare professionals and types of settings. The hearing aid market has evolved dramatically, and further evolution benefitting the consumer is inevitable, yielding expanded competition and greater consumer choice. At the same time, this evolution must not encourage people to self-diagnose and self-treat their hearing loss.

The President and FDA both strongly support “personalized medicine.” Although that term is typically used in a different context, the sine qua non of personalized medicine is patient-specific diagnosis. The current regulatory model permits tailoring of hearing aids to meet the specific needs of each patient. OTC hearing aids and PSAPs do not, because there is no diagnosis or tailoring. Giving patients greater flexibility in obtaining diagnoses and appropriately fitted FDA-regulated hearing aids, as well as greater flexibility in where to purchase them, will enhance access without sacrificing quality.

Other organizations have noted in their comments similar problems with the PCAST recommendations. Although the PCAST Report says that patients could self-diagnose, the American Academy of Otolaryngology – Head and Neck Surgery (“AAO-HNS”) writes it is “an overstatement to conclude that patients/consumers could or would be able to self-diagnose, self-treat, and self-monitor their particular hearing loss.” The American Academy of Audiology (“AAA”) expressed strong reservations as well: “Thus, our perspective is that the creation of a class of hearing aid as an over-the-counter consumer electronic would further confuse the consumer.” The American Speech-Language-Hearing Association (“ASHA”) was even more emphatic: “ASHA has grave concerns about the recommendation for a new class of over-the-counter hearing aids for those with mild to moderate hearing loss. Such a recommendation could pose hearing risks to the consumer if the underlying cause is not properly tested and diagnosed by a hearing healthcare professional, and if the purchased device is not properly fitted for the consumer.” The Academy of Doctors of Audiology (“ADA”) echoed that point, concluding, “there is no mechanism to ensure consistent with PCAST recommendations that only patients with ‘bilateral, gradual onset, mild-to-moderate, age-related hearing loss’ will purchase and employ these devices.”

In sum, OTC hearing aids and PSAPs substituted for hearing aids will not result in better access to products that can help patients. Expanding the choice of prescribers and striking down barriers to purchasing hearing aids, however, can have a positive impact without putting patients at risk.

15. HIA Supports Dramatic New Focus on Hearing Health

HIA believes there are steps that only the government can take that will have a dramatic impact on the number of people who seek to treat their hearing loss. The U.S. Preventative Services Task Force (“USPSTF”) concluded in 2012 that “current evidence is insufficient to assess the balance of benefits and harms of screening for hearing loss in asymptomatic adults aged 50 or older.” Yet, there are already multiple studies on the connections between untreated hearing loss and depression, dementia and falls, and more are in the works. HIA believes that the government is in a position to coordinate and facilitate further studies that would provide the USPSTF with the evidence needed to change existing recommendations regarding the importance of hearing screenings. HIA also believes that government bodies such as the Institute of Medicine should highlight the need for a far greater focus on hearing health by the medical community, especially general practitioners and geriatricians.

There are many physicians who have focused attention on hearing loss, and helped their patients as a result. In addition, HIA believes that the federal government should launch a national public awareness campaign to encourage hearing checks and to inform the public that hearing loss is not a benign condition that can be ignored. Congress should enact a hearing aid tax credit that would offer a tax credit for hearing aids.

Government agencies, focused on science and evidence, can have a profound positive impact on physician and consumer behavior.

Conclusion

In summary, the PCAST report's recommendations regarding OTC hearing aids and the marketing of unregulated PSAPs to address hearing loss are profoundly flawed in multiple respects. For example, contrary to the PCAST Report:

(i) "Disruptive" forces are already having a major impact on the hearing aid market, without sacrificing the critical involvement of a hearing professional;

(ii) The hearing aid industry has made tremendous progress in the innovation of beneficial hearing aid technologies;

(iii) The regulation of hearing aids by FDA is a critically important mechanism for ensuring that individuals with hearing loss are adequately and appropriately treated and have access to high-quality devices; and

(iv) Unfettered access to unregulated hearing loss devices puts consumers at risk.

In conclusion, we believe that PCAST's recommendations – regarding OTC hearing aids, diminished regulatory oversight of hearing aids, loosening restrictions on the marketing of PSAPs, and unregulated self-administered hearing tests to determine how hearing aids should be programmed – should not be adopted. These recommendations would reduce the use of effective means of treating hearing loss and would endanger Americans with hearing loss. Japan, a technologically advanced nation, has deregulated hearing aids, and has a significantly lower rate of both hearing aid usage and consumer satisfaction. The U.S. should not follow that failed model.

From: [REDACTED]
Sent: Wednesday, December 16, 2015 10:42 AM
To: [REDACTED]
Subject: [Fwd: PCAST: A scientific alarm by Larry Summers; Developments: The Optimistic Case for Rapid Learning Economics]
Attachments: untitled-[1.2]; 2015.1209.GrowingCaseforRapidLearning.pdf; 2015.1120.Case forOptimism.RapidLearningEconomics.pdf

----- Original Message -----

Subject: PCAST: A scientific alarm by Larry Summers; Developments: The Optimistic Case for Rapid Learning Economics
From: "Lloyd Etheredge" <[REDACTED]>
Date: Thu, December 10, 2015 4:35 pm
To: [REDACTED]

Dear Co-Chairs Holdren and Lander, Vice-Chairs Press and Savitz, and Members of the President Obama's Council of Advisers on Science and Technology:

I enclose a discussion and a scientific alarm (in an Op Ed by Larry Summers). He discusses the probability, based on historical experience, that an economic recovery in the US and other nations will be derailed by a recession within two ($p=.5$) to three ($p=>.67$) years.

There is nothing, scientifically, that we can do to prevent this. My earlier communication ("The Optimistic Case for Rapid Learning

Economics") reviewed CBO data, comparing two year forecasts of government and about 50 Blue Chip forecasting models since 1976.

Summers agrees with CBO and the scientific consensus that current models and data systems do not have the variables that allow us, specifically, to predict, monitor, or prevent recessions in the US and other countries. Summers also is sounding the alarm that governments do not have the scientific models, data systems, and policy tools, in a changed world, to mitigate these recessions when they occur.

This unexpected scientific stagnation is falling between the stools in Washington. Whatever agency or Presidential advisers that you imagine are responsible for solving this problem, and briefing the President about the option for rapid learning, they do not recognize the scientific challenge in their job descriptions. CBO, and everybody else, for several decades, simply report that the models and the government's (legacy) data systems "are not good at turning points" and keep using them.

You might ask the NSF Director: I do not believe that she will disagree with any of the scientific points that Larry Summers makes.

This is important: I think you will agree that the President really should be briefed swiftly and candidly by John Holdren. Members of PCAST also have unique qualifications to understand the new data and machine-learning capabilities, being used by NIH, that can be deployed for a rapid learning economics system. A good rapid learning design will include international scientific cooperation and private partnerships.

As a second example of our national system-level scientific breakdown, I also forward an Op Ed by Nobelist Robert Shiller surveying competing theories of the response of financial markets to pending interest rate changes by the Fed. You might think, by now, that the Federal Reserve system, or NSF, or the CEA, or CBO, or the academic economics profession (etc.) would have recognized a responsibility to design wider data systems with the behavioral variables to test these competing theories and forecasts. Actually, no.

Earlier, I would have suggested lighting a fire under people (e.g., at NSF). Now, I am not sure that using current institutions will get us the answers in time. It's a problem that has to be addressed and solved at your level.

with my best wishes, Lloyd Etheredge

Dr. Lloyd S. Etheredge, Project Director - Government Learning Policy Sciences Center, Inc./o 7106 Bells Mill Rd. Bethesda, MD

20817(301)-365-5241 (o); URL ><http://www.policyscience.net>< The Policy Sciences Center is a public foundation that creates and develops knowledge and practice to advance human dignity. It was founded in 1948 in New Haven, CT by Harold Lasswell, Myres McDougal, and George Dession, members of the Yale faculty. Information about the Center, the Society of Policy Scientists and the Policy Sciences journal is available at >www.policyscience.org<.

From: Pamela Langford [REDACTED]
Sent: Friday, December 18, 2015 12:44 PM
To: [REDACTED]
Subject: Fwd: National Security Agency Signals Intelligence Electronic Brain Link Technology
Attachments: pcast_public_comments_march_2012.pdf

My name is Pamela Langford. (Please forward this email to the appropriate person(s): A Roswell, GA resident told me that prominent members in Roswell, Georgia use Computer Brain Interface technology to communicate with persons in which they are interested--a practice that allows them to talk to individuals without leaving evidence of the communication.

One woman says she has been tortured by pain in her organs. She went to the ER and there were no signs of damage to the organs. She said multiple people talk to her. One says he is the Mayor, another says she is the City Manager and the other said he is the Chief of Police. She has not seen these people in person so she is not able to confidently collaborate who they are. She can hear a voice communicating with her in her brain. She also said she saw a woman outside her window using a hand-held, which she believes was used to interface with her. This woman is not paralyzed; nor, does she have any defects. She says words came out of her mouth that she did not think. So she believes the hand-held device was used to type the words that she spoke. And, she says the person was telling her what she was thinking--as if the device was interfacing with the part of her brain that handles thoughts and sending the signals to the hand-held device so the user could read her thoughts. She said at one point it felt like someone used their fingers or hands to beat on the device sending signals to her brain; and, as a result, she felt thumping on her brain. After reading the attached document I found her testimony very compelling. This woman is a Federal Government contractor who travels to Washington, DC and other areas for business. If Roswell is "not" investigated--it is very possible that this problem will make its way up through the states to other areas. She was visiting Woolwich, New Jersey today (12/16/2015). And, from about 7:00 am - 1:30 pm she was tortured. She believes a device was used to send signals to her brain to make her feel pain in her left kidney and other organs. She became weak and called 911. She went to the emergency room to be treated. A CT Scan was performed; but evidence of damage to her organs was not found. Is it possible for an Agency to use stored satellite transmissions to determine if such technology was used in Woolwich, NJ on 12/16/2015? And, is it possible this technology is similar to the NSA technology discussed below.

The attached document has the following paragraph:

I found the report referenced in the Subject line of this email. It has the following excerpt, which made me believe Roswell, GA may be using a similar technology to torture and communicate with certain residents:

Visual memory can also be seen. RNM can send images direct to the visual cortex, bypassing the eyes and optic nerves. NSA operatives can use this to surreptitiously put images in a surveillance subject's brain while they are in R.E.M. sleep for brain-programming purposes. Individual citizens occasionally targeted for surveillance by independently operating NSA personnel NSA personnel can control the lives of hundreds of thousands of individuals in the U.S. by using the NSA's domestic intelligence network and cover businesses. The operations independently run by them can sometimes go beyond the bounds of law. Long-term control and sabotage of tens of thousands of unwitting citizens by NSA operatives is likely to happen. NSA Domint has the ability to covertly assassinate U.S. citizens or run covert psychological control operations to cause subjects to be diagnosed with ill mental health.

Pamela Langford

1/5/2016

PCAST & NIH's \$2 billion/year increase: This could be economics.

From: "Lloyd Etheredge" <[REDACTED]>
Subject: PCAST & NIH's \$2 billion/year increase: This could be economics.
Date: Sun, December 20, 2015 4:52 pm
To: [REDACTED]

Cc: [REDACTED]

Dear PCAST Co-chairs Holdren and Lander, Vice Chairs Press and Savitz, and PCAST Members:

I enclose a message from NIH Director Francis Collins concerning last week's funding increase of \$2 billion/year to support NIH's national/global rapid learning system for physical health.

This should inspire everybody. The new system-level design strategy works. There is bipartisan support.

- An added \$2 billion/year for new, inclusive G-20 data systems and rapid learning could be economics. Probably, securing these national and global benefits will require PCAST-level attention re stunning institutional breakdowns and effective system design.

best wishes for the holidays,
Lloyd E.

Begin forwarded message:

From: "NIH OLIB (NIH/OD)" <[REDACTED]>
Subject: STATEMENT ON THE FY2016 OMNIBUS BILL
Date: December 18, 2015 at 5:15:13 PM EST
To: [REDACTED]
Reply-To: "NIH OLIB (NIH/OD)" <[REDACTED]>

U.S. Department of Health and Human Services
NATIONAL INSTITUTES OF HEALTH NIH News
NIH Office of the Director (OD) <<http://www.nih.gov/institutes-nih/nih-office-director>>
For Immediate Release: Friday, December 18, 2015

[REDACTED]

STATEMENT ON THE FY2016 OMNIBUS BILL

Today, President Barack Obama signed into law the FY2016 Omnibus Bill, giving the National Institutes of Health a much needed boost of \$2 billion in our fiscal year 2016 budget. This is the most encouraging budget outcome in 12 years. As Director of NIH, I welcome this development with a deep sense of gratitude. I applaud the bipartisan support for NIH and biomedical research that made this possible, and want particularly to thank the leadership of the House and Senate. This increase comes at just the right time to take advantage of remarkable opportunities to improve human health, powered by dramatic advances in scientific knowledge and technological innovation.

It has taken a lot of effort on the part of many voices -- patients, advocates, scientists, our many colleagues in the public and private sectors -- to make the case for biomedical research. We are unified by the knowledge that there is no better investment to help accelerate the course of medical progress.

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

Michael, Jennifer

From: 김진우 <[REDACTED]>
Sent: Friday, December 25, 2015 12:02 AM
To: [REDACTED]
Cc: s [REDACTED]
Subject: Greetings from the Presidential Advisory Council on Science and Technology of Korea
Attachments: PCAST_Greetings_From PACST of Korea.pdf

Dear John P. Holdren and Erio Lander, Chairperson

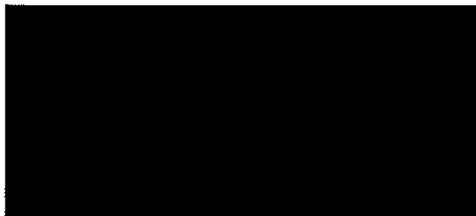
I am pleased to send greetings from the Vice Chairperson of the Presidential Advisory Council on Science and Technology (PACST) of Korea to you.

Please find attached the letter of greeting from the Vice Chairperson, the Chancellor Sung-chul Shin of DGIST, Korea.

Best Regards,

Jinwoo Kim

김진우 / Jinwoo Kim
과학기술기반팀장, 국가과학기술자문회의 지원단
미래창조과학부 서기관
Director, Presidential Advisory Council on Science & Technology



http://mail.msip.go.kr:80/jxmail/ko/jsp/mail/readCheck.jsp?read=ajwkim_send_mime_1451019719348_0< border=0 height=1 width=1>

Dear John P. Holdren and Eric Lander, Chairperson,

As the Vice Chairperson of the Presidential Advisory Council on Science and Technology (PACST) of Korea, it is my great pleasure to give greetings to you.

The PACST, which is chaired by the President of Korea, was founded in 1989 for the purpose of advising the President on future-oriented and emergent issues and policies that need to be addressed by the government. The PACST has been playing a pivotal role in supporting the President in formulating and implementing S&T policies to enhance national competitiveness.

As you know, Korea, an aid recipient just half a century ago, has transformed to a donor country and the world's 11th largest economy with its trade volume over one trillion dollars. This drastic and unprecedented development is often referred to as a miracle. This is mostly attributed to national strategies to further strengthen competitiveness in science and technology. For this reason, Korea is now acknowledged as one of the exemplary countries that has evolved from a primary industry-oriented nation into a technologically advanced one. Korea's scientific and technological capabilities have played integral roles in building the country as it is today, the 6th most advanced technological country in the world.

With ever increasing global competition, however, we still not only need to respond to new challenges and risks but also serve as a pioneer rather than a follower to make a great leap into a better future. The PACST helps to identify major national policy issues in the scientific and technological sector. Entering into the Park Geun-hye administration, the status and roles of the PACST have become more important than ever before in that S&T can lay the foundations in the course of Korea's soft landing into a developed country through creative economy.

To achieve this goal, the PACST sets its 2016 slogan as "**The S&T-based Job Creation Heading for the 21st Century.**" Under this motto, I set three ambitious strategies: '**Fostering Creative Talents,**' '**Reinforcing R&D Impacts,**' and '**Enhancing Collaborative Innovation.**' Regarding these issues, the PACST is conducting various activities of policy research and sectional meetings in addition to field visits more often to search for practical solutions.

