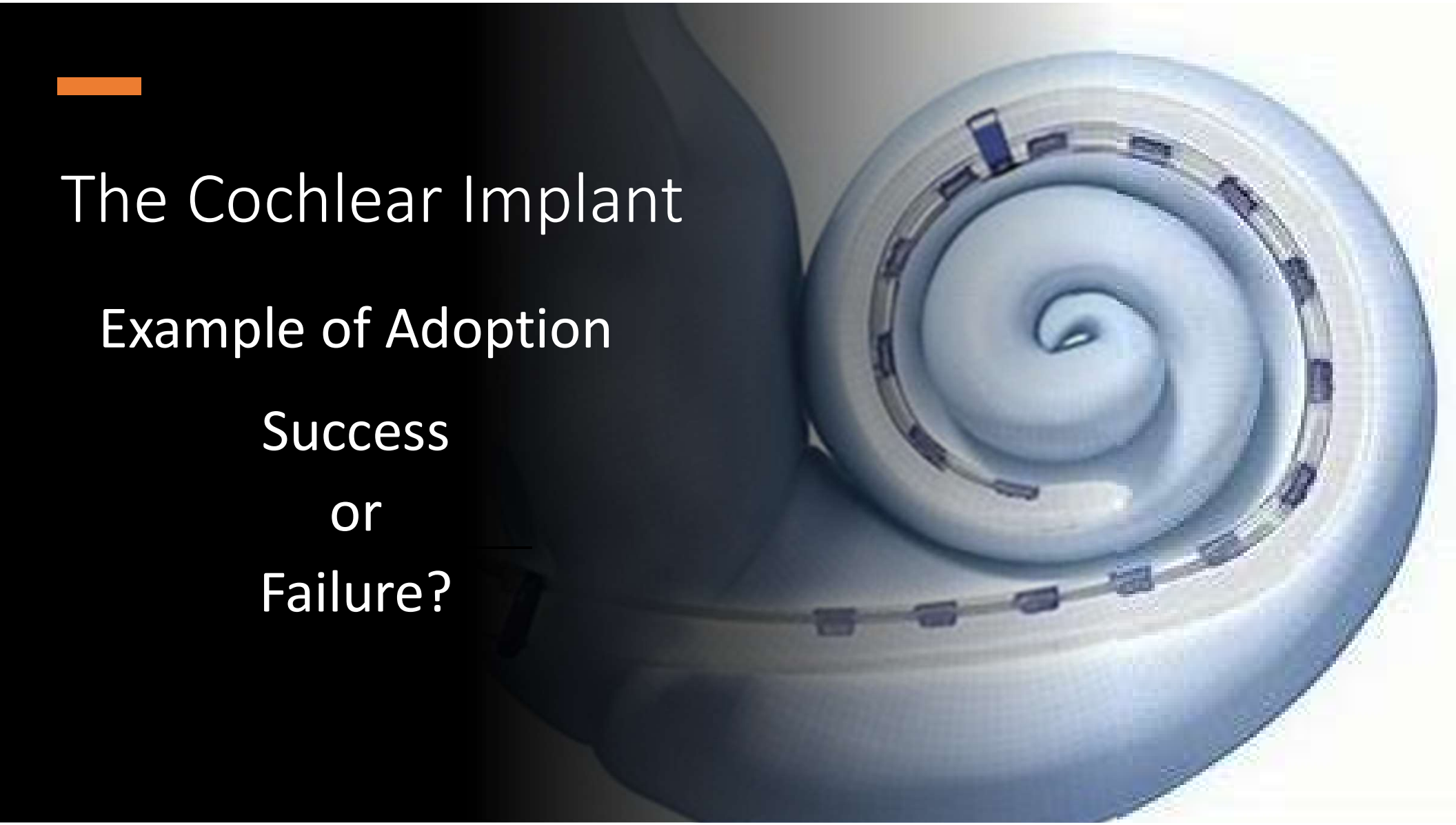
The Cochlear Implant

Example of Adoption

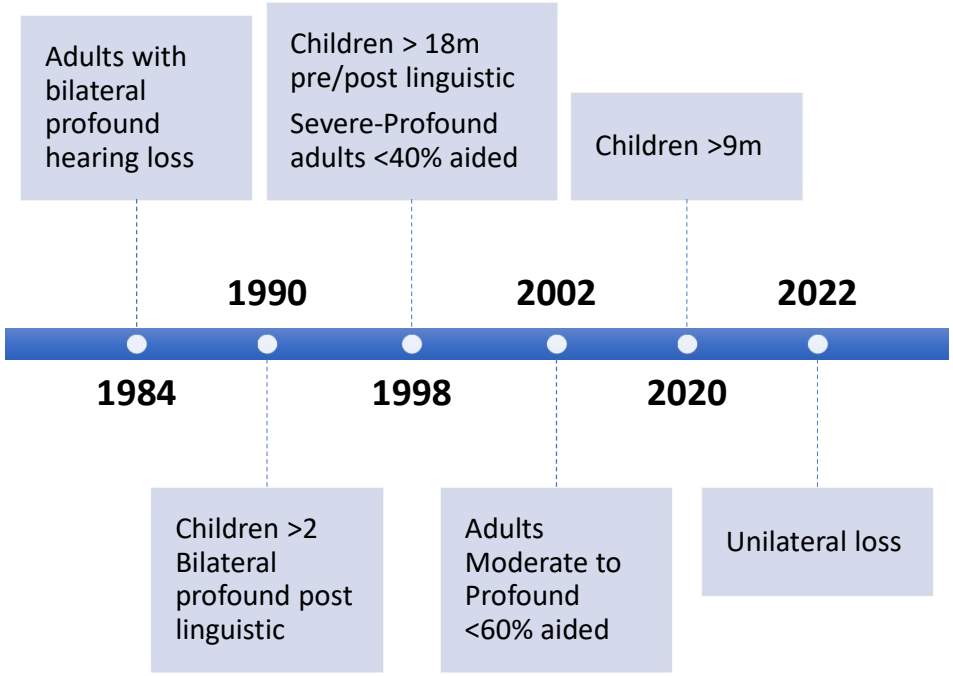
Success

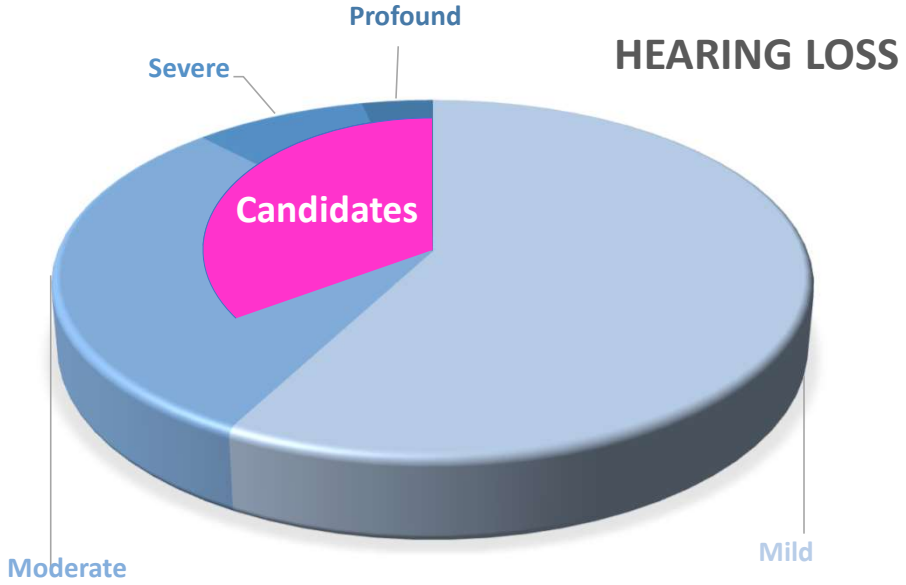
or

Failure?



IT TOOK ALMOST 20 YEARS TO GET ACCESS TO THE LEVEL OF LOSS WHERE CI'S PROVIDE BENEFIT OVER STANDARD AMPLIFICATION





ACCESSIBILITY TO PATIENTS BY REGULATORY APPROVALS

Prevalence of hearing loss according to the severity of hearing loss by... | Download Scientific Diagram (researchgate.net)

