Turning up the volume:
Hearing aid regulation in the United States

Strategic Firm Authority Interaction in Antitrust, Merger Control and Regulation

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Overview

- Overarching question: When can regulation unduly restrict competition?
- Methodology now exists for answering these questions broadly (OECD's Competition Assessment Toolkit described by Ghosal)
- Presentation focus: one example in which a combination of product and professional regulation result in limited supply/high prices by restricting competition from alternative products: hearing aid device and delivery regulation in the U.S.
- Hearing loss affects a large number of people. An estimated 31 million people in the U.S. have some form of hearing loss.
- Hearing aids are an important medical device for improving hearing, especially for the elderly, having a large effect on quality of life for users with partial loss of hearing and those who interact with them

Outline of presentation

- Description of process of fitting hearing aids
- History of hearing aid regulation
- Basic statistics
- Rough estimation of impact of regulation on hearing aid use
- Need for revision of regulatory considerations
- Conclusion

Economics of hearing aids

- Generally, hearing aids are not covered by insurance
  - Medicare, the U.S. health insurance program for the elderly, does not cover hearing aids; Medicaid, the federal health insurance program for the unemployed and poor, often does cover hearing aids
  - Supplemental insurance, either provided by former employer or purchased directly by individuals may, at times, cover hearing aids
- Hearing aid externalities
  - Private benefit to user
    - Better hearing
    - Better ability to maintain active lifestyle
  - Benefit to others who are better able to communicate with user
  - Reduced social costs from unemployment that can arise in working age population as a result of poor hearing
  - Reduced atrophy from non-hearing
- Hearing aids themselves can be costly, as can replacement parts (e.g., batteries)

Qualities of hearing aids

- Hearing loss takes a variety of forms (can occur to different degrees at different frequencies)
- Size
  - Completely in canal: invisible, weaker amplifier, small battery, custom made
  - In the canal: hardly visible, weaker amplifier, small battery
  - In the ear: visible, stronger amplifier, larger battery
  - Behind the ear: highly visible, strongest amplifier, largest battery
- Nature of amplification
  - Digital hearing aids – highest quality
  - Analog
    - Programmable
    - Constant ratio
- Cochlear implants – hearing for the medically deaf -- not the focus of this presentation

History of U.S. hearing aid regulation

- Prior to 1977
  - many cases of hearing aids fitted badly for users
  - unethical sales tactics combined with no returns policy
- 1976 FDA Interdepartmental Task Force on Hearing Aids report cited studies “indicating that patients bought hearing aids when their hearing loss required medical treatment”
- 1977 Hearing aid final rule:
  - Require medical evaluation by licensed physician prior to purchase of hearing aid
  - Require that hearing aids be fitted by state-licensed fitters or that a waiver be signed, in which clients acknowledge that they are choosing not to do so despite being informed the FDA believes it is in their best interest
  - Hearing aids are classified as medical devices

Description of process of fitting hearing aids

- Visit medical doctor
- Visit hearing aid specialist
- Undergo battery of time consuming exams, some using hi tech equipment, as recommended by professional organizations and, in part, to identify differential hearing loss by frequency
  - In minority of cases, these exams identify conditions benefiting from medical treatment that would otherwise not be detected
  - Hearing aids can be considered as amplifiers with, in more sophisticated models, equalizers built in
- Refit or buy new hearing aids after 5 years
- "The best place to buy a hearing aid is from a licensed hearing aid dispenser, or seller." – FDA "Straight Talk fro the FDA about hearing loss and hearing aids" (March, 2001)