Furthermore, I have a plan to hold a **Global Forum** by inviting the leaders and presidents of national councils or equivalent institutions that provide strategic advice on science, technology, and innovation to the highest public and private level in their countries of origin. The meeting will be proposed by the **PACST, governmental S&T related agencies, and international advisory council on S&T as a global network for mutual collaboration among peer institutions.** In this valuable forum, participants will present and discuss experiences, best practices and contributions of national councils to governments.

In this regard, I truly hope to have the opportunity to invite you, and to share your experience and expertise. There is no doubt that it will add great values for the national success of significant new initiative and leadership.

With the ambitious future vision based on S&T and hands-on experiences, the PACST will exert its utmost efforts as a mediator between the President and S&T fields.

We look forward to your continued support and meeting in the networking forums in the future.
Have great Christmas days and Happy New Year!

Warmest regards,
Sung-chul Shin
Vice Chairperson of the PACST



"The Stepping Stone for the Future of National S&T"

From: Daniel Fink [REDACTED]
Sent: Friday, January 01, 2016 8:44 AM
To: [REDACTED]
Subject: Fwd: Comments on: Aging America and Hearing Loss: Imperative of Improved Hearing Technologies

Dr. Holdren:

I forgot to mention two other important aspects related to noise and hearing loss.

1). Research done by Charles Liberman and colleagues at the Massachusetts Eye and Ear Infirmary (see [Hidden Hearing Loss from Everyday Noise - Scientific ...](#)) shows that there is no such thing as temporary auditory damage. All noise-induced auditory damage is permanent. The cumulative effect of too-loud noise is deafness in midlife to old age.

2). The “game changer” in the fight against too loud noise is the availability of free or inexpensive sound meter apps for smart phones. Research done at the National Institute of Occupational Safety and Health shows that these are almost as accurate as an OSHA-certified sound meter. (See [CDC - NIOSH Science Blog – So How Accurate Are These ...](#)). I would strongly encourage you and the entire PCAST staff to install these sound meter apps on your smart phones and then begin noticing how loud the world is. Although you really don’t need a sound meter to know how loud: if you can’t carry on a normal conversation, without straining to speak or to be heard, to someone about 3 feet away, the ambient noise level is above 70-75 decibels and you and the other person are sustaining permanent auditory damage.

Daniel

Daniel Fink MD

Begin forwarded message:

From: Daniel Fink [REDACTED]
Subject: Comments on: Aging America and Hearing Loss: Imperative of Improved Hearing Technologies
Date: January 1, 2016 at 4:44:05 AM PST
To: [REDACTED]
Cc: John Howard <[REDACTED]>

December 31, 2015

John P. Holden, Ph.D.
Director, Office of Science Technology and Policy
[REDACTED]

VIA EMAIL

Re: Comments on "Aging America and Hearing Loss: Imperative of Improved Hearing Technologies"

Dear Dr. Holden:

The report "Aging America and Hearing Loss: Imperative of Improved Hearing Technologies" has just come to my attention. I want to comment briefly to make two main points.

1. If there was mention of prevention of noise induced hearing loss in the report, I did not see it. This is a major omission.
2. There was no mention of the impact of a too-noisy environment on the ability of those with hearing loss to be able to understand conversation. Providing them with hearing aids will not help them much if they are trying to follow a conversation in a noisy environment.

I will cite a minimum of sources in this letter but can provide detailed references if needed.

PREVENTION OF NOISE INDUCED HEARING LOSS

The report documents the numbers of Americans, many of us older, with hearing loss. (see [Hearing Loss Prevalence in the United States](#)) (It does not mention millions of Americans with two other serious auditory disorders, tinnitus and/or hyperacusis. Noise induced hearing loss, tinnitus, and hyperacusis often occur together, with different features more prominent in different patients or in the same patient over time.) The overwhelming majority of those with hearing loss develop this from exposure to too loud noise, over a lifetime. There are other causes of hearing loss- ototoxic drugs, ear infections, genetic factors- but 90% of older persons with hearing loss develop this from noise exposure. (Noise induced hearing loss (NIHL) is so common in older Americans that it is considered normal- the terms presbycusis or age-related hearing loss are frequently used- and it may be "normal" in terms of being normative, but hearing loss is not part of the normal aging process. Studies of auditory acuity in primitive populations- the best known study is that of Rosen in the Mabaan population in the Sudan (I cannot find the link for that study but it is cited by Bergman ><http://archotol.jamanetwork.com/article.aspx?articleid=600299><)- find preservation of auditory acuity well into old age.) A Bushman in the Kalahari desert is reported to be able to hear an airplane 70 miles away.

The mantra of public health is that prevention of disease is both cheaper and more effective than treatment, and treatment is both cheaper and more effective than rehabilitation. (In technical terms, this is called primary prevention vs. secondary prevention vs. tertiary prevention.) Even with the exciting new technologies described in the report, people with noise induced hearing loss (NIHL) will not be made whole by better hearing aids. This unfortunately is true for two reasons: 1) Noise causes hearing loss by destroying the basic sense organ of sound, the hair cells in the Organ of Corti. Even with the best sound amplification technologies, delivering a higher amplitude wave to dead or damaged hair cells does not help hearing as much as providers of hearing aids or their users would like. Every primary care physician (I am a general internist) has had the experience of the patient getting the hearing aids but coming to the office with the hearing aids in pocket or purse. When asked, "Why aren't you using your hearing aids?", the patient replies, "Doc, I can hear things I couldn't hear before, but I still can't understand what someone is saying." This is because most NIHL is in the higher frequency ranges, where the consonant sounds (e.g., S F SH or V P T) so important to understanding speech are found. These

consonant sounds allow people to differentiate among words like Seer Fear Shear or Veer Peer Tear. Perhaps a good analogy is a visual problem. Lenses (eyeglasses or contact lenses) work because they are a mechanical or optical correction to an optical problem. The eye's cornea and native lens focus the visual image in front of or behind the retina. The optical correction focuses the image on the retina, and the user sees clearly. But hearing loss is akin to a retinal problem, e.g., macular degeneration or diabetic retinopathy. In those diseases, the basic sensory cell of vision, the rod or cone in the retina is destroyed. A better visual correction won't help. The logical equivalent of a hearing aid for a retinal problem is giving the patient a giant magnifying glass. Obviously, this doesn't work very well.

This is why prevention of NIHL is so important. There is an unrecognized epidemic of NIHL, with an apparent doubling of NIHL in 30 years.

(see <http://www.asha.org/public/hearing/Prevalence-and-Incidence-of-Hearing-Loss-in-Adults/>). This has occurred because the world has gotten noisier, with reports of noise levels of 80-100 dB or louder in restaurants (see [In New York City, Indoor Noise Goes Unabated - The New ...](#) or [For restaurant owners, striking the right noise level is key ...](#)), bars, clubs, gyms, ([Is your gym class making you deaf? - Daily Mail](#)), movie theaters ([Dangerously loud? Monitoring movie theater volume | KXAN ...](#)) and sports events (see [Loudest crowd roar at a sports stadium | Guinness World ...](#)). I note that this noise exposure at 141.2 decibels (dB) exceeded the maximum permitted occupational noise exposure in the United States of 140 dB), I think in large part this has occurred because of a misunderstanding of what a safe noise level is.

For more than 40 years, it has been known that the only safe noise exposure level is a 70 dB averaged over a 24 hour day. (see [Protective Noise Levels Condensed Version Of Epa Levels ...](#)) but this fact appears to have been forgotten. The National Institute on Deafness and Other Communication Disorders (NIDCD) website about Noise Induced Hearing Loss ([Hearing, Ear Infections, and Deafness](#)) states:

"Sound is measured in units called decibels. Sounds of less than 75 decibels, even after long exposure, are unlikely to cause hearing loss. However, long or repeated exposure to sounds at or above 85 decibels can cause hearing loss. The louder the sound, the shorter the amount of time it takes for NIHL to happen."

85 dB is an occupational noise exposure standard (see [Criteria for a Recommended Standard: Occupational Noise ...](#)). Unfortunately, due to statements like that from NIDCD quoted above, the safe noise level has been misunderstood and an occupational noise standard has been misapplied to the general public. (I note that I can find no supporting evidence for 75 dB to be a safe noise exposure level, and have written to NIDCD asking them for the source of this statement. Due to the logarithmic nature of the decibel (dB) scale, 75 dB is five times louder than 70 dB.)

There are several problems with this misapplication:

1. Workers, implicitly and sometimes explicitly (police, fire, military) accept risks that the general public is not exposed to, such as working with sharp tools or dangerous machinery or toxic substances or a hostile public. The public does not voluntarily accept such risks.
2. The occupational noise exposure standard is a compromise between employer needs and worker safety. At 85 dB, 16% of workers will suffer hearing loss over a 40 year career. This level of risk is unacceptable for the general public.

3. The occupational noise exposure standard is for an 8 hour day, for a 250 day work year, for a 40 year career. The public is exposed to noise for 24 hours a day, for 365 days a year, for a 78 year average life span. The Environmental Protection Agency (EPA) (see Appendix C in Information on Levels of Environmental Noise Requisite to ...) did the calculations for a safe noise exposure level for the public, taking these and other factors into consideration, and came up with the 70 dB average noise exposure level. (This is a calculated value, starting with the 85 dB level. The actual calculation came to 71.2 but the EPA rounded it down to 70, for the stated reason of an extra margin of safety and perhaps for ease of use.)

But if you search online for “safe” earphones marketed for children (see, for example <http://purosound.com/> but there are many more) you will find the 85 dB standard used. If you search the terms “audiology” and “safe noise” (see Home, Community, and Recreational Noise - American ... for example), you will find 85 dB used as the safe noise level. I note that none of the sites I found using 85 dB as a safe noise exposure standard mention a time limit. This is not correct. It is obvious that many people, including audiologists, think that 85 dB is a safe noise exposure level.

And I think that due to the innumeracy of the American public, most people (and perhaps even hearing professionals including physicians and audiologists) forget that the decibel scale is a logarithmic one, or if they know this, don't quite grasp what this means. So they think that 85 dB is only 21% louder than 70 dB, when in fact it is 1500% or 15 times louder, with 15 times as much ear-damaging sound energy. For reasons that I don't understand, 80 dB is perceived by the human ear as only twice as loud as 70 dB, but it contains twice as much ear-damaging sound energy.

(I have copied Dr. John Howard, the Director of the National Institute of Occupational Safety and Health, on this email in case you have any question about the occupational nature of the 85 dB noise exposure standard.)

The EPA noise levels document (Information on Levels of Environmental Noise Requisite to ...) mentions the Equal Energy Hypothesis in Appendix C, page C-11.. This hypothesis states that hearing loss is caused by the sum of all noise exposures multiplied by the time of each noise exposure over a lifetime. The general concept that what damages the auditory system is the sum of all noise exposures over a day or a year or a lifetime. I conceptualize this as noise exposure's effects on the ear are similar to sun exposure's effects on the skin. (This is not quite medically or scientifically correct. Noise causes the buildup of toxic products in the hair cells that damage or kill them. The ultraviolet light in the sun causes direct DNA damage in the chromosomes.) How skin looks in old age is the sum of all sun exposures, obviously with personal factors such as skin pigmentation factored in. Similar to sun exposure, where one tropical sunburn may have even worse effects than the actual ultraviolet exposure might indicate, very loud or impulsive noises may have a disproportionate impact on hearing.

How well older people hear is based on the sum of noise exposures over their lifetimes. To continue the analogy between noise exposure and sun exposure, the 15-fold difference between 70 dB and 85 dB is the difference between 15 minutes of sun exposure at midday to convert vitamin D to its active form, vs. 225 minutes of sun exposure. If people were misunderstanding the dermatologists' recommendation by the same margin that they are misinterpreting the safe noise level, there would be a lot more sunburn, wrinkles, age spots, and skin cancer.

I urge you and the President's Council of Advisors on Science and Technology to look into the issue of excess noise exposure for the public and to take the strongest possible stance that NOISE

CAUSES DEAFNESS. It is irresponsible not to do so. Again, the omission of prevention in the report is noticeable by its absence. I hope this will be addressed in future versions of the report, or in a correction or addendum.

THE IMPACT OF NOISY ENVIRONMENTS ON UNDERSTANDING CONVERSATION FOR PEOPLE WITH NORMAL HEARING AND FOR THOSE WITH HEARING LOSS

The report discusses hearing aids and new technology and making devices using the new technology available to the American public more easily and more cheaply. But another notable omission is the impact of a noisy environment on the ability of those with hearing loss, with or without hearing aids, to understand and to follow conversation. In a quiet environment, hearing aids work relatively well. In a noisy environment, much less so.

A too-noisy environment makes it difficult if not impossible even for those with normal auditory function to follow conversational speech. This was shown in Appendix D of the complete EPA 1974 report (Information on Levels of Environmental Noise Requisite to ...). I will copy the section including Figure D-1 below:

Indoor Speech Interference Due to Steady Noise

The effects of masking normally-voiced speech indoors are summarized in Figure D-1, which assumes the existence of a reverberant field in the room. This reverberant field is the result of reflections from the walls and other boundaries of the room. These reflections enhance speech sounds so that the decrease of speech level with distance found outdoors occurs only for spaces close to the talker indoors. At distances greater than 1.1 meters from the talker, the level of the speech is more or less constant throughout the room. The distance from the talker at which the level of the speech decreases to a constant level in the reverberant part of the room is a function of the acoustic absorption in the room. The greater the absorption, the greater the distance over which the speech will decrease and the lower the level in the reverberant field for a given vocal effort. The absorption in a home

Figure D-1. Normal Voice Sentence Intelligibility as a Function of the Steady Background Sound Level in an Indoor Situation D-1, D-2 & D-4

D-3

For the 48 million Americans, many of us older Americans, who suffer from auditory disabilities (partial hearing loss, tinnitus, and/or hyperacusis, in varying combinations) the impact of a noisy environment is even worse. We cannot follow conversations in noisy environments. Loud noise makes our tinnitus worse. For those of us with hyperacusis, loud noise is actually painful. The impact of noise on understanding conversation was studied in a 1993 study commissioned by the predecessor agency to the United States Access Board and done by Battelle Laboratories. I will send this report in a separate email but the cover page of the report is copied below. This study (done at the time when no-smoking areas were being proposed in restaurants, and the thought was that there would be quiet areas in restaurants for those with hearing problems) showed that those with hearing loss just can't follow conversations in noisy restaurants.

Unfortunately, partial hearing loss is not recognized by the federal government as a disability, despite the obvious fact that those of us with these auditory disabilities meet the definition of the Americans with Disabilities Act (ADA) for having a disability: "a person who has a physical or

mental impairment that substantially limits one or more major life activities.” There are no requirements that the environment be made quieter for us. There is no requirement for a reasonable accommodation to be made. And most often, the reasonable accommodation costs nothing: just turn down the volume of the music from rock concert levels to background music levels.

Those with partial hearing loss have no protection under ADA. When we can't go to a restaurant with our families because we can't follow the conversation; when we have to walk out of a store because the background music is turned up to rock concert volumes, making it painfully loud for us; or when we go home with our tinnitus worse because of noise exposure, we are being deprived of the ADA's legal guarantee that we have the “full enjoyment” of places of public accommodation within the definition of Title III of the ADA.

Another issue is that there are no standards for acceptable noise levels, or design features to assure acceptable noise levels, in indoor spaces (“places of public accommodation within the definition of Title III of the ADA”). A noise standard exists for classrooms (ANSI/ASA Standard 12.60) but not for other places. There are no federal standards or laws regulating indoor noise levels, and few local laws which are never enforced.

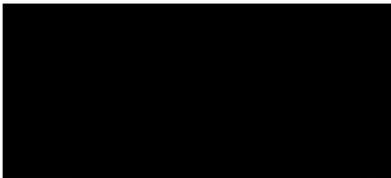
I urge you, the President's Council of Advisors on Science and Technology, and the president himself, to rethink the approach to noise in the United States, both in terms of prevention of NIHL, as well as the disability rights aspects of a too-noisy environment for those of us (again, most of us older Americans) who already have auditory disabilities. The noise and hearing issues in America are much greater than just making new hearing aid technologies available more cheaply. Even the best hearing aid won't function as well in a noisy environment as it will in a quieter one. I have much more to say on these issue, with correspondence and web links to support my statements, but I will stop now. Please do not hesitate to have someone from your staff contact me early in the new year. (Please note that I will be traveling out of the country from Jan. 2-9 and will have only limited internet access.)

Best wishes for a healthy, happy, and quiet New Year.