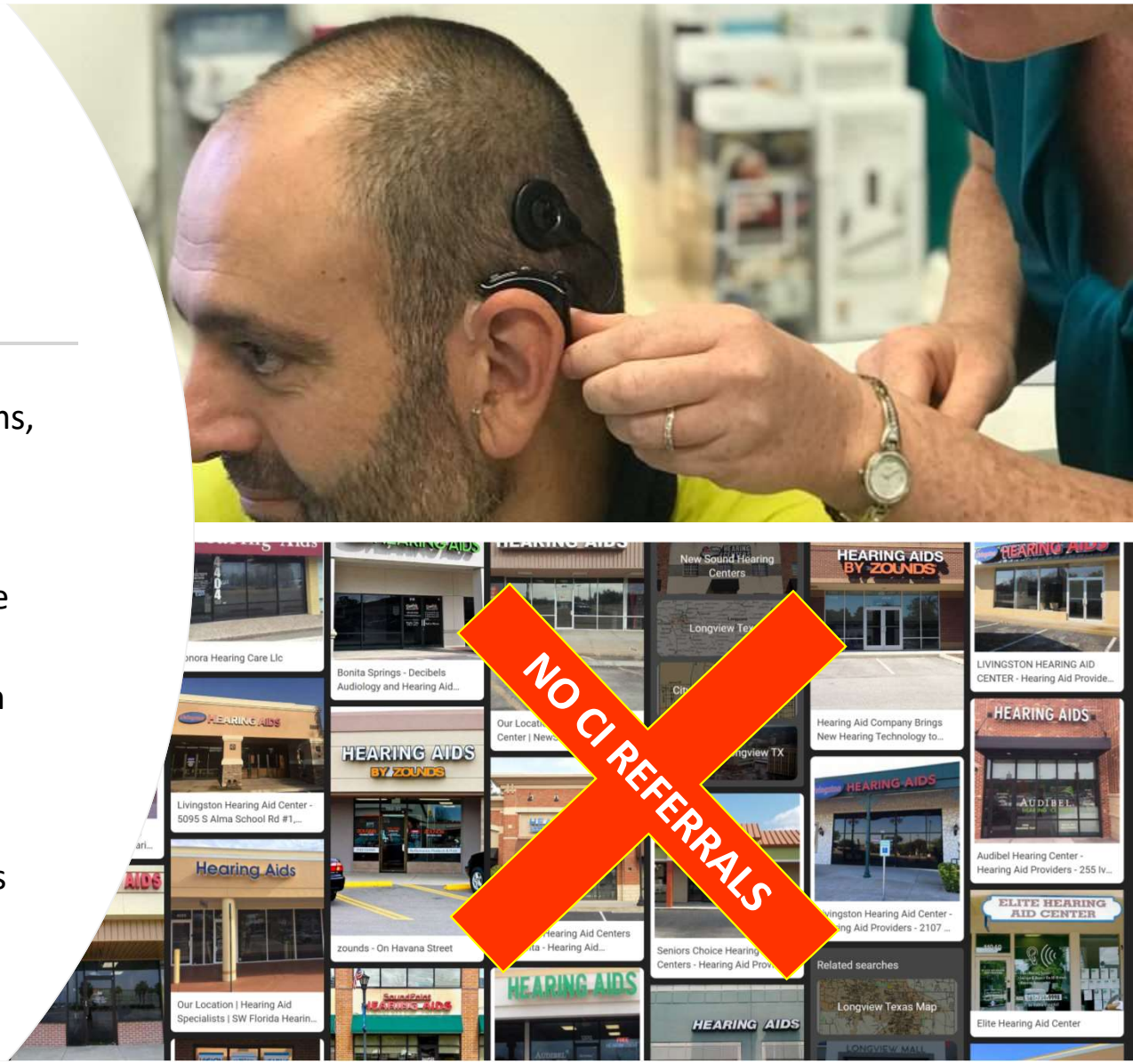
Prevalence of Hearing Loss by Severity in the United States - PMC (nih.gov)

Insurance & Cost

- With 21% US Adults & 36% Children on Medicaid, lack of coverage has a huge limiting effect on CI access.
  - To this day, 40% of States **DO NOT COVER ADULT CI's**
  - All 50 States cover CI's for children BUT: inadequate cost coverage and constrained candidacy still make CI's inaccessible to most children
  - Medicaid typically pays 10% of CI cost. Thus, few and dwindling centers will even accommodate Medicaid patients at all: **centers cannot afford to pay for their patients' treatments.**
  - A cochlear implant and surgery costs $50K-$100K ($25K implant)
- For 18% of US on Medicare and despite 2002 FDA expanded candidacy, moderate hearing loss patients with 40%-60% scores were denied access to CI's until **LAST YR 2022**!
- Public insurance *doesn't cover, inadequately covers, or limits access* to all other CI post implant services/equip.
- Private Insurance covers costs adequately, but its up to employers and plans to include coverage if at all.