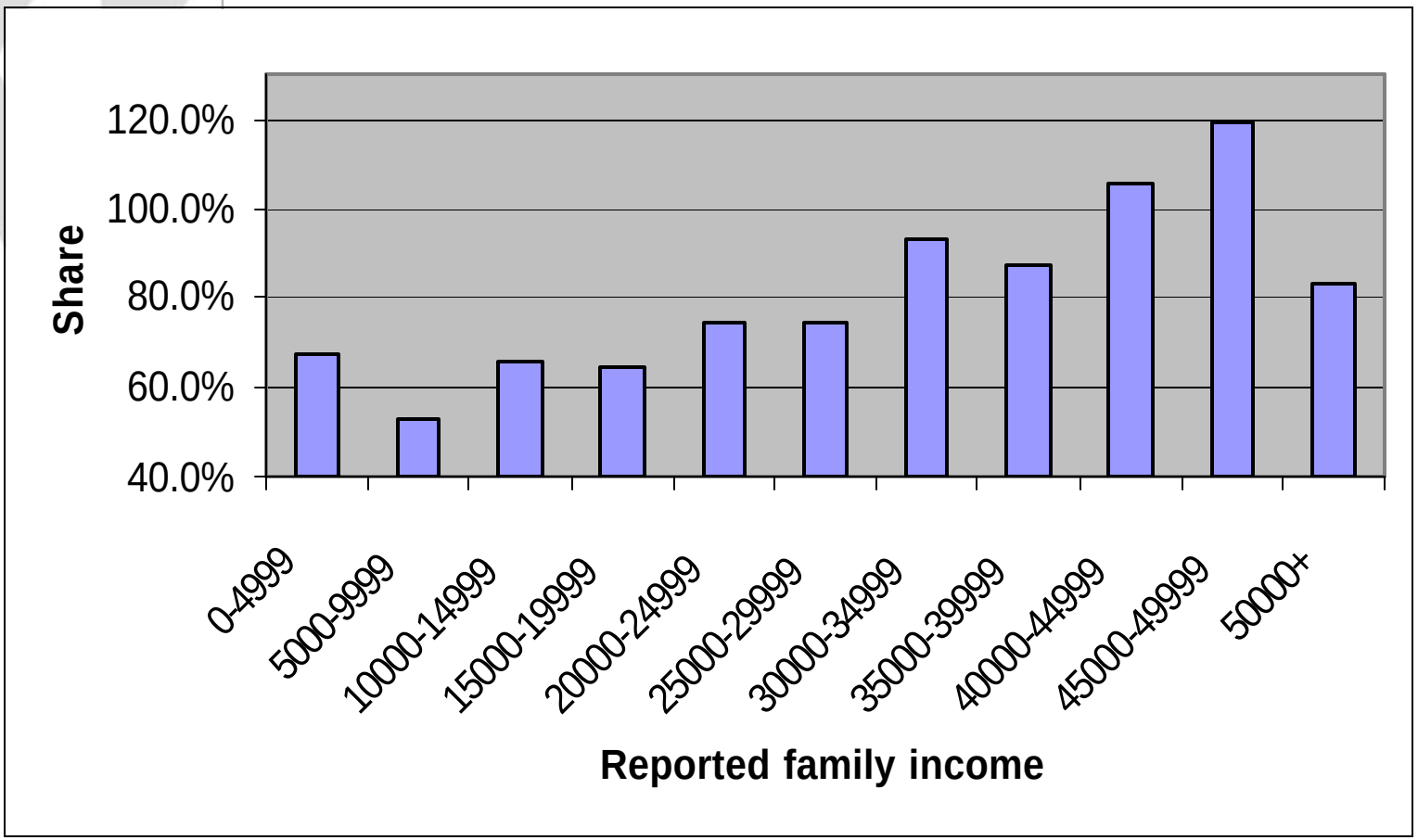
Professional organization actions

- Develop standards of care delivery that involve extensive (lengthy) testing
  - Ensures devices are well-suited to patient needs
  - Ensures medical problems are not overlooked
  - Reduces effective supply of “fitting opportunities”
- Develop model law for state regulations on hearing aids
  - Model law requires hearing aids to be delivered under supervision of someone who is a Board Certified Audiologist
- Upgrade professional requirements
  - As of Jan 1, 2007, for an individual to become a Board Certified Audiologist, a doctorate degree in audiology necessary
  - Consequence: More than 30 graduate schools of audiology lose certification
- Lobby for requirements to cover clients (especially children) with insurance