Sincerely,

Daniel

Daniel Fink MD



From: Daniel Fink
To: [REDACTED]
Cc: John Howard
Subject: Battelle Study: Quiet Areas in Restaurants
Date: Friday, January 01, 2016 7:47:12 AM
Attachments: Quiet Areas in Restaurants Final Report OA92004001.pdf

Dr. Holdren:

This is the PDF file containing the Battelle study, "Quiet Areas in Restaurants."

Please do not hesitate to contact me if you have any questions about this study, about noise causing deafness, or about noise making it difficult if not impossible for those with hearing loss, with or without the use of hearing aids, to follow conversations in noisy places.

Sincerely,

Daniel

Daniel Fink MD

[REDACTED]
Cell 510.200.0771

REPORT

FINAL REPORT

Quiet Areas in Restaurants

To

U.S. Architectural and Transportation

Barriers Compliance Board

43-

3832



December 1993

Final Report

Contract No. QA92004001

on

Quiet Areas in Restaurants

to

U.S. Architectural and Transportation Barriers Compliance Board

November, 1993

by

Ronald Moulder

 **Battelle**
... *Putting Technology To Work*
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Executive Summary

Under contract to the U.S. Architectural and Transportation Barriers Compliance Board (Access Board), Battelle conducted a program to develop guidelines for restaurants and cafeterias to provide quiet areas for hearing-impaired individuals. Public comment solicited in response to the Access Board's Notice of Proposed Rulemaking for the ADA Accessibility Guidelines for Buildings and Facilities yielded a significant number of comments concerning the need for "quiet areas" in restaurants so that hearing-impaired individuals could enjoy the experience of dining out. The commentors noted that noise levels and other characteristics of a restaurant affected the ability of hearing-impaired individuals to communicate effectively with persons sharing their table as well as servers.

The objective of this program was to develop guidelines for quiet areas in restaurants where hearing-impaired individuals could communicate effectively and enjoy the experience of dining out. To achieve this objective, a three task program was developed. Task 1 was a review of the literature on the speech communication problems of hearing-impaired individuals as it relates to the acoustical environment. Task 2 was field evaluations of the acoustical environment in various restaurants and cafeterias. Task 3 was the development of the guidelines for quiet areas in restaurants.

Over 21 million Americans have a hearing impairment. Over 24 percent of the individuals over 65 years old have a hearing impairment. Speech communication in a noisy and/or reverberant room is the number one complaint of hearing-impaired individuals. Hearing aids are effective only in relative quiet environments. They are ineffective in a noisy restaurant environment. A substantial amount of literature exists on the research done to date on speech communication by hearing-impaired individuals. This research shows that better speech communication by hearing-impaired individuals can be achieved by reducing the background noise levels and sound reverberation in restaurants.

Thirteen different restaurants and cafeterias were acoustically evaluated under this program. Limited menu and bars or taverns were not evaluated because it was felt that these types of restaurants were not visited by people to enjoy the experience of dining out. The noise levels in restaurants surveyed ranged from 55 to 68 dBA when averaged over a half hour time interval during the busiest time of the day. Most of the noise levels measured in the restaurants exceeded the human voice level of 58 dBA at 3 ft.

The average reverberation times in the restaurants evaluated ranged from 0.36 to 0.95 seconds, which are about average for rooms where good speech intelligibility is desired for people with no hearing impairment. However, for hearing-impaired individuals, reverberation times should range from 0.20 to 0.50 seconds. Based on the restaurant evaluations, most dining rooms are too noisy and reverberant for good speech communication by hearing-impaired individuals.

The proposed guidelines developed under this program recommend that the noise level in a dining room not exceed 58 dBA and that the reverberation time not exceed 0.50 seconds for average size dining rooms. These guidelines should permit about 20 to 30 percent of hearing impaired individuals to have good speech communication in a restaurant at a distance of 3 feet or less between talker and listener.

To achieve these guidelines, restaurants and cafeterias must use better sound absorbing materials and limit the number of customers in quiet area dining rooms. Both of these measures will lower dining room noise levels and reverberation and allow hearing-impaired individuals to have better speech communication while dining out.

The ceiling area in a dining room is the best location for sound absorbing materials. A ceiling is equal distance from everyone in a room. The standard types of ceilings used today in restaurants are not sufficient for controlling noise levels and reverberation. The standard ceilings need to be replaced with higher sound absorbing ceilings and in some cases supplemented with sound absorbing wall panels. Installing high sound absorbing ceilings and wall panels accomplishes two objectives. First, they reduce the overall noise level in a dining room and second, they reduce reverberation times, both of which are desirable.

To further reduce background noise levels in restaurants, the number of customers in a dining room must be limited. The major source of noise in a dining room is talking by customers. The number of customers recommended in a dining room depends on the type of customers (older adults or families), the amount of sound absorption present, and the reverberation time in the dining room. The seating density (i.e., the number of sq ft per person) should not be less than approximately 10 sq ft per person. Typical seating densities in quiet dining rooms should range from 15 to 30 sq ft per person.

It was the consensus of the volunteer Advisory Panel appointed for this program that the proposed guidelines were reasonable, achievable, and met the needs of hearing-impaired individuals. The Advisory Panel, which was appointed by Battelle with the approval of the Access Board, included architects, restaurant operators, acoustical consultants, speech and hearing educators, and an

individual from an organization that helps hearing-impaired individuals. Some members felt that all restaurants should fall under the proposed guidelines. Also, some members felt that a similar program should be initiated for all public areas and in particular for schools. Finally, some members felt that a demonstration project should be funded to document that the proposed guidelines do improve speech communication by hearing-impaired individuals in dining rooms.

Quiet Areas in Restaurants Advisory Panel

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Consensus Opinion of the Advisory Panel

To assist Battelle and the Access Board an Advisory Panel was appointed for this program. Originally, 8 members were appointed from a list of 12 potential members submitted by Battelle to the Access Board. A ninth member was appointed later as a representative from a manufacturer of acoustical materials. A list of the Advisory Panel members is in Attachment A. The Advisory Panel members were given a copy of all three task reports and asked to review the documents and submit their comments. Comments on the proposed guidelines were received from 8 out of the 9 panel members. Their comments and opinions are summarized below.

It was the consensus opinion of the members that the proposed guidelines met the objective of the program to develop guidelines for quiet areas in restaurants and cafeterias where hearing-impaired individuals could have improved speech communication so that they could enjoy the experience of dining out. A couple of members thought that the guidelines should be more stringent so that a larger percentage (i.e., larger than 20 to 30 percent) of hearing-impaired individuals would benefit from the proposed guidelines. However, the vast majority of the members felt that the guidelines were a good balance between the needs of hearing-impaired individuals and the cost and practicality of reducing restaurant background noise further. A panel member recommended that the proposed guidelines apply only to larger restaurants. Restaurants with 25 or fewer seats for example would be exempt from the guidelines. One member felt that all restaurants and cafeterias should be made to comply with the proposed guidelines. Another member asked what percentage of dining space must be set aside for a quiet area. Two members felt that the program should be increased in scope to include other public areas such as schools. Finally, two members stated that a program should be initiated to demonstrate the proposed guidelines can be achieved and do provide better speech communication for hearing-impaired individuals.

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Final Task Reports

- Task 1. Literature Review**
- Task 2. Acoustical Evaluation of Restaurants**
- Task 3. Proposed Guidelines**

Task 1. Literature Review

Final Report

on

**Speech Communication By Individuals
With a Hearing Impairment in the
Presence of High Ambient Noise and Reverberation
A Review of the Literature**

to

U.S. Architectural and Transportation Barriers Compliance Board

November, 1993

by

Ronald Moulder

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Speech Communication By Individuals With a Hearing Impairment in the Presence of High Ambient Noise and Reverberation - A Review of the Literature

Introduction

It is estimated that over 21 million Americans have a hearing impairment. This represents approximately 8.5 percent of the American population. For individuals over 65 years old, about 24 percent have a hearing impairment⁴³. Hearing impairment is the third most prevalent chronic disability for this age group. Because of the increasing noisy environment we work and play in and the increasing elderly population, the percentage of hearing-impaired individuals is increasing every year. Hearing loss is a major socioeconomic problem in this country today.

The major problem with individuals with hearing loss is speech communication. This problem is compounded when speech communication is attempted in a noisy and/or reverberate environment such as in a poorly designed or crowded restaurant. Understanding speech communication problems by the elderly with a hearing impairment is difficult because understanding speech communication problems by normal-hearing individuals is a complex process involving more than just hearing ability²¹. High frequency hearing loss and the accompanying loudness recruitment¹ accounts for much of the difficulty that hearing-impaired individuals have in understanding speech²². Hearing aids help speech communication in quiet, but are ineffective in noisy or reverberant environments³⁶. Reducing ambient noise levels and reverberation will do more to solving speech communication problems of hearing-impaired individuals than any other single solution.

Background

Before discussing the results of the literature search on speech communication by individuals with a hearing impairment, a short discussion on hearing loss or impairment is appropriate. Hearing

¹ Recruitment is the otological condition of the hearing impaired in which weak sounds are not heard while strong sounds are heard as loudly as by the normal ear.

loss for the most part is a gradual phenomenon. It usually occurs over a period of time and there are degrees or severity of hearing loss. The six classes of hearing impairment are⁸:

Class A (not significant)

Average hearing level (AHL) less than 25 dB (no difficulty with speech)

Class B (slight handicap)

AHL more than 25 dB but less than 40 dB (difficulty with faint speech)

Class C (mild handicap)

AHL more than 40 dB but less than 55 dB (frequent difficulty with normal speech)

Class D (marked handicap)

AHL more than 55 dB but less than 70 dB (frequent difficulty with loud speech)

Class E (severe handicap)

AHL more than 70 dB but less than 90 dB (can understand only shouted or amplified speech)

Class F (extreme handicap)

AHL greater than 90 dB (can not understand even amplified speech).

The hearing threshold level is the sound level in decibels required for the ear to first detect a sound at a particular frequency or pitch. The decibel (dB) is a unit used to express the intensity of a sound. The higher the level of sound the higher the decibel value. Normal conversational speech measured 3 feet from the talker is about 50 to 65 dB³⁵. The average hearing level (AHL) sound level is relative to that required for a person with no hearing loss. That is, a person with no hearing loss would have an AHL of 0 dB at all of the test frequencies. The test frequencies are 500, 1000, and 2000 hertz in the better ear. Most individuals have hearing loss at the middle and high frequencies (i.e., 1000 to 8000 Hz). The aging process alone can cause hearing loss, which is called presbycusis.

Speech is made up of vowel and consonant sounds. The speech frequency range is from approximately 200 - 2500 Hz. For the most part, vowel sounds provide the acoustical energy in speech and consonant sounds provide the information. Vowel sounds are usually low and middle frequency sounds and consonants are usually high frequency sounds and lower in level. Thus, a person with a hearing loss has difficulty hearing the consonant sounds. Therefore, speech intelligibility is reduced.

There are several systems used to predict speech intelligibility. The oldest and most prominent is the articulation index (AI). The AI is a rating scheme that goes from 0 to 1.0. The higher the AI

number the better the speech intelligibility. This rating scheme and others will be discussed later during the discussion of the results of the literature search.

Literature Search Results

As one would expect much research has been done in the area of hearing loss and speech communication. Research in the area of speech communication by people with a hearing impairment can be divided into five general categories. These categories are:

1. Speech communication problems of the hearing-impaired.
2. Speech intelligibility rating schemes both subjective and objective.
3. Speech intelligibility and hearing aids.
4. Speech intelligibility in the presence of various background noises.
5. Speech communication in reverberant environments.

The two areas where the most research has been done are rating schemes and speech intelligibility in the presence of background noise. The results of the literature search in each of these areas will be discussed separately.

Speech Communication Problems of Hearing-Impaired

A major question is whether the loss of speech intelligibility by hearing-impaired individuals is due to a loss in high frequency hearing, a loss in the ability to process the temporal structure of speech, or a combination of both factors. Speech sounds fluctuate in sound level (temporal structure). For good speech intelligibility it is important that an individual be able to track these fluctuations. Masking background sounds may also have a temporal structure that can interfere with temporal structure of speech. Studies have determined that both high frequency hearing loss and temporal resolution of speech sounds are important for good speech intelligibility by hearing-impaired individuals. Thus, a hearing aid with simple sound amplification is not a solution in itself for the hearing-impaired³⁷.

Speech Intelligibility Predicting or Rating Schemes

As mentioned earlier the most frequently used method for predicting or rating speech intelligibility is the articulation index (AI). Other schemes or systems are also used. They are:

- Speech Transmission Index (STI)
- Speech Reception Threshold (SRT)
- Speech Intelligibility Level (SIL).

Each of these schemes is discussed extensively in the literature. They will be briefly described in this report with a comment concerning their appropriateness to speech intelligibility by hearing-impaired individuals.

The articulation index (AI) was originally proposed in 1947 to measure telephone conversation intelligibility and has been standardized as an American National Standards Institute (ANSI) standard (ANSI Standard S3.5). Speech intelligibility is predicted from the weighted sum of the signal-to-noise ratios within specific frequency bands multiplied by a weighting factor for each band. The signal-to-noise ratio is the sound level difference in decibels between the speech sound and the background noise. The AI ranges from 0.0 to 1.0 with a higher number indicating better speech intelligibility. The AI has been used successfully for many years for individuals with normal hearing. It also does not assess the effects of unsteady noise or reverberation. Recent studies have indicated that it can be used with individuals with mild to moderate hearing loss²⁵. It, however, tends to overestimate the speech intelligibility of people with moderately severe to severe hearing loss. It also does not assess the effects of unsteady noise or reverberation. Recent studies have shown that modifications to the weighting factors used in calculating the AI could greatly improve its accuracy in predicting speech intelligibility by individuals with a hearing impairment^{32,33}. More research needs to be done to determine what the appropriate weighting factors should be.

The speech transmission index (STI) is a relative new rating scheme to predict speech intelligibility. It was originally proposed in 1985. The STI scheme or method is based on the characteristics of actual continuous speech. Continuous speech is first reduced to an amplitude-modulated speech spectrum. The basic requirement for good speech intelligibility is for a speech signal to pass through an acoustical environment with its original modulation (temporal structure) characteristics unchanged. The more a speech signal's modulation is changed the less it will be intelligible. The degree to which a room or sound system preserves the original modulation of speech

is therefore a good indicator of its suitability for good speech transmission. The STI is calculated from the measurement of modulated signals in a room at different frequency bands and the conversion of this information to equivalent signal-to-noise ratios, which are then summed, multiplied by weighting factors, and then averaged to produce a single STI rating number, which ranges from 0 to 1. The higher the STI value, the better the speech intelligibility. The original work done with STI did not include individuals with hearing impairments. Recent studies have shown that there are some problems using STI when hearing-impaired individuals are involved¹⁹. A modified version of STI (MSTI) has been proposed as the best alternative presently available. Again as with the AI more research needs to be done concerning the appropriate modifications to the STI so that it can be used for hearing-impaired individuals.

The speech reception threshold (SRT) is the sound pressure level of speech at which 50 percent of the speech is intelligible to a listener³⁶. Different meaningful sentences are used to determine the SRT of an individual. The SRT is a clinical tool used to determine speech intelligibility. Over a large range of values, the SRT for normal-hearing listeners depends only on the signal or speech-to-noise ratio. The SRT takes into account both external and internal ear noise. Tests have shown that in critical conditions even a difference of a few decibels in speech-to-noise ratios result in a large difference in understanding speech. A 1 dB increase in speech-to-noise ratio results in a 20 percent higher or better intelligibility score for sentences¹². Tests have also shown that for individuals with a hearing-impairment, noise levels higher than 50 to 60 dB(A) are a major problem in terms of speech intelligibility³⁶.

The speech intelligibility level (SIL) curves are a family of curves which give the quality of the speech intelligibility expressed as a percentage of correctly understood monosyllabic words or as a speech-to-noise ratio and the speaker's effort. Using the SIL curves one can establish maximum noise levels in a particular space in order to achieve verbal communication. For instance in restaurants, the maximum noise level for a normal voice conversation at six-foot distance between talker and listener is 48 dB. Speech intelligibility level curves were developed for normal-hearing individuals. It has not been proven that they are applicable to individuals with a hearing impairment. Research needs to be done to determine its applicability to hearing-impaired individuals.