Providers

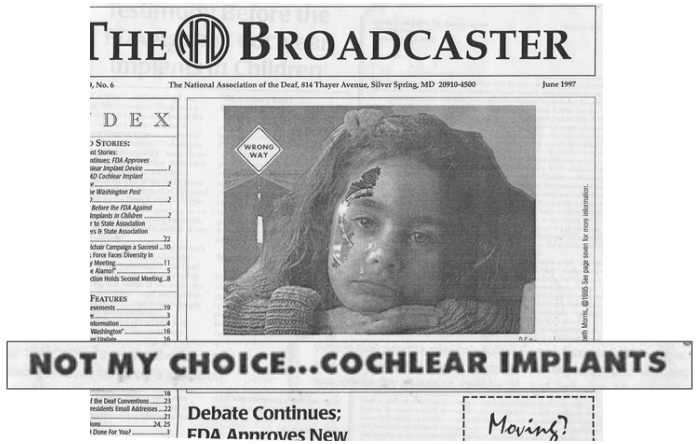
- High cost to run cochlear implant programs, usually unable to support Medicare or Medicaid patients.
- High post op care for life of the patient, rehabilitation and maintenance, with little cost support from payers.
- High incentives for hearing aid fitting with little training or incentive to make CI referrals. It is a disincentivized referral pathway to CI from hearing aids.
- Fewer and fewer cochlear implant centers support the growing demand.



Community Barriers & Awareness

"The overwhelming response to CIs from the Deaf community has not been eager acceptance but rather hostile rejection"

- From the outset, the Deaf Community railed against cochlear implants, even showing up to dissuade hearing parents from implanting their young deaf children.
- Their stance softened to: clinicians must advise parents of sign language as a considered option.
- There is also a low awareness in the general population and even in the medical community of cochlear implants and candidacy.


THE NAD BROADCASTER

The National Association of the Deaf, 814 Thayer Avenue, Silver Spring, MD 20910-4500 June 1997

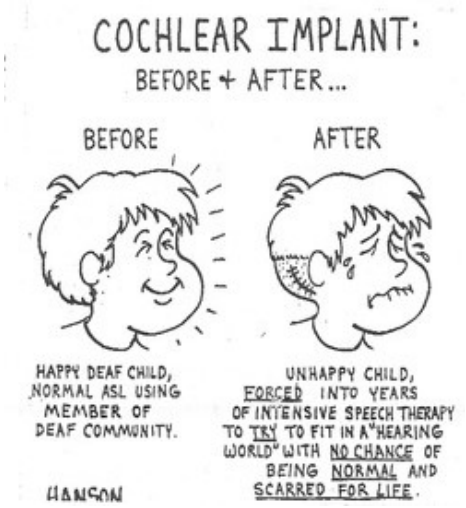
DEX

WRONG WAY

NOT MY CHOICE...COCHLEAR IMPLANTS

Debate Continues;

Moving?



Barriers Result in a *Profoundly* Low Penetration

- Less than 10% of candidates who would benefit from cochlear implants will ever get one.
- The total CUMULATIVE number of US patients who received a cochlear implant since 1985 – in almost 40 YEARS – is about 200,000 people.
- About 50% of candidate children today receive a cochlear implant.
- Less than 5% of candidate adults will get a cochlear implant.

"Second Sight gains FDA nod for retinal system that may never be produced"

Retinal Implants

Second Sight Regulatory Path to the Ledge

- Founded in 1998, Second Sight filed for approval of the Argus II Retinal Prosthesis in 2009-2010.
- The FDA reneged on endpoints for approval after the company completed trials.
  - FDA demanded Second Sight conduct new trials based on the idea the company had to establish new endpoints for approval, not the ones the FDA agreed to in the first place.
  - FDA instructed the company to validate the new endpoints before doing the new trials.
  - This technology was novel, and there were no previously established endpoints to define benefit in this patient population.
- Submission was withdrawn, new trials done, resubmitted in 2011, approval granted in 2013.
- This after-the-fact recantation of approval endpoints nearly destroyed the company and set Second Sight up for eventual failure: starved of the resources needed to move forward, the company teetered on collapse ever since.
- In 2020, Covid was the final blow that essentially killed Second Sight. The company is still in existence, but it is unlikely to recover.

Take Aways & Last Thoughts

- Regulatory – Approve devices earlier in treatment paradigm
- Insurance
  - Need a dedicated Industry Organization who's mission is the industry/patient advocacy
  - Cost Benefit Trials – Do in conjunction w Regulatory
- Establish referral Pathways/Providers
- Capital Capital Capital $$$ Funds to Develop, Make, Market & Sell