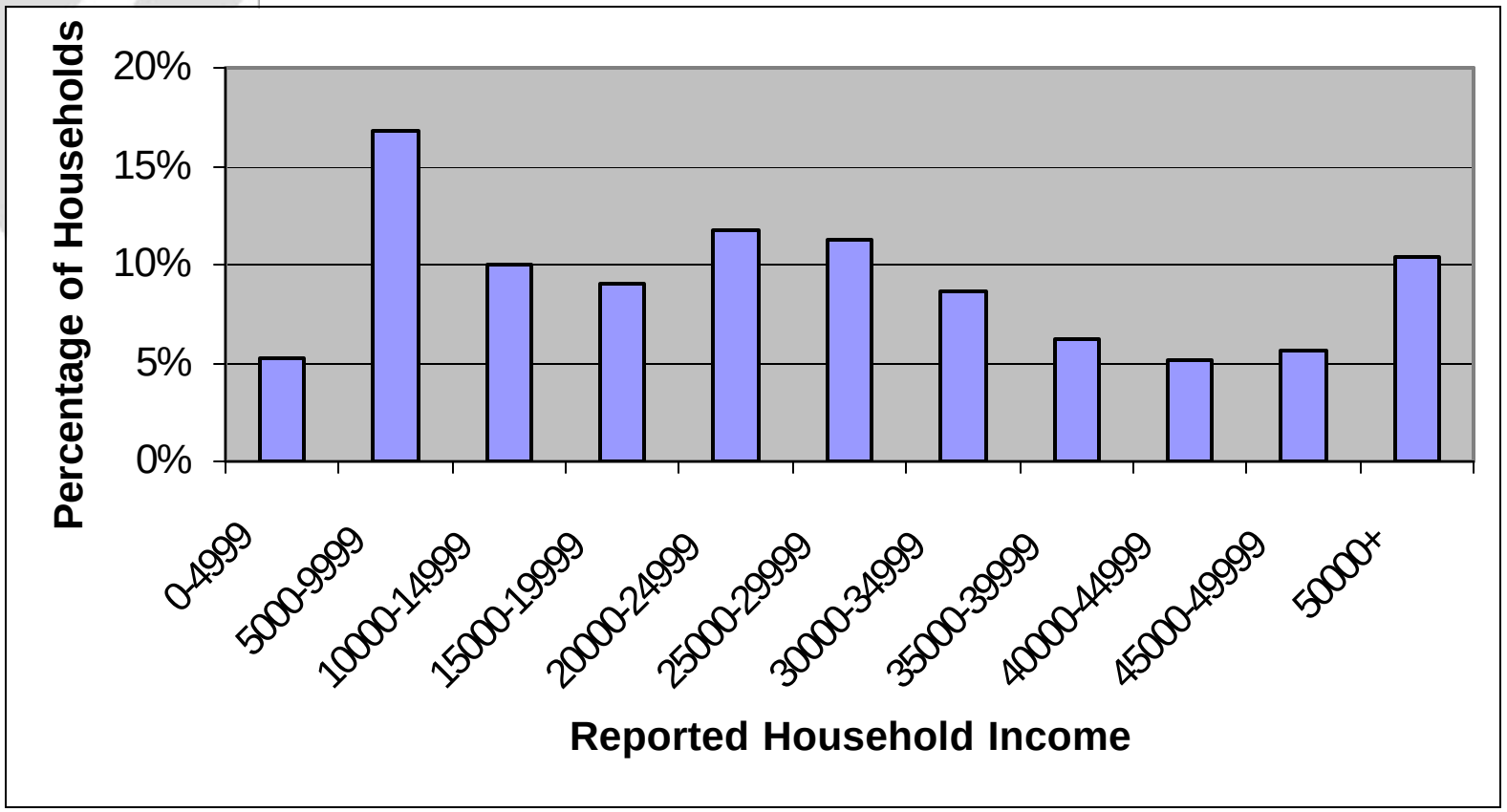
Basic statistics

- 31.5 million persons hearing impaired (Better Hearing Institute Market Trak VIII Semi-Annual Hearing Aid Market Survey, 2006)
- About 7 million persons with hearing aids
- About 10k audiologists, 13k hearing professionals
- 75-80% of those who would benefit from hearing aids (hearing impaired) have not purchased them
- Reasons hypothesized for not purchasing hearing aid:
  - Stigma
  - High cost ($1500-$6000 per hearing aid)
  - Absence of insurance
- National Council on the Aging survey showed that 55 percent of the surveyed seniors not using hearing aids find cost to be a barrier

Share of seniors reporting hearing problems who have hearing aids, by income, 1994



Income Distribution Among Over 65



Impact of lower price

- If seniors in income brackets between $0-$29,999 achieved a 0.9 penetration of hearing aid users among those who self-identify as being hard of hearing, total wearers of hearing aids would increase by 589,000.
- This is a conservative estimate, as some comparisons with foreign countries with nationally provided hearing aids suggest that provision is about 3% of population, or a roughly 50% increase from the U.S. level. This would be an increase in wearers from about 7.875m to 11.812m, or approximately 3m.
- Full analysis:
  - Increased use by low income and high income
  - Change of behavior (e.g., spouse gives gift of standardized hearing aid)

Possible revision of regulatory considerations

- Insure hearing aids
  - This does not deal with the issue of excessive cost
  - When audiologists propose legislation to have hearing aids covered by Medicare, one of their key demands is the right to balance bill patients, thus ensuring the government cannot determine a reasonable price of service and enforce it
- Provide tax deduction
  - Propose $500 tax reduction available at most every 5 years against purchase of hearing aids
- Problem: neither of these solutions deal with underlying source of problem: complex, expensive services required by regulation without giving purchasers a low-cost option
- Over-the-counter solution has clear potential to lower costs

Over-the-counter hearing aids

- FDA received proposal for “over the counter hearing aids”
  - Petition to permit sale of hearing aids over the counter