Speech Intelligibility and Hearing Aids

Hearing aids have been used for many years to improve the hearing of individuals with a hearing loss. It has been shown that hearing aids do improve speech communication for some individuals. However, this improvement is marginal³⁷. One reason is that most hearing aids amplify both speech signals and the background noise equally. Thus, the important speech or signal-to-noise ratio is unchanged using a hearing aid. Another reason is that present hearing aids do not provide binaural hearing. Today new and more sophisticated hearing aids are being developed with advanced electronics that use directional microphones and sound filtering circuits. These new hearing aids filter out the noise that is below or above the speech frequencies. They also have automatic gain-control systems that boost low level sounds more than high level sounds.

Speech Intelligibility in the Presence of Various Background Noises

Very few conversations take place in an environment where there is no background noise. Thus, when determining speech intelligibility, background noise must be considered. There are many different types of background noise sources such as traffic, machinery, wind, birds, and other people's voices. Substantial research has been conducted to investigate the effects of these noise sources on speech intelligibility by hearing-impaired individuals. The critical parameter is the speech-to-noise ratio or in decibels how much higher or lower in level is the speech signal compared with the background noise level. Speech-to-noise ratios can range from negative values where the speech level is below the background noise to positive numbers where speech is higher in level than the background noise. Most positive speech-to-noise ratios range from 0 to 15 dB.

Research has found that in most cases speech intelligibility for normal-hearing individuals is affected less by fluctuating interfering noise, like speech, than by continuous noise³⁸. However, research conducted with hearing-impaired individuals have shown that competing speech is more disruptive than it is for normal-hearing individuals. Listeners with sensorineural hearing loss have an extra handicap in perceiving speech that is masked by competing speech²³. For groups with sensorineural hearing lost and different maximum discrimination scores, the effectiveness of the competing speech is 12 to 15 dB greater than for listeners with normal hearing.

Since fluctuating interfering noises are much more common in daily situations than steady-state

noises, the speech reception threshold for fluctuating interfering masking noises offers a better measure of speech communication for hearing-impaired listeners. Hearing loss for speech with increasing age is caused more by a deterioration in auditory processing than in the central processing of the speech signals by the brain. The location of the speaker relative to the listener and the direction of the masking also affects speech intelligibility. Best intelligibility is obtained when the speaker is in front of the listener and good illumination permits lip reading.

Speech Communication in Reverberant Environment

A reverberant sound field where there is very little sound absorption is the second most deleterious environment for hearing-impaired individuals^{14,26}. The first is a noisy environment. Thus, environments that contain both noise and reverberation are particularly troublesome to individuals with hearing impairments. Restaurants often are especially bad in this regard.

The reverberation in a room is determined by measuring the reverberation time. The reverberation time is the length of time in seconds that it takes for a sound to decay or die down by 60 dB. Reverberation time is measured by generating a sound level in a room and then turning off the sound source. As the sound in the room decays, the sound level is measured to obtain a rate of decay in dB per second. From the rate of decay, the reverberation time can be calculated. Reverberation times are measured at a set of particular test bands or frequencies such as 125, 250, 500, 1000, 2000 and 4000 Hz. Research has shown that for good speech intelligibility reverberation times should be less than 1 second³⁰.

Literature Search Data Base

The primary literature data base system searched was INSPEC. This data base contains over 4 million citations, with abstracts to the worldwide literature in physics, electronics and electrical engineering, computers and control, and information technology. This data base includes the field of acoustics. The two major publications from which literature was obtained were the Journal of the Acoustical Society of America and the Journal of Speech and Hearing Research. Once articles were obtained the references in these articles were used to further select references to review. Thus, there was a cascading effect. A few articles led to more articles which led to more articles.

The first search words used were "speech communication" or "intelligibility" and "hearing impaired." It was critical that the search be limited to information about hearing-impaired individuals. Searches were also conducted using words such as acoustics, noise, restaurants, and noise control. The initial searches went back in time to 1970. The bulk of the material reviewed came from references given in the first few articles received. Another source of articles was the Subject Index published by the Journal of the Acoustical Society of America. They have a subject index titled, "Speech Perception by hearing-impaired individuals."

The literature search process included first obtaining titles or brief abstracts of papers and articles. From this information the titles that were thought to be of interest were selected and a more detailed abstract was obtained. If an abstract appeared to be in the area of interest a copy of the actual article was obtained. Over 50 articles or papers were obtained and reviewed under this program. They are listed in the appendix of this report by author.

In addition to conducting a literature search the members of the advisory panel were contacted and requested to suggest any information or articles that they thought would be of some benefit. Some suggestions were received from the panel members. Suggestions were also received from Mr. David Lubman, the acoustical consultant working with Battelle on this program. Finally five associations active in the area of hearing-impaired individuals were contacted for any additional information they might have on speech communication by hearing-impaired individuals. These organizations were:

- National Association for Hearing and Speech Action
- American Speech-Language-Hearing Association
- American Auditory Society
- American Hearing Research Foundation
- Self Help for Hard of Hearing People.

Based on the extent of the literature that was searched and the articles received, we feel confident that a good review of the subject of speech communication by hearing-impaired individuals was conducted. If during the course of this program we learn of additional information that should be included in this report, it will be included in the final version of this report to be delivered at the end of this program.

Appendix

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Task 2. Acoustical Evaluation of Restaurants

Final Report

on

**Acoustical Evaluation of
Restaurant and Cafeteria
Dining Rooms**

to

U.S. Architectural and Transportation Barriers Compliance Board

November, 1993

by

Ronald Moulder

 **Battelle**
... *Putting Technology To Work*
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Acoustical Evaluation of Restaurant and Cafeteria Dining Rooms

Introduction

As part of the federally funded program on "Quiet Areas in Restaurants" acoustical measurements were made in several restaurant and cafeteria dining rooms. The purpose of these measurements was to quantify the acoustical environment in various types of restaurants. The results of these tests will be used in the development of recommendations to the U.S. Architectural and Transportation Barriers Compliance Board (USATBCB) to establish requirements for quiet areas in restaurants so that people with a hearing impairment can effectively communicate so that they can enjoy the dining out experience.

The types of restaurants to be surveyed were selected by Battelle with the approval of USATBCB. The key phrase in selecting the types of restaurants to be surveyed was "...integral to the enjoyment of the experience of dining out." We felt that based on this phrase, an individual would select an eating establishment because of the quality of the food, ambience, cost and location. Also considered was the need or desire to have conversation during the dining out experience. Thus, establishments such as a bar or tavern, which usually have a high noise level and where one would not go necessarily to enjoy the experience of dining out, were excluded from the types of restaurants to be surveyed. Likewise, limited menu (i.e., fast food) restaurants were also excluded because one would usually not visit these establishments to enjoy the dining out experience. We consciously made a distinction between social interaction and enjoying the dining out experience.

Based on the above criteria the following types of restaurants were selected for evaluation under this program:

1. Restaurants where a bar is not the central theme of the establishment.

Examples of restaurants where a bar is not the central theme of the establish are Red Lobster, The Olive Garden, Denny's, and Chi Chi's.

2. Commercial cafeterias such as MCL and Piccadilly cafeterias.
3. Restaurants in moderate to high priced hotels or motels.

4. Banquet establishments.

The above types of restaurants account for more than 60 percent of the dollar sales in restaurants and cafeterias in the United States that serve food to the public according to the National Restaurant Association.

Restaurant Selections

The restaurants and cafeterias to be evaluated were selected from eating establishments around central Ohio. The main reason was to minimize travel costs. It was also felt that all of the different types of restaurants to be evaluated could be found in this area where Battelle is located. A total of 13 restaurants and cafeterias were selected. In one restaurant measurements were made in two different dining rooms. The names of the restaurants or cafeterias evaluated were:

1. Buxton Inn
2. Casa Lupita
3. Chi Chi's
4. Damon's
5. Darla's
6. Grand Host East
7. Granville Inn
8. Indian Mound Smorgasbord
9. Jai Lai
10. MCL Cafeteria
11. Natoma
12. Red Lobster
13. Rhodes Hall Cafeteria

A description of each restaurant or cafeteria can be found in Attachment A of this report.

Measurement Procedure

In each restaurant and cafeteria two sets of acoustical measurements were made. The first set of measurements were made to determine the reverberation time in each dining room with no customers present. The reverberation time is the time in seconds that it takes for a loud sound to decay or die down in level 60 dB or to a level that is just audible. For good speech communication, a reverberation time of 0.2 to 1.0 seconds is desirable. Because high sound levels must be generated in order to measure reverberation times, it was not possible to make these measurements with customers present. Reverberation times were measured for the one-third octave bands from 100 to 4000 Hz. Measurements were made using the Integrated Impulse Response method. For each one-third octave band a limited-bandwidth noise burst is generated and fed to an amplifier/loudspeaker system. The room impulse response, which is sampled after each burst, is squared and reverse-integrated. This results in a decay which is equivalent to the squared ensemble average of an infinite number of decays. The reverberation times were then calculated from the decays. At least three sets of decays were made for each one-third octave band.

The second set of measurements made in the restaurants was the recording of the sound pressure levels in the dining rooms with customers present. The sound level in the dining room was tape recorded using a DAT (digital audio tape) recorder over a time period from 30 to 45 minutes during peak restaurant activity. The tape recorded levels were then analyzed using a digital statistical analyzer. The digital statistical analyzer calculates exceedance levels during the measurement period. Exceedance levels (A-weighted sound pressure levels) are the sound levels that are exceeded a certain percentage of the time over the measurement time interval (30 minutes). Thus, the level that is exceeded 50 percent of the time is listed as L(50) and so on for the L(99), L(90), L(10) and L(1) levels. The analyzer also determines the maximum (L(max)) and the minimum (L(min)) levels measured during the measurement period. Finally, the equivalent sound level (L(eq)) for the measurement time is also calculated. The L(eq) value is approximately equal to the average sound pressure level measured during the measurement interval. Exceedance levels were measured because of the need to have detailed sound level data for each restaurant. At a latter date one expression for stating the noise in a restaurant will be chosen. All microphone measurement locations

were at a normal seating position at a table near the middle of the dining room.

Since the noise level in a restaurant was not constant over the measurement interval, it was decided to present restaurant noise levels using the exceeded noise level format. Restaurant noise levels are not constant because the number of customers during the measurement period fluctuates and the customers are not always talking at the same time. Plus there is the "cocktail party effect" where people talk louder as other people talk louder in order to be heard. The number of customers in the restaurant usually starts at a low point, increases to a maximum number, and starts to decline during the 30 minute measurement interval. Only in a few cases was the restaurant basically full during the entire measurement interval. Most measurements were made during the lunch period when there was a maximum number of customers in a very short time period.

For each restaurant the maximum seating density (people/100 sq ft) was determined as well as the maximum seating density during the time of the sound level measurements. In most cases, the maximum seating density during the measurement interval was less than the maximum seating density of the restaurant. The measured data can be used to predict the maximum noise levels for the maximum seating condition, if necessary. In two restaurants one-third octave band sound levels were determined from the tape recorded data during maximum seating density to obtain a spectrum of the sound in a restaurant.

Since the sound levels in the restaurants when occupied were due to the customers in restaurant and not external noise sounds, other acoustical measurements were not made. There was no need to measure the sound transmission loss of exterior walls, windows, and doors since traffic noise could not be heard in the dining rooms. Also, none of the restaurants were below other occupants in the building, thus there was no need to measure impact noise transmission. Finally, noise from the kitchen could not be heard in the dining areas especially when the dining rooms were 25 percent or more full. Kitchen noise in the restaurants simply was not a problem. Thus, restaurant dining room evaluations were limited to quantifying the dining room acoustical environment with and without customers.

Results and Discussions

Reverberation Measurements

The reverberation times were measured in order to determine the amount of sound absorption in the dining rooms with no customers present. The reverberation time is a function of room volume and the amount of sound absorption present in the dining room. The following equation equates reverberation time to room volume and sound absorption:

$$T = \frac{0.049V}{A}$$

where

T = reverberation times in seconds

V = room volume in cu ft

A = sound absorption in sabins

As can be seen from the above equation a short reverberation time does not necessarily mean a large amount of sound absorption. The volume of the room must also be considered. For good speech intelligibility reverberation times should be short. Also, short reverberation times usually mean that the build up of sound levels in a dining room will be minimized. The reverberation times from 500 to 2000 Hz were averaged to obtain a single number to quantify the times measured. This frequency range is approximately the same range as for speech sounds and is commonly used to express an average reverberation time.

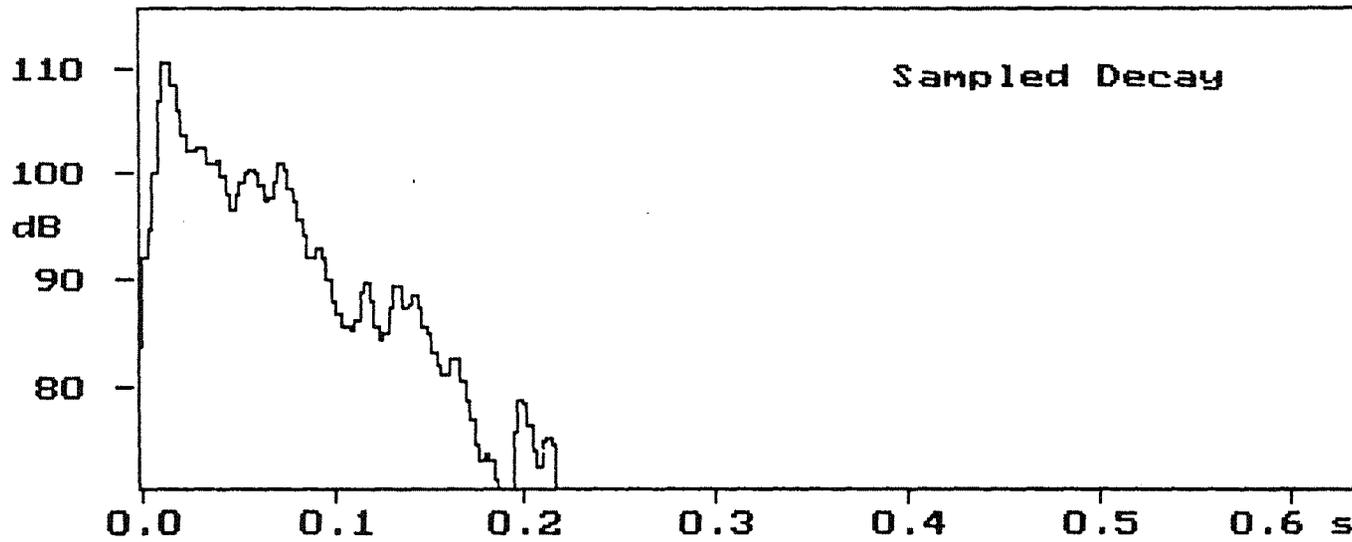
Table 2-1 lists the one-third octave band and average reverberation times measured in each dining room. The restaurants are listed from the shortest to longest measured times. Except for the Grand Host East banquet facility the average reverberation times ranged from 0.36 to 0.59 seconds. The average reverberation time for the Grand Host East was approximately twice as long as for the other restaurants. The times for this dining room were longer because the dining room volume was much larger than the other dining rooms and there was less absorption. The average sound absorption coefficient (0.22) was the lowest of all the restaurants measured.

Except for the Grand Host East dining rooms the reverberation times in the dining rooms were

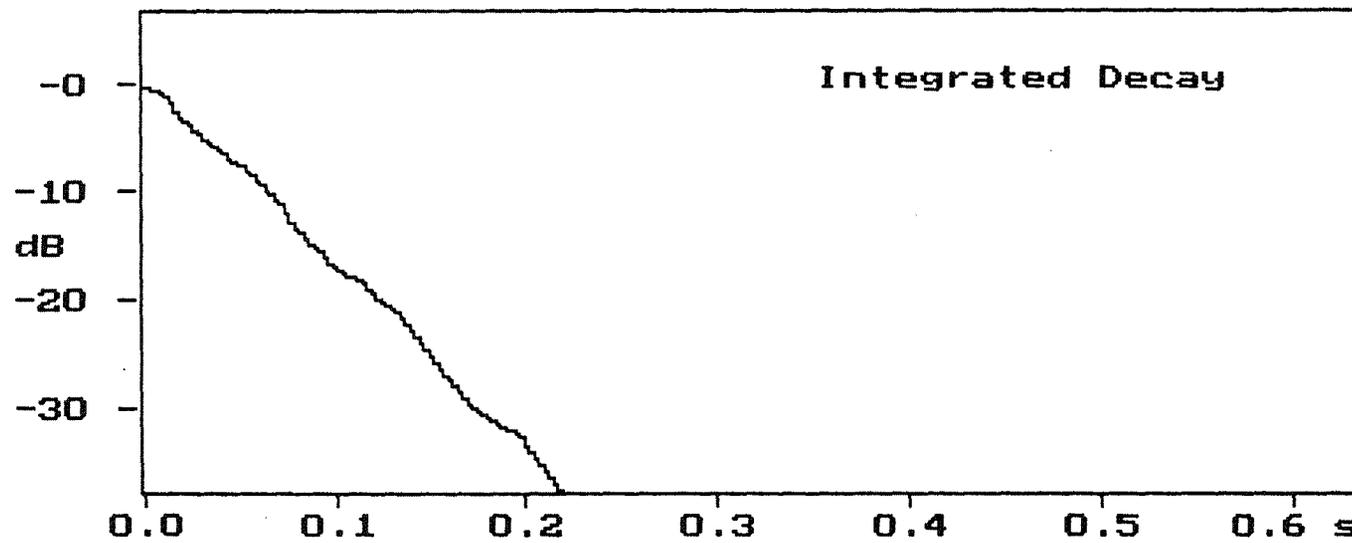
Table 2-1 Restaurant Reverberation Times In Seconds

Ranking	Restaurant	One-third octave band center frequencies, Hz																Average 500 - 2000 Hz	
		100	125	160	200	250	315	400	500	630	800	1000	1250	1600	2000	2500	3150		4000
1	DARLA'S	0.71	0.77	0.54	0.65	0.56	0.38	0.36	0.28	0.35	0.34	0.36	0.36	0.42	0.42	0.53	0.5	0.5	0.36
2	BUXTON INN	0.42	0.27	0.37	0.42	0.39	0.57	0.4	0.42	0.38	0.3	0.36	0.38	0.33	0.36	0.36	0.36	0.37	0.36
3	CHI CHI'S	0.54	0.65	0.46	0.43	0.45	0.52	0.44	0.37	0.37	0.35	0.4	0.33	0.35	0.4	0.36	0.42	0.42	0.37
4	RED LOBSTER	0.49	0.4	0.49	0.43	0.44	0.4	0.38	0.35	0.37	0.36	0.42	0.39	0.4	0.35	0.37	0.39	0.41	0.38
5	CASA LUPITA	0.71	0.5	0.38	0.4	0.4	0.46	0.43	0.48	0.45	0.43	0.4	0.35	0.37	0.38	0.41	0.37	0.39	0.41
6	NATOMA RM 2	0.47	0.39	0.44	0.32	0.35	0.4	0.39	0.47	0.34	0.33	0.33	0.48	0.45	0.46	0.36	0.36	0.34	0.41
7	GRANVILLE INN	0.75	0.43	0.43	0.54	0.48	0.54	0.5	0.45	0.47	0.41	0.45	0.43	0.44	0.41	0.41	0.38	0.37	0.44
8	INDIAN MOUND	0.44	0.8	0.68	0.56	0.75	0.65	0.6	0.48	0.42	0.51	0.4	0.46	0.45	0.46	0.55	0.57	0.63	0.45
9	JAI LAI	0.91	1.05	0.52	0.68	0.48	0.46	0.37	0.43	0.48	0.45	0.43	0.48	0.5	0.5	0.5	0.45	0.47	0.47
10	RHODES HALL	0.73	0.84	0.95	0.85	0.87	0.8	0.73	0.76	0.43	0.47	0.41	0.46	0.46	0.54	0.65	0.66	0.71	0.50
11	MCL CAFETERIA	0.58	0.62	0.64	0.49	0.54	0.54	0.52	0.5	0.46	0.47	0.61	0.47	0.54	0.61	0.58	0.53	0.52	0.52
12	DAMON'S	0.55	0.56	0.39	0.52	0.45	0.5	0.52	0.55	0.65	0.64	0.58	0.58	0.51	0.55	0.5	0.45	0.43	0.58
13	NATOMA RM 1	0.52	0.47	0.43	0.49	0.43	0.53	0.49	0.52	0.61	0.5	0.64	0.64	0.62	0.62	0.64	0.58	0.57	0.59
14	GRAND HOST EAST	1.15	0.94	1.2	0.93	0.87	0.83	0.73	0.72	0.73	0.84	0.84	1.14	1.23	1.14	1.33	1.2	1.08	0.95

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FREQ. = 630 Hz
 FILE = NATOMAB1
 BW = 1/3 oct.



Tr30 = 0.35 s
 Tr20 = 0.36 s
 EDT = 0.39 s

2-8

Figure 2-1. Typical decay curve measured in a restaurant.

Table 2-2 . Average Sound Absorption In Restaurants

Ranking	Restaurant	Average Rev. Time 500 - 2000 Hz	Room Volume, cu. ft.	Avg. Sound Absor, sabins	Room Surface Area, ft.	Avg. Sound Absor. Coeff.
1	CASA LUPITA	0.41	50104	6009	12340	0.49
2	JAI LAI	0.47	61200	6419	13080	0.49
3	DARLA'S	0.36	20000	2711	5800	0.47
4	GRANVILLE INN	0.44	20520	2300	5508	0.42
5	MCL CAFETERIA	0.52	26508	2484	6674	0.37
6	INDIAN MOUND	0.45	19080	2058	5596	0.37
7	RED LOBSTER	0.38	6000	780	2200	0.35
8	BUXTON INN	0.36	4441	602	1836	0.33
9	CHI CHI'S	0.37	3200	427	1360	0.31
10	NATOMA RM 1	0.59	13500	1116	3840	0.29
11	DAMON'S	0.58	17020	1438	5064	0.28
12	RHODES HALL	0.50	7812	759	2798	0.27
13	NATOMA RM 2	0.41	2176	260	1056	0.25
14	GRAND HOST EAST	0.95	37200	1922	8888	0.22

2-9

Ranking: Largest to smallest average sound absorption coefficient

Lupita restaurant at the request of the restaurant manager. By making periodic sound measurements in this restaurant an average sound level was determined. The L(50) value of 58 dBA determined for this restaurant was due mainly to the loud background music being played. The background music could be heard over any sounds coming from customers. It should be noted that during the measurement of the sound levels, the restaurant managers were instructed not to deviate from their normal procedures. Thus, the volume of the background music in the restaurants was at their normal settings.

The L(10) exceedance level (i.e., the sound level exceeded 10 percent of the time) is a good indicator of the average maximum sound level measured during the measurement interval. The L(90) is a good indicator of the average minimum sound level measured. The L(99) value is a good indicator of the background sound level in the restaurant when the customers are creating a minimum amount of sound. Usually the L(50) and L(eq) values are within a couple dB of each other as one would expect. The maximum sound level could be caused by many acoustical events. In one case, the maximum value was achieved when a plate was dropped on the floor and broke. In other cases it was produced by someone coughing, sneezing, laughing or shouting. It is only presented for information purposes.

Table 2-4 is a list of the exceedance levels in the restaurants and are ranked according to the L(50)N level. The L(50)N exceedance level was obtained by normalizing the L(50) level to a seating density of 10.4 people/100 sq ft. The 10.4 people/100 sq ft was the highest seating density (Jai Lai Restaurant) encountered during the restaurant evaluations. By normalizing the L(50) data to a seating density of 10.4 people/100 sq ft, the sound levels measured in each restaurant can then be compare as though they all had the same seating density. This ranking will allow comparisons with the other rankings to determine the extent of the correlation between measured sound levels and the acoustical environment in the dining rooms.

Table 2-5 is a listing of the exceedance levels and the ranking of the dining rooms as a function of L(eq). This ranking can also be used to compare the sound levels and acoustical environments in the restaurants. Table 2-6 is a listing of the exceedance levels and the ranking of the restaurants by seating density during the time of the measurements.

Table 2-7 is a list of the restaurants and their ranking for T(60), L(eq), L(50), L(50)N, seating density, and average absorption coefficient. The bottom half of Table 2-7 is the actual values for each of the ranking parameters. For each ranking except average absorption coefficient the higher the ranking the smaller the parameter. The rankings for the average absorption coefficient are the

Table 2-4 A-weighted Exceedance Sound Levels, dB(A)
 Ranking by L(50)N

Ranking	Restaurant	L (max)	L (1)	L (10)	L (50)	L(50)N	L (90)	L (99)	L (min)	L (eq)	Seating Density (measurement)	Seating Density (when full)
1	RED LOBSTER	72	65	57	52	57	48	47	45	55	2.8	9.4
2	DARLA'S	73	63	58	53	60	50	47	45	55	2.1	4.2
3	MCL CAFETERIA	76	69	62	57	60	54	52	49	59	4.9	5.4
4	INDIAN MOUND	72	65	59	55	61	52	49	48	57	2.4	7.1
5	CHI CHI'S	70	64	62	59	61	57	55	54	59	6.8	16.9
6	BUXTON INN	72	66	61	55	62	50	46	32	57	2	4.7
7	GRANVILLE INN	77	70	63	58	63	55	54	53	61	3	3.2
8	NATOMA ROOM 1	73	68	63	59	63	55	52	50	60	4.5	9.1
9	DAMON'S	76	72	68	62	63	61	59	54	65	7.4	7.4
10	GRAND HOST EAST	80	65	61	57	65	54	52	52	59	1.8	3.1
11	JAI LAI	83	73	69	65	65	62	60	59	66	10.4	10.4
12	RHODES HALL	74	71	68	65	67	61	58	57	65	6	8.3
13	NATOMA ROOM 2	84	77	71	66	68	62	60	58	68	5.9	7.8
14	CASA LUPITA	-	-	-	58	-	-	-	-	-	-	-

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L (max) : Maximum sound level measured during the measurement period
 L (1) : Sound level exceeded 1% of the time during the measurement period
 L (10) : Sound level exceeded 10% of the time during the measurement period
 L (50) : Sound level exceeded 50% of the time during the measurement period
 L(50)N: L(50) value normalised for a seating density of 10.4 people/100 sq. ft.
 L (90) : Sound level exceeded 90% of the time during the measurement period
 L (99) : Sound level exceeded 99% of the time during the measurement period
 L (min) : The lowest sound level measured during the measurement period
 L (eq) : The equivalent sound level for the measurement period
 The measurement period was 30 minutes
 Seating Density: seats/100 sq. ft.
 Ranking: Lowest to highest Value

Table 2-5 A-weighted Exceedance Sound Levels, dB(A)
 Ranking by L(eq)

Ranking	Restaurant	L (max)	L (1)	L (10)	L (50)	L (90)	L (99)	L (min)	L (eq)	Seating Density (measurement)	Seating Density (when full)
1	DARLA'S	73	63	58	53	50	47	45	55	2.1	4.2
2	RED LOBSTER	72	65	57	52	48	47	45	55	2.8	9.4
3	BUXTON INN	72	66	61	55	50	46	32	57	2	4.7
4	INDIAN MOUND	72	65	59	55	52	49	48	57	2.4	7.1
5	GRAND HOST EAST	80	65	61	57	54	52	52	59	1.8	3.1
6	MCL CAFETERIA	76	69	62	57	54	52	49	59	4.9	5.4
7	CHI CHI'S	70	64	62	59	57	55	54	59	6.8	16.9
8	NATOMA ROOM 1	73	68	63	59	55	52	50	60	4.5	9.1
9	GRANVILLE INN	77	70	63	58	55	54	53	61	3	3.2
10	RHODES HALL	74	71	68	65	61	58	57	65	6	8.3
11	DAMON'S	76	72	68	62	61	59	54	65	7.4	7.4
12	JAI LAI	83	73	69	65	62	60	59	66	10.4	10.4
13	NATOMA ROOM 2	84	77	71	66	62	60	58	68	5.9	7.8
14	CASA LUPITA	-	-	-	58	-	-	-	-	-	-

2-13

L (max) : Maximum sound level measured during the measurement period
 L (1) : Sound level exceeded 1% of the time during the measurement period
 L (10) : Sound level exceeded 10% of the time during the measurement period
 L (50) : Sound level exceeded 50% of the time during the measurement period
 L (90) : Sound level exceeded 90% of the time during the measurement period
 L (99) : Sound level exceeded 99% of the time during the measurement period
 L (min) : The lowest sound level measured during the measurement period
 L (eq) : The equivalent sound level for the measurement period
 The measurement period was 30 minutes
 Seating density: seats/100 sq. ft.
 Ranking: Lowest to Highest Value

Table 2-6 A-weighted Exceedance Sound Levels, dB(A)
 Ranking by Seating Density

Ranking	Restaurant	L (max)	L (1)	L (10)	L (50)	L (90)	L (99)	L (min)	L (eq)	Seating Density (measurement)	Seating Density (when full)
1	GRAND HOST EAST	80	65	61	57	54	52	52	59	1.8	3.1
2	BUXTON INN	72	66	61	55	50	46	32	57	2	4.7
3	DARLA'S	73	63	58	53	50	47	45	55	2.1	4.2
4	INDIAN MOUND	72	65	59	55	52	49	48	57	2.4	7.1
5	RED LOBSTER	72	65	57	52	48	47	45	55	2.8	9.4
6	GRANVILLE INN	77	70	63	58	55	54	53	61	3	3.2
7	NATOMA ROOM 1	73	68	63	59	55	52	50	60	4.5	9.1
8	MCL CAFETERIA	76	69	62	57	54	52	49	59	4.9	5.4
9	NATOMA ROOM 2	84	77	71	66	62	60	58	68	5.9	7.8
10	RHODES HALL	74	71	68	65	61	58	57	65	6	8.3
11	CHI CHI'S	70	64	62	59	57	55	54	59	6.8	16.9
12	DAMON'S	76	72	68	62	61	59	54	65	7.4	7.4
13	JAI LAI	83	73	69	65	62	60	59	66	10.4	10.4
14	CASA LUPITA	-	-	-	58	-	-	-	-	-	-

2-14

L (max) : Maximum sound level measured during the measurement period
 L (1) : Sound level exceeded 1% of the time during the measurement period
 L (10) : Sound level exceeded 10% of the time during the measurement period
 L (50) : Sound level exceeded 50% of the time during the measurement period
 L (90) : Sound level exceeded 90% of the time during the measurement period
 L (99) : Sound level exceeded 99% of the time during the measurement period
 L (min) : The lowest sound level measured during the measurement period
 L (eq) : The equivalent sound level for the measurement period
 The measurement period was 30 minutes
 Seating density: seats/100 sq. ft.
 Ranking: Lowest to Highest Value

Table 2-7 Overall Ranking Of The Restaurants

Ranking Based On:

Restaurant	Average T(60)	L(eq)	L(50)	L(50)N	Seating Density (measurement)	Average Absor. Coeff.
BUXTON INN	2	3	3	6	2	8
CASA LUPITA	5	-	8	-	-	1
CHI CHI'S	3	7	10	5	11	9
DAMON'S	12	11	11	9	12	11
DARLA'S	1	1	2	2	3	3
GRAND HOST EAST	14	5	5	10	1	14
GRANVILLE INN	7	9	7	7	6	4
INDIAN MOUND	8	4	4	4	4	6
JAI LAI	9	12	13	11	13	2
MCL CAFETERIA	11	6	6	3	8	5
NATOMA RM 1	13	8	9	8	7	10
NATOMA RM 2	6	13	14	13	9	13
RED LOBSTER	4	2	1	1	5	7
RHODES HALL	10	10	12	12	10	12

Measured Values of:

Restaurant	Average T(60)	L(eq)	L(50)	L(50)N	Seating Density (measurement)	Absor. Coeff.
BUXTON INN	0.36	57	55	62	2	0.33
CASA LUPITA	0.41	-	58	-	-	0.49
CHI CHI'S	0.37	59	59	61	6.8	0.31
DAMON'S	0.58	65	62	63	7.4	0.28
DARLA'S	0.36	55	53	60	2.1	0.47
GRAND HOST EAST	0.95	59	57	65	1.8	0.22
GRANVILLE INN	0.44	61	58	63	3	0.42
INDIAN MOUND	0.45	57	55	61	2.4	0.37
JAI LAI	0.47	66	65	65	10.4	0.49
MCL CAFETERIA	0.52	59	57	60	4.9	0.37
NATOMA RM 1	0.59	60	59	63	4.5	0.29
NATOMA RM 2	0.41	68	66	68	5.9	0.25
RED LOBSTER	0.38	55	52	57	2.8	0.35
RHODES HALL	0.5	65	65	67	6	0.27

opposite. A low number means low sound absorption. One would expect the acoustical environment to be better when the average absorption coefficient is large.