  - Petition to eliminate the requirement that adults obtain a medical clearance before a hearing aid can be sold to them
- Eliminates the control of web of government and professional regulation over issuance of hearing aids (though such hearing aids could still be approved by FDA)
- Provide competition to professional dispensing services
- Cost difference could be enormous: $200 per hearing aid vs. $2000.
- Evidence that cost difference would be large:
  - Hunters’ hearing enhancers ($200-$500)
  - NHS cost for mass produced digital hearing aids: about $150
  - Mail order Internet services

Considerations in over-the-counter proposal

- FDA rejected over-the-counter proposal
  - "lack of, or at best delayed, diagnosis can lead to irreparable damage, further deterioration of hearing, or increased risks of surgery for the hearing aid user" Rothstein letter to Mead Killion, Feb 13, 2004
- FDA did not at all address the issue of balancing the benefits of low-price products competing against against high-priced hearing aids
- Consumer benefits would accrue through:
  - New consumers of hearing aids who were previously deterred by high prices
  - Reduce extent of medical problem of atrophy of hearing potential due to non-use of hearing aids
  - Existing customers of hearing aids who would have chosen an over-the-counter option were it available
  - Price competition with over-the-counter could result in lowering costs for dispensed hearing aids
- Consumer costs:
  - Loss of some medical diagnoses that arise as a result of medical approval requirement
- Note that other medical diagnoses might be made as a result of patients who currently do not have hearing aids reading a warning in the hearing aid package that encourages visits to physicians in specific circumstances

Conclusion

- The complex web of national and state regulation and professional self-regulation create an environment of limited supply of cheap hearing aids
- The generally high prices for hearing aids lead to 1/2 million - 3 million people not having hearing aids who would otherwise likely have them
- A rigorous re-appraisal of hearing aid regulation is merited, that would focus on both costs and benefits of increased availability of alternative products (e.g., over-the-counter)