In order to determine if there is a correlation between sound level (L(50) or L(50)N)) and any other parameter, all one needs to do is compare the rankings for these parameters. For the most part there is a correlation between L(50)N and T(60) or average absorption coefficient. There are, however, some exceptions to this correlation. The lack of correlation for these restaurants can be explained. For instance, the L(50)N ranking for the Indian Mound Smorgasbord is 4 while its T(60) ranking is 8. This comparison indicates that the L(50)N was lower than one would expect based on the reverberation times in the dining room. Looking at the average absorption coefficient ranking which is a 6 indicates that there is only a slight correlation mismatch. For the MCL Cafeteria there also is a lack of correlation of rankings for T(60) and L(50)N, which are 11 and 3, respectively. The explanation for this lack of correlation is that the customers in the restaurant at the time of the sound level measurements were older retired people who did not talk much and were fairly very quiet. Finally, the difference in ranking correlation for the Natoma No. 2 dining room can be traced to the low sound absorption values and ceiling in this room. These two factors caused the high sound levels in this room.

Table 2-8 is a list of the one-third octave band sound pressure levels measured in a restaurant at 8 different times over the measurement interval. The four highest levels were averaged to determine the maximum average one-third octave band sound levels. These values are plotted in Figure 2-2. Figure 2-2 shows that the highest sound levels are obtained in the speech frequency range of 250 to 2000 Hz. This is expected since the sound levels were produced by speech sounds. These high sound levels make speech communication difficult because they mask speech sounds.

Conclusions

Several conclusions can be made from the acoustical evaluations conducted in these restaurants and cafeterias. The conclusions will be used as the bases for the acoustical environment recommendations or guidelines to be proposed under Task 3. The conclusions are:

1. The sound level in restaurants varies with time and are primarily dependent on the number of customers in the dining room.

Table 2-8 Sound Levels In A Restaurant Measured At Eight Different Times

One - third octave band center frequency, Hz	One-third octave band sound pressure levels, dB									Average 3,4,5&6
	#1	#2	#3	#4	#5	#6	#7	#8	#9	
100	54	50	51	51	50	51	55	57	49	51
125	52	52	55	54	53	55	54	55	55	54
160	53	52	57	58	52	53	53	56	54	55
200	53	55	58	60	53	56	57	59	58	57
250	55	56	58	59	56	58	57	60	60	58
315	51	52	57	60	58	59	55	58	56	59
400	54	53	59	61	59	59	55	56	57	60
500	53	57	60	65	60	62	55	56	58	62
630	56	50	62	64	61	64	55	55	56	63
800	54	48	59	65	58	62	55	53	55	61
1000	52	45	55	64	57	58	51	50	53	59
1250	48	43	55	63	55	59	49	50	51	58
1600	49	43	56	61	55	57	48	48	47	57
2000	46	41	54	57	52	54	45	48	46	54
2500	44	38	52	56	52	52	44	45	41	53
3150	41	36	49	52	50	49	42	43	38	50
4000	38	37	47	49	48	47	39	41	36	48
5000	33	31	41	44	46	44	38	37	33	44
A-weighted level,dB(A)	61	58	67	72	66	69	61	62	63	69

2-17

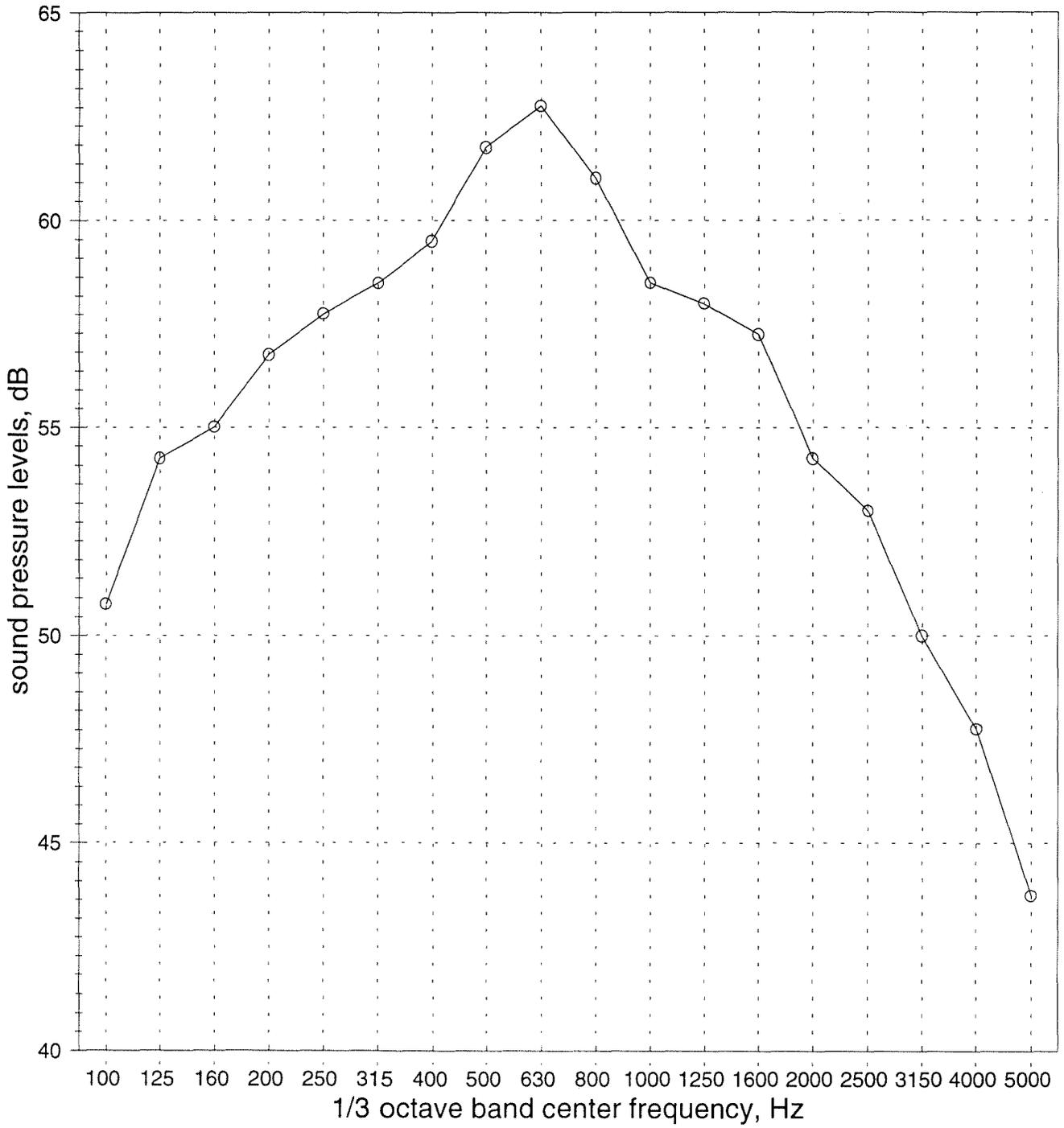


Figure 2-2. One-third octave band sound levels in a typical restaurant surveyed.

2. With only a few customers in the dining room, it is possible that the background music is the highest sound source in the restaurant.
3. The sound levels in a restaurant are directly proportional to the seating density (i.e., people/100 sq ft or sq ft/person).
4. At times the sound level in the dining rooms exceeded a normal voice conversation levels (50-65 dB) at 3 feet, thus speech sounds are masked or covered up by background noise making speech communications difficult, if not impossible, by the hearing impaired.
5. Reverberation times are usually less than 1 second in dining rooms and average sound absorption coefficients for all the surfaces in a dining room usually are between 0.20 and 0.50.
6. The sound levels in a restaurant are directly related to the amount of sound absorption in the dining rooms. Higher average sound absorption coefficients usually mean lower sound levels.
7. Most restaurants have an acoustical ceiling to help control the acoustical environment and provide sound absorption.
8. The size and shape of dining rooms and the total number of customers are secondary factors for determining the amount of noise in a dining room. The primary factor is seating density.

Attachment A

Restaurant Descriptions

Buxton Inn

Granville, Ohio

General Description: Old inn and restaurant with several dining rooms. Measurements made in the main dining room. Clientele mainly business people and college staff.

Size of Dining Room: 27.5 by 19 by 8.5 ft high

Room Construction: Plaster walls and ceiling (NRC 0.10), carpet and pad, wood tables with table cloths and wood chairs, and no booths.

Seating Capacity: 24 (seating density: 4.7 people/100 ft²)

Maximum Occupancy During Tests: 10 people (seating density: 2.0 people/100 ft²)

Background Music: None

Time of Measurements: 12:20 p.m. - 12:50 p.m.

Casa Lupita

Newark, Ohio

General Description: Mexican restaurant. Measurements made during a Sunday buffet. No tape recording sound levels were made at the request of the restaurant manager.

Size of Dining Room: 56 by 82 by 9-20 ft high (vaulted ceiling)

Room Construction: Acoustical ceiling with 1 by 1 ft tiles (NRC 0.50), plaster walls, carpet and pad, wood tables and chairs, and booths.

Seating Capacity: Not determined.

Maximum Occupancy During Tests: 12 people

Background Music: Yes, (very loud) and significant contributor to overall sound level)

Time of Measurements: 10:30 a.m. - 11:30 a.m.

Chi Chi's Restaurant

Columbus, Ohio

General Description: Multi-outlet mexican food restaurant. Multi-dining rooms separated by planter walls.

Size of Dining Room: 20 by 16 by 10 ft high

Room Construction: Acoustical ceiling (2 by 2 ft lay-in panels, NRC 0.60), carpet and pad, stucco walls with exterior windows, wood table and chairs, and booths

Seating Capacity: 54 people (seating density: 16.9 people/100 ft²)

Maximum Occupancy During Tests: 22 people (seating density: 6.8 people/100 ft²) (60% of tables occupied)

Background Music: Yes (low level)

Time of Measurements: 12:01 p.m. - 12:31 p.m.

Damon's Restaurant

Newark, Ohio

General Description: Single dining room, multi-outlet restaurant specializing in BBQ ribs. Family restaurant usually full during dinner time.

Size of Dining Room: 46 by 37 by 10 ft high

Room Construction: Acoustical ceiling (2 by 2 ft lay-in panels, NRC 0.60), gypsum wallboard walls, carpet and pad, wood tables and chairs, and booths.

Seating Capacity: 122 people (seating density 7.4 people/100 ft²)

Maximum Occupancy During Tests: 120 people (seating density: 7.4 people/100 ft²)

Background Music: None

Time of Measurements: 7:00 p.m. - 7:30 p.m.

Darla's Restaurant

Newark, Ohio

General Description: Restaurant in a Best Western Hotel. Measurements made in the evening. Clientele was young families.

Size of Dining Room: 50 by 40 by 10 ft high

Room Construction: Acoustical ceiling (2 ft by 4 ft lay-in panels, NRC 0.60), brick and gypsum wallboard walls with some windows, carpet and pad, wood and vinyl tables and chairs, and no booths.

Seating Capacity: 78 people (seating density: 4.2 people/100 ft²)

Maximum Occupancy During Tests: 39 (seating density: 2.1 people/100 ft²)

Background Music: None

Time of Measurements: 7:08 p.m. - 7:38 p.m.

Grand Host East Banquet Facility

Columbus, Ohio

General Description: A banquet hall that serves Sunday brunch as well as catering banquets. Measurements made during Sunday brunch.

Size of Dining Room: 62 by 50 by 12 ft high

Room Construction: Acoustical ceiling (2 ft by 2 ft lay-in panels, NRC 0.60), moveable partition and gypsum wallboard walls, carpet and pad, wood tables with table cloths and wood chairs, and no booths.

Seating Capacity: 96 people (seating density: 3.1 people/100 ft²)

Maximum Occupancy During Tests: 57 people (seating density: 1.8 people/100 ft²)

Background Music: Yes (50 dBA)

Time of Measurements: 12:10 p.m. - 12:40 p.m.

Granville Inn

Granville, Ohio

General Description: Old inn with a single dining room. Relatively expensive. Lunch patrons are business people and older women.

Size of Dining Room: 57 by 30 by 12 ft high

Room Construction: Plaster ceiling (NRC 0.10), wood paneling and plaster walls, carpet and pad, a few exterior windows, wood tables with table cloths and padded wood seats, and no booths.

Seating Capacity: 55 people (seating density: 3.2 people/100 ft²)

Maximum Occupancy During Tests: 51 people (seating density: 3.0 people/100 ft²)

Background Music: None

Time of Measurements: 11:55 a.m. - 12:25 p.m.

Indian Mound Smorgasbord

Heath, Ohio

General Description: Cafeteria with one large dining room divided into two sections by a dessert and beverage bar. At time of measurements most of the patrons were elderly people (retired).

Size of Dining Room: 53 by 36 by 10 ft high (Section where measurements were made.)

Room Construction: Acoustical ceiling (2 by 4 ft lay-in panels, NRC 0.60), carpet and pad, plastic and wood tables, metal chairs, gypsum wallboard walls and no windows.

Seating Capacity: 136 people (seating density: 7.1 people/100 ft²)

Maximum Occupancy During Tests: 46 people (seating density: 2.4 people/100 ft²) (75% of tables occupied)

Background Music: Yes (low level)

Time of Measurements: 11:35 a.m. - 12:30 p.m.

Jai Lai Restaurant

Columbus, Ohio

General Description: Large restaurant with one main dining room and a bar area. During lunch there are mainly business people.

Size of Dining Room: 85 by 60 by 12 ft high

Room Construction: Acoustical tile ceiling, NRC 0.30 (probably painted by owners), glass or vinyl covered gypsum board walls, carpet and pad, wood tables and chairs, and booths.

Seating Capacity: 530 people (seating density: 10.4 people/100 ft²)

Maximum Occupancy During Tests (in area of measurements): 90 (seating density: 10.2 people/100 ft²)

Background Music: Yes (low level)

Time of Measurements: 12:12 p.m. - 12:42 p.m.

MCL Cafeteria

Columbus, Ohio

General Description: Two dining rooms frequented mostly by the elderly. Measurements made in the large main dining room.

Size of Dining Room: 47 by 47 by 12 ft high

Room Construction: Acoustical ceiling (2 by 2 ft lay-in panels, NRC 0.60), carpet and pad, gypsum wallboard walls with a few windows, wood tables and chairs, and booths.

Seating Capacity: 120 people (seating density: 5.4 people/100 ft²)

Maximum Occupancy During Tests: 109 people (seating density: 4.9 people/100 ft²)

Background Music: Yes (low level)

Time of Measurements: 11:30 a.m. - 12:00 p.m.

Natoma Restaurant

Newark, Ohio

General Description: Two dining rooms frequented mainly by business people at lunch and the older generation at night. Measurements were made in each dining room.

Size of Dining Room: Room #1 - 50 by 18 by 15 ft high
Room #2 - 16 by 16 by 8.5 ft high

Room Construction: Room #1 - Molded metal tiles (NRC -0.10), carpet and pad, wood paneling and plaster walls, wood tables and chairs, and booths. Room #2 - Wood planking ceiling (NRC 0.10), carpet and pad, wood paneling and gypsum wallboard walls, wood tables and chairs, and no booths. Openings to Room #1.

Seating Capacity: Room #1 - 80 people (seating density: 9.1 people/100 ft²)
Room #2 - 20 people (seating density: 7.8 people/100 ft²)

Maximum Occupancy During Tests: Room #1 - 40 people (seating density: 4.5 people/100 ft²)
Room #2 - 15 people (seating density: 5.9 people/100 ft²)

Background Music: None

Time of Measurements: Room #1 - 12:05 p.m. - 12:35 p.m.
Room #2 - 12:09 p.m. - 12:39 p.m.

Red Lobster Restaurant

Lancaster, Ohio

General Description: A multi-dining room national chain restaurant. Dining areas separated by planter walls.

Size of Dining Room: 30 by 20 by 10 ft high

Room Construction: Acoustical ceiling (2 by 2 ft lay-in panels, NRC 0.60), vinyl covered gypsum wallboard walls with some windows, carpet and pad, wood tables and chairs, and booths.

Seating Capacity: 56 people (seating density: 9.4 people/100 ft²)

Maximum Occupancy During Tests: 17 people (seating density: 2.8 people/100 ft²)

Background Music: None

Time of Measurements: 12:10 p.m. - 12:40 p.m.

Rhodes Hall Cafeteria

Ohio State University

General Description: Multi-dining room cafeteria in a medical building serving students, staff, and medical interns.

Size of Dining Room: 31 by 28 by 9 ft high

Room Construction: Acoustical ceiling (2 by 2 ft lay-in panels, NRC 0.60), carpet and pad, gypsum wallboard walls with some exterior windows, and plastic and wood tables and chairs.

Seating Capacity: 72 people (seating density: 8.3 people/100 ft²)

Maximum Occupancy During Tests: 52 people (seating density: 6.0 people/100 ft²) (All tables occupied.)

Background Music: None

Time of Measurements: 11:38 a.m. - 12:08 p.m.

Task 3. Proposed Guidelines

Final Report

on

**Accessibility Guidelines and Technical
Provisions with Justifications**

for

Quiet Areas in Restaurants for Hearing-Impaired Individuals

to

U.S. Architectural and Transportation Barriers Compliance Board

November, 1993

by

Ronald Moulder



Battelle

... Putting Technology To Work

505 King Avenue

Columbus, Ohio 43201-2693

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Accessibility Guidelines and Technical Provisions with Justifications

Introduction

It is estimated that over 21 million Americans have some degree of hearing impairment, which is about 8.5 percent of the population¹. For individuals 65 or older, more than 24 percent have a hearing impairment². Hearing impairment is the third most prevalent chronic disability for the age group over 65³. The most common cause of hearing impairment is presbycusis⁴, which is the loss of hearing due to the aging process. Such a hearing loss occurs even for people who have had no ear diseases or have not been exposed to high noise levels.

The major problem of hearing impaired individuals is speech communication. Individuals with a hearing impairment often complain of being unable to understand speech in noisy or reverberant environments⁴. The worst noisy environment is one in which competing speech sounds are present and tend to mask or cover-up speech communication. Research has shown that speech communication by individuals with normal hearing is less affected by interfering speech than for individuals with a hearing impairment⁵. Substantial research has been done to try to understand and explain the speech communication problems of hearing impaired individuals when interfering speech signals and reverberation are present. Most of the research has been done with the elderly since a large percentage of individuals 60 years or older have a hearing impairment.

Background

Before addressing the issues critical to speech communication by hearing impaired individuals, several concepts or terms need to be defined. An important term is *normal hearing*, which is the median hearing level obtained for a large group of young adults between the age of 18 to 25 years who have no known history of ear-disease and no appreciable exposure to high-level noise⁶. A set of sound pressure levels which represent the normal hearing threshold at the frequencies from 500 to 6000 Hz have been established as the zero reference level for audiometry. Thus, one's hearing loss is

usually expressed as so many decibels down from this normal hearing reference level. Over 75 percent of the population has some hearing loss referenced to normal hearing⁶. An individual is considered to have a slight hearing impairment if there is an average hearing (threshold) level (AHL) for 500, 1000, and 2000 Hz in the better ear of at least 24 dB⁷. That is to say an individual's hearing loss has to be at least 24 dB before that person is classified as having a hearing impairment. A hearing level of 90 dB or greater is considered profound or extreme hearing impairment. Most hearing loss occurs at the high frequencies.

The predominate method for expressing an individual's ability to understand speech is the Speech-Reception Threshold (SRT). The SRT is the sound pressure level of speech at which a listener can understand 50 percent of the spoken sentences. For good speech intelligibility 65 - 70 percent of sentences should be understandable. The 50 percent for the SRT is only a threshold criterion. Another term related to speech intelligibility is the Speech Transmission Index (STI), which correlates the reception of nonsense syllables in a given acoustical environment to a listener's ability to understand what they hear. This index, which ranges from 0 to 1, takes into account the distance from the talker to the listener, ambient noise levels, and reverberation time in a room. Research done with normal-hearing individuals has shown that an STI value below 0.4 is a poor listening condition. From 0.4 to 0.6 it is fair, from 0.6 to 0.8 it is good, and above 0.8 it is excellent⁴. These values were established with a background noise consisting of speech babble. For individuals with a hearing impairment the STI values need to be 0.1 to 0.3 higher in order to achieve the same degree of speech intelligibility as for normal hearing individuals⁴.

From measurements of the SRT in quiet and in the presence of defined noise levels, the speech hearing loss (SHL) in quiet (SHL_{A+D}) and in noise (SHL_D) can be calculated⁸. The SHL_{A+D} and SHL_D are related to SRT by the following equation:

$$SRT = 10 \log \left[10^{(L_o + A + D)/10} + 10^{(L_N - \Delta L_{SN} + D)/10} \right] \quad (1)$$

where

L_o = SRT in quiet, dBA

L_N = sound pressure level of the noise, dBA

ΔL_{SN} = SRT expressed in speech-to-noise ratio, dB

A + D = hearing loss for speech in quiet, dB

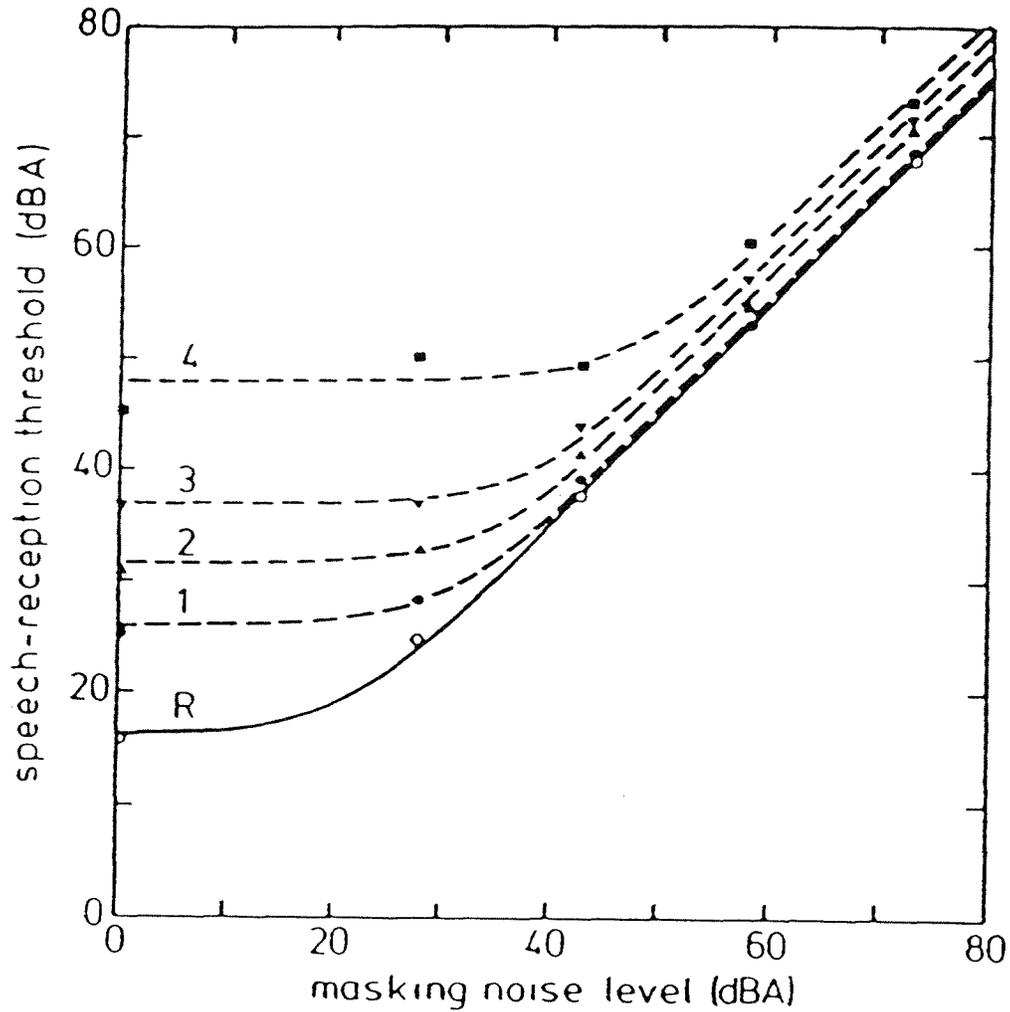
D = hearing loss for speech in noise, dB.

The *speech-to-noise ratio* is the difference in dB between the sound level of speech and the sound level of background noise. A positive value means that the speech sound pressure level is greater or above the background noise level. A final term that needs to be defined is *reverberation time*. It is the time in seconds that it takes a sound to decay or die down 60 dB in level.

Discussion

As mentioned earlier a substantial number of research programs on speech intelligibility and hearing impaired individuals have been conducted. Messrs. A. J. Duquesnoy and R. Plomp of the Free University in The Netherlands are two of the most prominent researchers in this area. Their research has demonstrated that the SRT and STI can be used to determine speech intelligibility in both noisy and reverberant sound fields¹⁰. They advocate that hearing loss in noise should always be measured in order to obtain a good insight into the speech hearing ability of a subject⁹. They have conducted research on the effect of various reverberation times on SRT in the presence of noise (i.e., speech babble). They have discovered that higher STI values are required to compensate for the increased SRT in noise on the part of hearing-impaired listeners. These higher STI values can be achieved by improving the speech-to-noise ratio and by reducing the reverberation time in a room. In reverberant rooms, they state that reducing reverberation time can improve speech intelligibility substantially. Reverberation times are best reduced by adding more sound absorption to a room, which in addition to lowering reverberation times also reduces background noise levels⁸. Plomp's research has shown that in critical conditions even a difference of a few decibels in the speech-to-noise ratio results in a large difference in speech intelligibility. He has found that near the 50 percent speech-reception threshold a 1 dB increase in speech-to-noise ratio results in about an 18 percent higher intelligibility score for sentences by hearing impaired individuals⁸. Thus, 1 dB changes in either speech or noise levels are very critical and important for speech intelligibility.

Research that A. J. Duquesnoy has done with the elderly who have a hearing impairment due to presbycusis has shown a relationship between SRT and masking noise levels as a function of SHL_D (speech hearing loss in noise). Figure 3-1 is a plot of SRT versus masking noise level for five



Curve

- R = Normal hearing group
- 1 = Individuals with an SHL_D of 0.3 dB
- 2 = Individuals with an SHL_D of 2.2 dB
- 3 = Individuals with an SHL_D of 3.7 dB
- 4 = Individuals with an SHL_D of 5.4 dB

Figure 3-1. SRT for sentences as a function of masking noise level. The curves marked R, 1, 2, 3, and 4 represent groups with different SHL_D values (from Reference No. 9).

groups of individuals with normal hearing and various SHL_D values.

Normal speech levels at 3 ft range from 50 to 65 dBA¹¹. The average level is 58 dBA for men and 55 dBA for women. From Figure 3-1 one can see that for a speech-reception threshold of 58 dBA and an SHL_D of 3.7 dB (Curve 3), the masking level should not exceed 58 dBA. This is one of the relationships that will be used in establishing the guidelines for quiet areas in restaurants.

As mentioned earlier, reverberation time is also important in determining speech intelligibility. In restaurants most conversations take place with the listeners typically 3 ft from the talker. Thus, only the direct sound from the listener must be considered. Interfering speakers are all situated at much larger distances from the listener so that their direct sound contribution is small, but their indirect sound contribution is large. For these conditions, any change in reverberation time only affects the level of the indirect interfering speech. Theory predicts that for every halving of reverberation time, there is a 3 dB reduction in the indirect noise level, or a reduction factor of 0.82 of reverberation time results in a 1 dB reduction in SHL_D ⁴.

In studies done by Messrs. Duquesnoy and Plomp^{9,10}, tests were conducted with elderly subjects suffering from presbycusis. Their study showed that a reverberation time range of 0.25 to 0.50 seconds resulted in an STI of 0.55 (fair listening condition) when the speech-to-noise ratio was 0 to 3 dB for hearing impaired individuals with an SHL_D of 3.7 dB. This relationship will also be used to establish the guidelines for quiet areas in restaurants.

Proposed Guidelines

Based on the research that has been done (see Discussion) with hearing impaired individuals and their ability to have effective speech communication in a noisy and reverberant environment, several guidelines can be established for quiet areas in restaurants and cafeterias. Approximately 25 percent of the population over 60 years old have an SHL_D of 3.5 dB and approximately 10 percent over 48 have an SHL_D of 3.5 dB. Thus, one can see that there are a significant number of people that have at least an SHL_D of 3.5 dB⁴. Figure 3-2 is a plot of percentage hearing impaired verses age for different SHL_D values. Guidelines will be proposed that will allow a person with an SHL_D of 3.5 dB or less to have effective (fair) speech communications in a restaurant or cafeteria.

According to Plomp the best descriptor of the noise level in a room is the L_{eq} or $L(eq)$ value measured over a 5 to 10 minute time interval⁸. Thus, this descriptor will be used to express the

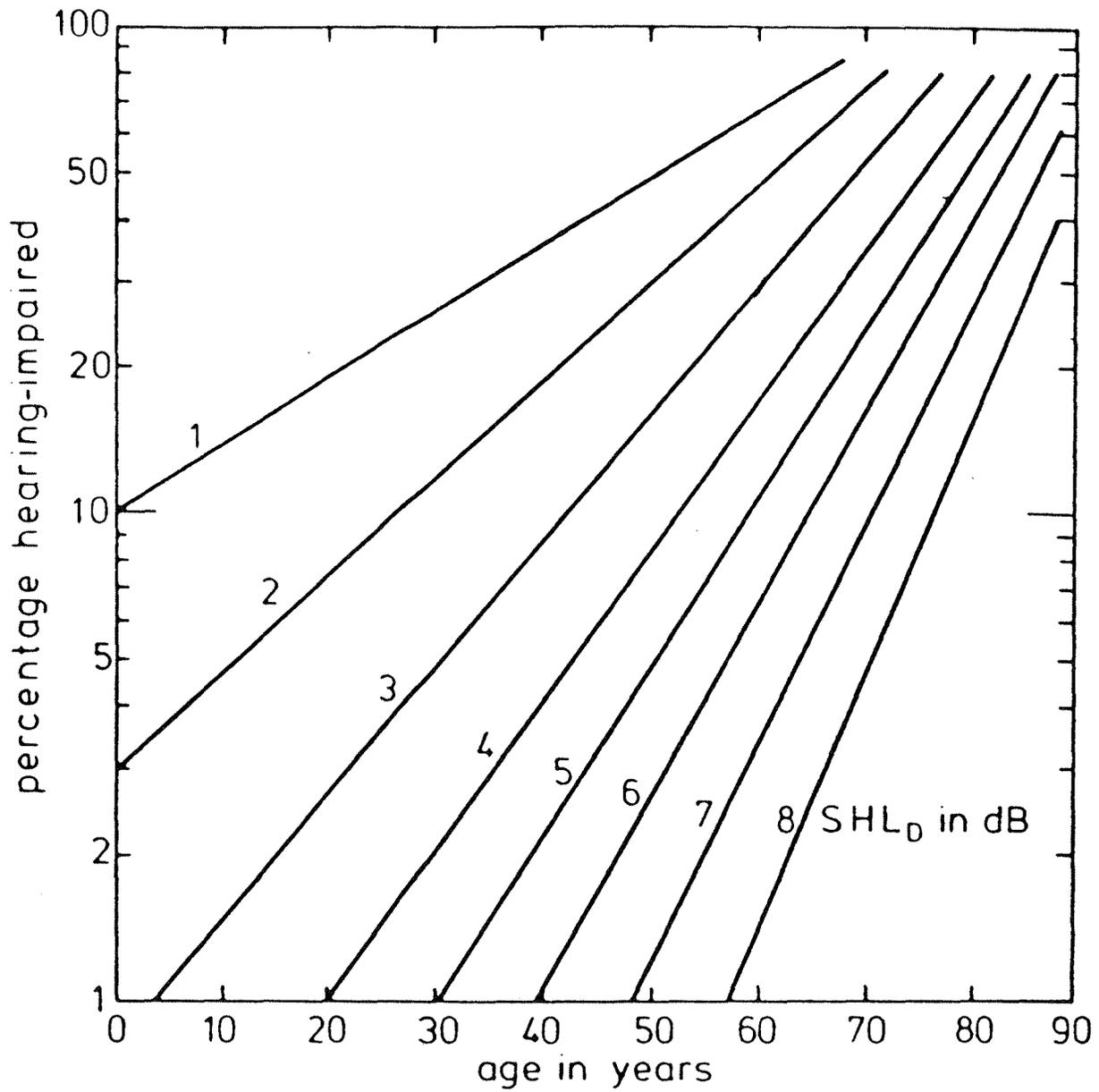


Figure 3-2. Plot of percentage of hearing impaired people as a function of age for different SHL_D values (from Reference 4).

noise level in restaurants and cafeterias. As stated earlier, we will assume that the voice level of a talker at 3 ft is $L_{eq} = 58$ dBA. From the previous discussion the minimum speech-to-noise ratio in a restaurant for fair speech intelligibility for hearing impaired individuals is approximately 0 dB when the reverberation time is 0.25 to 0.50 seconds. Thus, the proposed minimum acoustical guidelines for quiet areas in restaurants or cafeterias are:

- The maximum background sound level L_{eq} or the average sound level measured over a 5 minute time interval should not exceed 58 dBA in order for the minimum speech-to-noise ratio to be equal to 0 dB. This maximum sound level is based on a talker - listener distance of 3 ft. For distances greater than 3 ft the maximum sound level should be reduced 6 dBA for every doubling of the distance between talker and listener.
- The maximum average reverberation time in a dining room should not exceed 0.5 seconds for the frequency range from 500 to 2000 Hz measured at 1/3 or 1/1 octave band frequencies. Shorter times are recommended since the added amount of sound absorption will also reduce overall noise levels. This maximum value is for a small dining room (i.e., 1000 - 2000 cu ft). As the room volume is increased the maximum reverberation time can increase (see Figure 3-4).¹⁴

The measured sound levels L_{eq} in the restaurants surveyed during this program ranged from 55 to 68 dBA. The reverberation times ranged from 0.36 to 0.95 seconds. Thus, there is a need to lower both the noise levels and reverberation times in restaurants.

Architectural Considerations

Several factors influence or control the background noise levels and reverberation times in restaurants. These factors are:

- Noise sources and levels adjacent to the dining area.
- Heating, ventilating and air conditioning noise.
- Background music.
- Number of customers per given area (i.e., seating density).
- Amount of sound absorption in the dining area.

Each of these factors can be controlled by the architect or designer and the owner of the restaurant.

The most effective architectural treatment for reducing background noise levels is the addition of sound absorbing materials in the dining area. Adding sound absorption also reduces the reverberation time, which is desirable. The preferred sound absorption treatment is the installation of an acoustical ceiling. Sound absorbing wall panels can also be installed, but, they are not as effective as an acoustical ceiling. Their best use is to supplement an acoustical ceiling. Installing a carpet and pad on the floor adds little sound absorption to a room. A carpet and pad does reduce foot traffic noise as well as noise due to chairs being moved across the floor. When installing a ceiling the noise reduction coefficient (NRC) for the ceiling material should be at least 0.65 with an NRC 0.80 to 0.85 the preferred value in order to effectively use the ceiling area for sound absorption. Also, sound absorbing ceiling baffles may be suspended from the ceiling to increase the NRC of existing or new ceiling that has an NRC below the recommended 0.80 to 0.85.

The addition of sound absorbing materials to a room serves a dual purpose. It lowers the noise level and also lowers the reverberation time. In order to provide a quiet area in a restaurant for hearing impaired individuals, additional measures besides adding sound absorption must be implemented. There are two sources of noise that must be addressed. The first is background noise from adjacent areas entering the quiet area. This potential noise source can be controlled by locating the quiet area away from other sources of noise such as a bar area, kitchen, or lobby. If necessary, the quiet area can be separated from these noisy areas and the main dining room by a partition or high planter wall. A glass partition is an excellent wall to use since it blocks the passage of sound and at the same time it doesn't visually isolate the quiet area from the rest of the dining area. Another way to acoustically isolate a quiet area is to use high backed booths with the backs being at least 5 ft tall.

The second source of noise in the quiet area is the customers. Sound level measurements made during the restaurant evaluation task of this program showed a direct correlation between seating density and noise levels. Obviously, as more people are seated in a dining area the higher the noise level will be. Thus, the seating density must be limited in the quiet area. Establishing a maximum seating density for a quiet area in a restaurant is difficult. Many factors such as seating density, amount of sound absorption in the dining area, and the type of customers affect the overall noise level in a dining area. As a general rule, if the reverberation time is short (i.e., less than 0.50 seconds) then the seating density can be increased since the higher amount of sound absorption in the dining area will reduce the overall background noise produced by other diners in the room. The type of customers in the dining room also affects the overall background noise level. Experience and

measurements have shown that older adults tend to be quieter than younger adults and children. Also, families tend to generate higher noise levels than just adults. Based on the noise level measurements made during the restaurant evaluation phase of this program, Figure 3-3 gives recommended dining room reverberation time as a function of seating density for quiet areas for adult or family type restaurants. The minimum seating density (sq ft/person) should not be less than 10 sq ft/person for any type of restaurant in order to keep noise levels to below 58 dBA. Figure 3-4 is a graph of the increase in reverberation time that can be added to the value determined in Figure 3-3 due to a large dining room.

The architect or designer should use the following procedure in designing a quiet area in a restaurant:

1. Determine the size of the quiet area dining room.
2. Determine the desired seating density (sq ft/customer) in the dining room and type of customers that will be visiting the restaurant. If it varies select family as the type of restaurant.
3. From Figure 3-3 determine the required reverberation time based on the seating density and the type of customers expected.
4. From Figure 3-4 determine how much the reverberation time determined in Step 3 can be increased due to the volume of the quiet area dining room.
5. Once the required reverberation time has been determined, the following equation should be used to determine how much sound absorbing material must be used in the dining room:¹²

$$A = \frac{0.049V}{T} \quad (2)$$

where

- A = sound absorption in dining room expressed in sabins
 T = reverberation time in seconds
 V = volume of dining room in cu ft.

The amount of sound absorption (A) in a room is determined by multiplying the surface area of a material by that material's average sound absorption coefficient or noise reduction coefficient (NRC). The average sound absorption coefficient for a material is determined by averaging the absorption

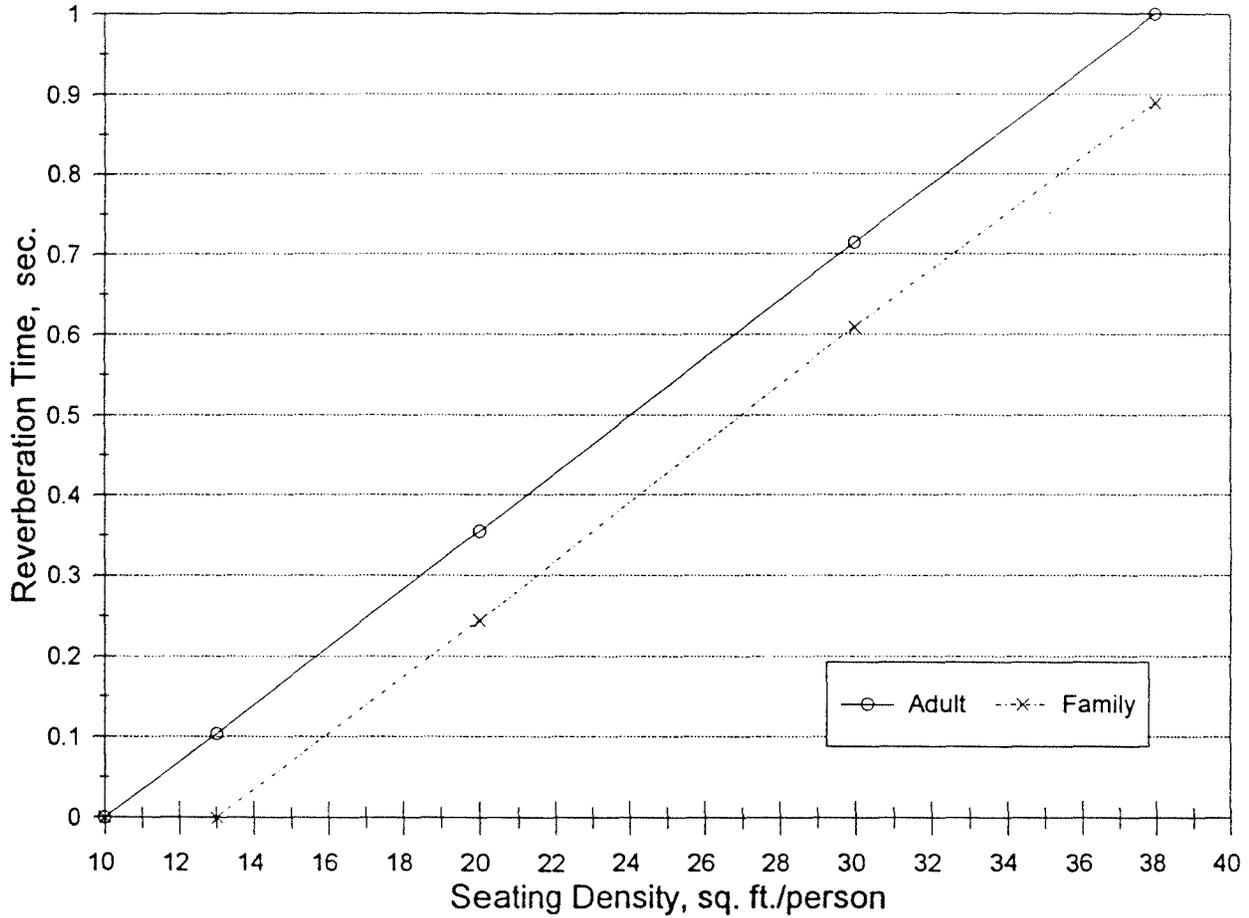


Figure 3-3. Recommended reverberation time as a function of seating density for quiet areas in restaurants in adult or family type restaurants.

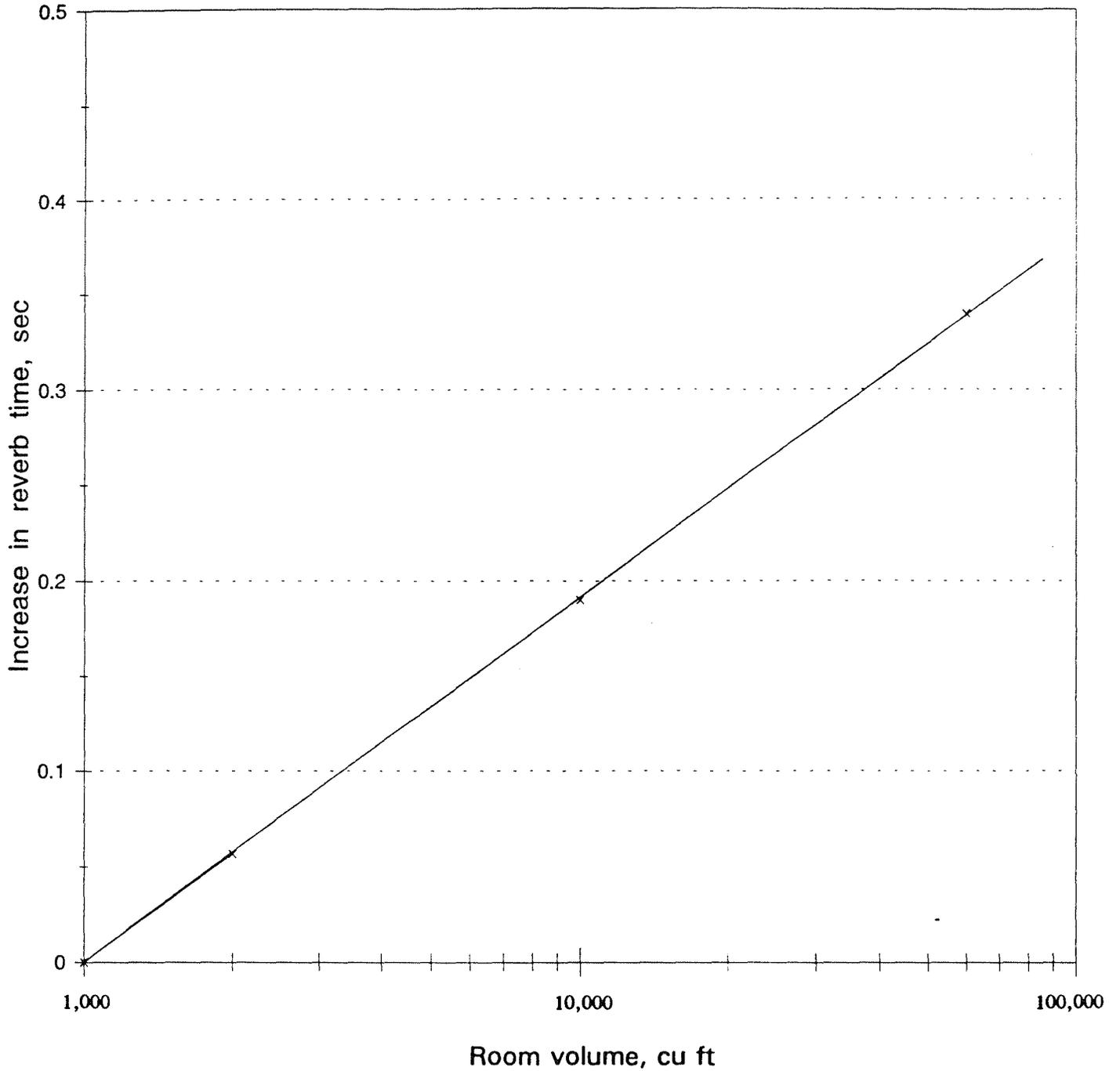


Figure 3-4. Graph showing the amount the reverberation time can be increased over that given by Figure 3 due to the volume of the dining room.

coefficients in the range from 500 to 2,000 Hz. Since most manufacturers do not publish sound absorption coefficients, the single number rating of NRC, which they do publish, can be used in place of the average absorption coefficient for approximation purposes.

As an example, assume the following quiet area dining room will be built:

Size:	25 x 20 x 10 ft	V = 5,000 cu. ft.
Walls:	colspan="2">painted gypsum wallboard	
Ceiling:	to be selected	
Floor:	carpet and pad on concrete	
Furniture:	wood tables and chairs	
Seating Density:	20 sq ft/person	
Customers Type:	Adult	

From Figure 3-3 for a seating density of 20 sq ft/person and adult customers, the recommended reverberation time in the dining room is 0.35 seconds. From Figure 3-4 the increase in reverberation time that can be added to the 0.35 seconds due to the volume (5,000 cu ft) of the room is 0.13 seconds. Thus, the design reverberation time is $0.35 + 0.13 = 0.48$ seconds.

Equation 2 is now used to determine the amount of sabins of absorption required in the dining room to achieve the desired reverberation time of 0.48 seconds:

$$A = \frac{(0.049)(5,000)}{0.48} \quad \text{sabins}$$

$$A = 510 \text{ sabins}$$

The ceiling area is $25 \text{ ft} \times 20 \text{ ft} = 500 \text{ sq ft}$. The ceiling must have a very high average sound absorption or NRC in order to obtain the maximum amount of sound absorption. A ceiling with an NRC 0.85 is chosen. Therefore, the ceiling sound absorption is:

$$A = (0.85)(500) = 425 \text{ sabins}$$

There is a need to obtain $510 - 425 = 85$ sabins from the other materials in the dining room. The carpet and pad has an NRC of approximately 0.25. The painted gypsum wallboard has an NRC of

approximately 0.05. The tables and chairs have very little sound absorption and are not considered.

The total amount of sabins in the dining room is therefore:

Ceiling	=	425 sabins
Floor - 25 ft x 20 ft x 0.25	=	125
Walls - 2 x 25 ft x 10 ft x 0.05	=	25
2 x 20 ft x 10 ft x 0.05	=	<u>20</u>
Total		595 sabins

Thus, the total amount of sabins in the dining room is 595 which is greater than the required 510 sabins. Therefore, this dining room should have an average noise level less than 58 dBA with a reverberation time of less than 0.50 sec. The seating density must not exceed 20 sq ft per customer or a maximum of 25 customers in the dining room.

If the above proposed guidelines and architectural recommendations are followed in designing a quiet area in a restaurant or cafeteria, 20 to 30 percent of hearing impaired individuals should be able to have effective speech communication in dining rooms. People with a severe or profound hearing impairment will probably still be unable to effectively communicate verbally in the proposed quiet areas in restaurants.

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